United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508C) | EPA 738-R-99-004 April 1999

Reregistration Eligibility Decision (RED)

Chlorothalonil

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency has completed its reregistration eligibility review and decisions on the pesticide chemical case 0097 for the active ingredient chlorothalonil. The enclosed Reregistration Eligibility Decision (RED), which was approved on September 30, 1998, contains the Agency's evaluation of the data base of this chemical, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It also includes requirements for additional data (generic) on the active ingredient to confirm the risk assessments.

To assist you with a proper response, read the enclosed document entitled "Summary of Instructions for Responding to the RED." This summary also refers to other enclosed documents which include further instructions. You must follow all instructions and submit complete and timely responses. **The first set of required responses is due 90 days from the receipt of this letter. The second set of required responses is due 8 months from the date of this letter.** Complete and timely responses will avoid the Agency taking the enforcement action of suspension against your products.

Please note that the Food Quality Protection Act of 1996 (FQPA) became effective on August 3, 1996, amending portions of both pesticide law (FIFRA) and the food and drug law (FFDCA). This RED takes into account, to the extent currently possible, the new safety standard set by FQPA for establishing and reassessing tolerances. However, it should be noted that in continuing to make reregistration determinations during the early stages of FQPA implementation, EPA recognizes that it will be necessary to make decisions relating to FQPA before the implementation process is complete. In making these early case-by-case decisions, EPA does not intend to set broad precedents for the application of FQPA. Rather, these early determinations will be made on a case-by-case basis and will not bind EPA as it proceeds with further policy development and any rulemaking that may be required.

If EPA determines, as a result of this later implementation process, that any of the determinations described in this RED are no longer appropriate, the Agency will pursue whatever action may be appropriate, including but not limited to reconsideration of any portion of this RED.

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division/Product Reregistration Branch representative Karen Jones at (703) 308-8047. Address any questions on required generic data to the Special Review and Reregistration Division/Reregistration Branch II representative, Jill Bloom at (703) 308-8019.

Sincerely,

Lois A. Rossi, Director
Special Review and
Reregistration Division (7508C)
Office of Pesticide Programs

Enclosures

SUMMARY OF INSTRUCTIONS FOR RESPONDING TO THE REREGISTRATION ELIGIBILITY DECISION (RED)

1. **DATA CALL-IN (DCI) OR "90-DAY RESPONSE"**--If **generic data** are required for reregistration, a DCI letter will be enclosed describing such data. If **product specific data** are required, a DCI letter will be enclosed listing such requirements. If **both generic and product specific data** are required, a combined Generic and Product Specific DCI letter will be enclosed describing such data. However, if you are an end-use product registrant only and have been granted a generic data exemption (GDE) by EPA, you are being sent only the **product specific** response forms (2 forms) with the RED. Registrants responsible for generic data are being sent response forms for both generic and product specific data requirements (4 forms). **You must submit the appropriate response forms (following the instructions provided) within 90 days of the receipt of this RED/DCI letter; otherwise, your product may be suspended.**

2. **TIME EXTENSIONS AND DATA WAIVER REQUESTS**--No time extension requests will be granted for the 90-day response. Time extension requests may be submitted only with respect to actual data submissions. Requests for time extensions for product specific data should be submitted in the 90-day response. Requests for data waivers must be submitted as part of the 90-day response. All data waiver and time extension requests must be accompanied by a full justification. All waivers and time extensions must be granted by EPA in order to go into effect.

3. **APPLICATION FOR REREGISTRATION OR "8-MONTH RESPONSE"--You must submit the following items for each product within eight months of the date of this letter (RED issuance date).**

a. **Application for Reregistration** (EPA Form 8570-1). Use only an original application form. Mark it "Application for Reregistration." Send your Application for Reregistration (along with the other forms listed in b-e below) to the address listed in item 5.

b. **Five copies of draft labeling** which complies with the RED and current regulations and requirements. Only make labeling changes which are required by the RED and current regulations (40 CFR 156.10) and policies. Submit any other amendments (such as formulation changes, or labeling changes not related to reregistration) separately. You may, but are not required to, delete uses which the RED says are ineligible for reregistration. For further labeling guidance, refer to the labeling section of the EPA publication "General Information on Applying for Registration in the U.S., Second Edition, August 1992" (available from the National Technical Information Service, publication #PB92-221811; telephone number 703-605-6000).

c. **Generic or Product Specific Data**. Submit all data in a format which complies with PR Notice 86-5, and/or submit citations of data already submitted and give the EPA identifier (MRID) numbers. Before citing these studies, you must **make sure that they meet the Agency's acceptance criteria** (attached to the DCI).

d. **Two copies of the Confidential Statement of Formula (CSF)** for each basic and each alternate formulation. The labeling and CSF which you submit for each product must

comply with P.R. Notice 91-2 by declaring the active ingredient as the **nominal concentration**. You have two options for submitting a CSF: (1) accept the standard certified limits (see 40 CFR §158.175) or (2) provide certified limits that are supported by the analysis of five batches. If you choose the second option, you must submit or cite the data for the five batches along with a certification statement as described in 40 CFR §158.175(e). A copy of the CSF is enclosed; follow the instructions on its back.

e. **Certification With Respect to Citation of Data and Data Matrix** Complete and sign EPA forms 8570-34 and 8570-35 for each product.

4. **COMMENTS IN RESPONSE TO FEDERAL REGISTER NOTICE**--Comments pertaining to the content of the RED may be submitted to the address shown in the Federal Register Notice which announces the availability of this RED.

5. **WHERE TO SEND PRODUCT SPECIFIC DCI RESPONSES (90-DAY) AND APPLICATIONS FOR REREGISTRATION (8-MONTH RESPONSES)**

By U.S. Mail:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
EPA, 401 M St. S.W.
Washington, D.C. 20460-0001

By express:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202

6. **EPA'S REVIEWS**--EPA will screen all submissions for completeness; those which are not complete will be returned with a request for corrections. EPA will try to respond to data waiver and time extension requests within 60 days. EPA will also try to respond to all 8-month submissions with a final reregistration determination within 14 months after the RED has been issued.

REREGISTRATION ELIGIBILITY DECISION

CHLOROTHALONIL

LIST A

CASE 0097

US ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
SPECIAL REVIEW AND REREGISTRATION DIVISION

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CHLOROTHALONIL REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Antimicrobials Division	
Adam Heyward, Marshall Swindell	Regulatory Management Branch II
Tim McMahon	(formerly HED toxicologist)
Biological and Economic Analysis Division	
Art Grube, David Widawsky	Economic Analysis Branch
Steve Tomasino, Leo Lasota	Antimicrobials and Plant Pathogens Branch
Environmental Fate and Effects Division	
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Special Review and Reregistration Division	
Jill Bloom	Reregistration Branch II
Mark Perry, Karen Jones	Product Reregistration Branch

Office of General Counsel:

Andrea Medici

GLOSSARY OF TERMS AND ABBREVIATIONS

A	Acre
ADI	Acceptable Daily Intake. A now-defunct term for reference dose (RfD).
AE	Acid Equivalent
a.i. or ai	Active Ingredient
BCF	Bioconcentration Factor
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DCI	Data Call-In notice
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level--a lifetime drinking water exposure at and below which adverse, non-carcinogenic health effects are not anticipated to occur.
EEC	Estimated Environmental Concentration--the estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FDA	Food and Drug Administration
FI	Formulation Intermediate
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FRSTR	Final Reregistration Standard and Tolerance Reassessment
FOB	Functional Observation Battery
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory --used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HAL	Health Advisory Level
HDT	Highest Dose Tested
LC_{50}	Median Lethal Concentration--a statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose--a statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD_{lo}	Lethal Dose-low--lowest Dose at which lethality occurs.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
LOEL	Lowest Observed Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal--used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
µg/g	Micrograms Per Gram

GLOSSARY OF TERMS AND ABBREVIATIONS

mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number)--EPA's system of recording and tracking submitted studies.
N/A	Not Applicable
NOEC	No effect concentration
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
ORETF	Occupational and Residential Exposure Task Force
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PCT	Percent Crop Treated
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q_1*	Carcinogenic Potential, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REFS	OPP's computerized reference system for product registrations
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
SLN	Special Local Need, Registrations Under Section 24(c) of FIFRA
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
FAO/WHO	Food and Agriculture Organization/World Health Organization
WP	Wettable Powder
WPS	Worker Protection Standard

ABSTRACT

EPA has completed its reregistration eligibility decision for the pesticide chlorothalonil and determined that products containing chlorothalonil, when labeled and used as specified in this document, are eligible for reregistration. This decision includes a comprehensive reassessment of the required target data base supporting the use patterns of currently registered products. This decision considered the requirements of the "Food Quality Protection Act of 1996" (FQPA) which amended the Federal Food Drug and Cosmetic Act and the Federal Insecticide Fungicide and Rodenticide Act, the two Federal statutes that provide the framework for pesticide regulation in the United States. FQPA became effective immediately upon signature and all reregistration eligibility decisions (REDs) signed subsequent to August 3, 1996 are accordingly being evaluated under the new standards imposed by FQPA.

In establishing or reassessing tolerances, FQPA requires the Agency to consider aggregate exposures to pesticide residues, including all anticipated dietary exposures and other exposures for which there is reliable information, as well as the potential for cumulative effects from a pesticide and other compounds with a common mechanism of toxicity. The Act further directs EPA to consider the potential for increased susceptibility of infants and children to the toxic effects of pesticide residues, and to develop a screening program to determine whether pesticides produce endocrine disrupting effects.

Chlorothalonil is a broad spectrum, non-systemic protectant pesticide mainly used as a fungicide to control fungal foliar diseases of vegetable, field, and ornamental crops. It is also used as a wood protectant, antimold and antimildew agent, bactericide, microbiocide, algaecide, insecticide, and acaricide. The exact mechanism of action is not known.

Due to risk concerns and uncertainties in the risk assessments, the registrants have agreed to prohibit the following uses on manufacturing product labels, and delete them from their end-use product labels or cancel end-use products registered only for these uses: home lawn, in-container preservative, and antimildew additive for use in paints, packaged in “pillow-packs” or otherwise intended for sale over-the-counter. The antifoulant use for chlorothalonil is not supported by available data. These uses will not be reregistered or allowed on new labels in the absence of appropriate data and an Agency risk management decision.

The Agency has determined that as a condition of reregistration, the registrants of technical and manufacturing-use products containing chlorothalonil must certify a maximum level of HCB in these products of 40 ppm, with interim dates and milestones, for achieving this level by January 1, 2003. Failure to achieve any of the milestones will ultimately result in automatic cancellation.

Some changes are required to mitigate risks to handlers and those who are exposed to chlorothalonil during reentry into treated areas. The Agency is requiring changes which include: the use of closed systems or water soluble packaging for wettable powder formulations, personal

protective equipment, specialized reentry equipment, reentry warnings, and the designation of ignitable fogger products as Restricted Use Pesticides. To mitigate risks to wildlife and the environment, the Agency is requiring that maximum application rates and regimens be made explicit on product labels, that some application rates and numbers of applications be reduced from current maximums, and that buffer zones be established for treated areas adjacent to marine/estuarine areas. The Agency is also establishing requirements for groundwater and surface water, and related protective statements. Additional data for residues on foliage, acute effects on marine/estuarine organisms, fish early life stage, aquatic plant growth, post-application/reentry exposure, and exposure of handlers from wood-treatment uses are being required to confirm the Agency's risk assessment and conclusions.

The Agency has reassessed chlorothalonil food and feed tolerances under the standards of FQPA and determined that, based on available information, tolerances for chlorothalonil are generally adequate for reregistration. An increased tolerance must be proposed for green onions.

Before reregistering the products containing chlorothalonil, the Agency is requiring that product specific data, revised Confidential Statements of Formula (CSF) and revised labeling be submitted within eight months of the issuance of this document. These data include product chemistry for each registration and acute toxicity testing. After reviewing these data and any revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister a product. Those products which contain other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration.

I. INTRODUCTION

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. There are five phases to the reregistration process. The first four phases of the process focus on identification of data requirements to support the reregistration of an active ingredient and the generation and submission of data to fulfill the requirements. The fifth phase is a review by the U.S. Environmental Protection Agency (referred to as "the Agency") of all data submitted to support reregistration.

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration" before calling in data on products and either reregistering products or taking "other appropriate regulatory action." Thus, reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) was signed into law. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq*., and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq*. The FQPA amendments went into effect immediately. As a result, EPA is embarking on an intensive process, including consultation with registrants, States, and other interested stakeholders, to make decisions on the new policies and procedures that will be appropriate as a result of enactment of FQPA. This process will include a more in-depth analysis of the new safety standard and how it should be applied to both food and non-food use pesticides. The FQPA does not, however, amend any of the existing reregistration deadlines set forth in §4 of FIFRA. Therefore, the Agency will continue its ongoing reregistration program while it continues to determine how best to implement FQPA.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of chlorothalonil, including the risk to infants and children for any potential dietary, drinking water, and dermal or oral exposures as stipulated under the FQPA. The document consists of six sections. Section I is the introduction. Section II describes chlorothalonil, its uses, data requirements and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV presents the reregistration decision for chlorothalonil. Section V discusses the reregistration requirements for chlorothalonil. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW

A. Chemical Overview

The following active ingredient is covered by this Reregistration Eligibility Decision:

!	**Common Name:**	Chlorothalonil
!	**Chemical Name:**	2,4,5,6-Tetrachloroisophthalonitrile
!	**Chemical Family:**	Polychlorinated aromatic
!	**CAS Registry Number:**	1897-45-6
!	**OPP Chemical Code:**	081901
!	**Empirical Formula:**	$C_8Cl_4N_2$
!	**Basic Manufacturers**	GB Biosciences; Veterans Ilex; Sipcam Agro USA, Inc.
!	**Trade and Other Names:**	Bravo, Daconil, Tuffgard

B. Use Profile

The following is information on the currently registered uses with an overview of use sites and application methods. A detailed table of chlorothalonil's uses can be found in Appendix A, "Uses Evaluated for Reregistration."

Type of Pesticide: Fungicide, mildewicide, bactericide, microbiocide, algaecide, insecticide, acaricide

Mode of Action: Broad spectrum, non-systemic; exact mechanism not known

Use Sites include: Terrestrial Food Crop--coffee, cucurbits, celery, tomato, peanuts, cole crops, papaya, passion fruit, onions (dry and green), carrot (including tops), garlic, leek, potato, shallot, beans (succulent and dry), cranberry, strawberry, sweet corn, apricot, cherry, nectarine, peach, plum, prune, peppermint, spearmint; Terrestrial Food and Feed Crop-- tomato, corn, peanuts, soybeans, parsnip, potato, beans (dry and snap), sweet corn, sugar beet, forage-fodder grasses, hay; Terrestrial Feed Crop--forage grasses (forage, fodder, hay); Terrestrial Non-Food Crop--Christmas trees, preservatives in paint and adhesives, flowering almond, ornamental herbaceous plants, ornamental turf (residential, commercial, industrial, recreational), golf course turf, ornamental sod farm, ornamental woody shrubs and vines, ornamental and/or shade trees,

flowering crabapple, flowering quince, flowering cherry, flowering peach, flowering plum, wood or wood structure protection treatments (seasoned, unseasoned), pressure treatment to forest products; Terrestrial Non-Food and Outdoor Residential--ornamental herbaceous plants, ornamental lawns and turf, ornamental nonflowering plants, ornamental woody shrubs and vines, ornamental and/or shade trees; Terrestrial and Greenhouse Non-Food Crop--ornamental herbaceous plants, ornamental nonflowering plants, ornamental woody shrubs and vines, ornamental and/or shade trees; Aquatic Food Crop--cranberry; Greenhouse Food Crop-- tomato; Greenhouse Non-Food Crop–flowering almond, ornamental herbaceous plants, ornamental nonflowering plants, ornamental woody shrubs and vines, ornamental and or shade trees, flowering quince, flowering cherry, flowering peach, flowering plum, cut flowers; Forestry--Christmas tree plantations, Douglas-fir (forest, shelterbelt), forest trees (softwoods, conifers), pine (forest, shelterbelt), spruce, spruce pine; Outdoor Residential--ornamental herbaceous plants, ornamental lawns and turf, residential lawns; Indoor Non-Food--adhesives, coatings, resin emulsions, in-can preservation of paints, paint films and the surfaces they cover

Target Pests: Fungi and bacteria, including *Alternaria* blight, anthracnose, botrytis, brown patch of turf, certain cankers, needle casts, certain scabs and curls, downy mildews, powdery mildews, scab, needle cast, snow molds, rusts, wood rot fungi; also some mites and insects

Formulation Types Registered:

Technical grade: 96 to 98%
Formulation intermediates: 29.6 to 96%
End-use products
With single active ingredient:
- Dust: 5.0 to 98%
- Emulsifiable concentrate: 12.5 to 54%
- Flowable concentrate: 11.24 to 54%
- Granular: 5.0 to 11.25%
- Impregnated material: 20.0%
- Liquid-ready to use: 0.087 to 98%
- Soluble concentrate: 12.5% to 54%
- Dry flowable (water dispersible granules): 40.4 to 90.0%
- Wettable powder: 50 to 75.0%

With multiple active ingredients (chlorothalonil and at least one other ai):
- Dust: 5.0% + 1 ai
- Emulsifiable concentrate: 3.75 to 20.0% + 1 ai
- Flowable Concentrate: 14.7 to 40.0% + 1 ai
- Liquid-ready to use: 0.7% + 1 ai, 11.0% + 2 ai’s
- Dry flowable (water dispersible granules): 50.0% + 1 ai, 27.0% + 2 ai’s
- Wettable Powder: 6.0 to 72.0% + 1 ai

Methods and Rates of Application: The methods and rates of application for chlorothalonil products are very numerous. Some examples are cited here. Rates are in lbs ai/A unless

otherwise noted. Dust formulations are applied with a hand-held duster, and the dosage cannot be calculated from the labels. Granular formulations (dry and water dispersible) may be applied at 1.25 lbs ai for ornamental shade trees, and 4.12 lbs ai to Christmas tree plantations, forests and shelterbelts, 1 lb ai to ornamental herbaceous plants; and 2.5 lbs ai for ornamental nonflowering plants through chemigation and solid set irrigation. Wettable powder formulations are applied at 1.12 to 2.2 lbs ai through chemigation equipment, as low or high volume foliar sprays to vegetables; as a low volume foliar via aircraft at 2.2 lbs ai to vegetables; or as low and high volume foliar sprays to turf at 7.5 to 22.7 lbs ai. Dry flowable and flowable concentrate formulations are applied as low or high volume foliar sprays by ground sprayers, chemigation, or aircraft from 1.6 to 6.2 lbs ai to vegetables; and to fruit trees using high and low volume sprays by ground sprayers or aircraft at 3.0 to 4.2 lbs ai. Ready-to-use formulations are reserved for brush on or dip treatments for wood protection. Impregnated formulations are applied as a fog via a thermal fog generator at 0.44 lb ai/1000 sq. ft.

Frequency and number of applications: Chlorothalonil treatments are preventative and since the compound does not have systemic capabilities, chlorothalonil may be applied several times a season to a growing crop. When explicitly stated on the label, number of applications may range from one to 10 and minimum intervals between multiple applications may range from five to 30 days.

C. Estimated Usage of Pesticide

This section summarizes the best estimates available for the pesticide uses of chlorothalonil. These estimates are derived from a variety of published and proprietary sources available to the Agency. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources.

Predominant uses of chlorothalonil are peanuts (about 34% of total chlorothalonil used in the US), potatoes (about 12%), tomatoes (about 7%), paint (about 13%), and golf courses (about 10%). Other important sites include lawns, and cucurbits. Table 1 summarizes chlorothalonil's usage by site.

Table 1. Estimated Annual Usage of Chlorothalonil

Site	Acres Grown (x 1000)	Acres Treated (X 1000) (Range)		% of Crop Treated (Range)		Lbs AI Applied (X 1000) (Range)		% of Total AI[1]
Agricultural sites								
Apricot	19	9	10	46	51	22	35	<1
Berries	161	23	49	14	31	100	230	<1
Cabbage, fresh	74	34	47	46	64	100	173	<1
Cantaloupes	113	37	39	33	35	37	74	<1
Carrots	108	38	65	35	61	160	323	<1
Celery	28	22	28	79	100	105	214	<1
Cherries	128	30	42	24	33	82	172	<1
Cotton	12,429	24	44	<1	<1	49	107	<1
Cucumber, fresh	52	28	47	53	89	225	374	2
Melons, honeydew	27	7	13	25	50	26	53	<1
Nectarines	29	14	22	48	76	45	72	<1
Onions, dry	144	89	134	62	93	387	582	3
Peanuts	1,610	1,152	1,500	72	93	5,010	7,024	34
Potatoes	1,421	558	821	39	58	1,810	3,493	12
Tomatoes	500	187	278	37	56	1,040	1,469	7
Watermelon	258	133	138	51	54	225	365	2
Non-Agricultural sites								
Container-grown nursery crops	161	28		18		360		2
Field-grown cut flowers, greens	22	4		18		69		<1
Golf courses						1,441		10
Greenhouse crops	11	1		10		16		<1
Lawn care operator						575		4
Paint						2,000		13
Sod farms						49		<1
TOTAL[2]						14,893		

[1] Calculated as ratio of low end lb ai applied/TOTAL

[2] Not the sum of individual poundage or 100% total ai; table includes only largest uses, largest % crop treated, and sites of special cases

Data from this table primarily cover the years 1990-1996, and represent weighted averages, with the most recent years and more reliable data weighted more heavily. There are some apparent discrepancies in calculated numbers due to rounding. Blank cells indicate that data are not available.

D. Data Requirements

The Agency required the registrants to submit studies as specified in 40 CFR Section 158. Data from these studies are sufficient to characterize the risks associated with the uses described in this document. Appendix B includes all data requirements identified by the Agency for currently registered uses needed to support reregistration.

E. Regulatory History

Chlorothalonil was first registered in the United States in 1966 for use on turfgrass with the first food crop registration following in 1970 for potatoes. A Registration Standard was issued by the Agency for chlorothalonil in September 1984 (NTIS #PB85-247245). The Standard evaluated the existing data base and required that additional data be submitted. A September 1988 draft Standard was put out for comment. With comments from this draft incorporated, a second Registration Standard was printed in March 1990, but due to a change in Agency policy, the Standard was never issued. Instead, the data requirements captured in the Standard were included in a DCI issued July 31, 1991. The DCI required additional data in multiple disciplines. This Reregistration Eligibility Decision reflects a reassessment of all data which were submitted in response to both the September 1984 Registration Standard and the July 31, 1991 DCI.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

Additional product chemistry data are required to support 11 Manufacturing-Use Products (MPs) registered to GB Biosciences Corporation (an affiliate of Zeneca Ag Products) and one MP registered to Veterans Ilex, Incorporated. The outstanding product chemistry data requirements will not delay a reregistration decision for chlorothalonil, and chlorothalonil is eligible for reregistration with respect to the product chemistry data requirements.

Structure of Chemical:

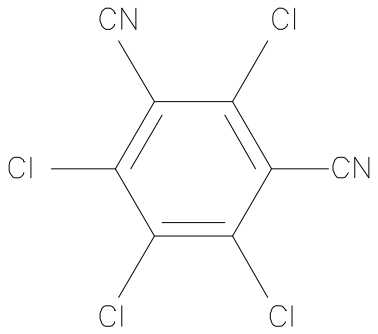

Table 2. Description of Chlorothalonil

Empirical Formula	$C_8Cl_4N_2$
Molecular Weight	265.9
CAS Registry Number.	1897-45-6
Shaughnessy Number	081901

Technical chlorothalonil is a white crystalline solid with a melting point of 250-251° C. Chlorothalonil is practically insoluble in water at 25° C (ca. 0.6 ppm) and only slightly soluble in acetone, chloroform, ethanol, kerosene, methyl ethyl ketone, mineral oil, toluene, and xylene (≤8.0% by weight). The technical product is stable under normal storage temperatures, on exposure to ultraviolet radiation, and in moderate alkaline or acidic aqueous media.

Manufacturing-Use Products

There are 11 Manufacturing Use Products registered to GB Biosciences Corporation, three MPs registered to Sipcam Agro USA, Inc., and one MP each registered to Veterans Ilex Incorporated, Westbridge Industries Incorporated, and Thor Chemie GMBH. GB Biosciences is a subsidiary of Zeneca Corporation and is the current registrant of chlorothalonil products which have been transferred from SDS Biotech to Fermenta Plant Protection to Fermenta ASC Corporation to ISK Biotech Corporation to ISK Biosciences Corporation, all without change in company number. Sipcam Agro USA is the name of the registrant of chlorothalonil products formerly known as Sostram Corporation.

Contaminants

The chlorothalonil September 1984 Registration Standard required that levels of hexachlorobenzene (HCB), a recognized impurity in technical chlorothalonil, must be at or below 0.05% (500 ppm) for registration or reregistration of the products, and that analytical methods for

determination of HCB must be acceptable to the Agency. GB Biosciences has documented a reduction in HCB levels to 0.004% or less. Recent analysis of the Veterans Ilex technical as manufactured by a modified process indicates that HCB levels are now below 0.05%. However, because the HPLC analytical method used has not yet been validated, additional data are required. Certification of new, lower levels of HCB is required in this document (see Section IV and V).

A June 1987 Data Call-In (DCI) required data concerning polyhalogenated dibenzo-p-dioxins and dibenzofurans (PCDDs and PCDFs) in technical chlorothalonil. Although additional data are required concerning the levels of PCDDs/PCDFs in chlorothalonil, initial studies indicate that PCDFs are present in the Veterans Ilex technical, and that no PCDDs/PCDFs are present at levels at or above the Agency-specified LOQs in the GB Biosciences technical chlorothalonil as produced at the facilities identified as Chlorothalonil Unit I or Chlorothalonil Unit II. The registrant is required to submit a revised CSF (Confidential Statement of Formula) in which upper limits are certified for all analytes that were detected. For all other technicals, data and revised CSFs are still outstanding. For guidance in proposing these certified limits, the registrant should refer to EPA guidance on this issue ("Polyhalogenated Dioxins and Dibenzofurans as Contaminants in Pesticides," Product Chemistry CSF Requirement, S. Funk HED/CBRS, August 6, 1996).

Status of Product Chemistry Data

The current status of the product chemistry data requirements for chlorothalonil products is presented in data summary tables attached as Appendix B. Refer to these tables for a listing of the outstanding product chemistry data requirements.

B. Human Health Assessment

1. Toxicology of Chlorothalonil

The toxicological data base on chlorothalonil is adequate and will support reregistration eligibility.

Acute Toxicity

Table 3 summarizes the acute toxicity values and categories for technical chlorothalonil.

Table 3. Acute Toxicity of Technical Chlorothalonil

Test	Results	Toxicity Category
Oral LD_{50} - Rat	> 10,000 mg/kg	IV
Dermal LD_{50} - Rabbit	> 10,000 mg/kg	IV
Inhalation LC_{50} - Rat	0.094 mg/L (M); 0.092 mg/L (F)	II
Eye Irritation - Rabbit	Severe irritation	I
Dermal Irritation - Rabbit	Slight erythema at 72 hrs	IV
Dermal Sensitization - Guinea Pig	Non-sensitizing	--

The oral LD_{50} exceeded 10,000 mg/kg (Toxicity Category IV). Clinical signs of toxicity included epistasis, lacrimation, dyspnea, vocalization, ataxia and tremors (MRID 00094941). The dermal LD_{50} also exceeded 10,000 mg/kg (Toxicity Category IV). Signs of toxicity included diarrhea, lacrimation, reduced muscle tone and erythema (MRID 00094940).

The acute inhalation LC_{50} was 0.094 mg/L in males and 0.0925 mg/L in females (Toxicity Category II) (MRID 00094942). Clinical signs included respiratory disfunction; labored breathing; gasping; excessive ocular nasal and oral secretions; eyes partially and completely closed; decreased activity; wet rales; and dry rales.

Instillation of chlorothalonil (96%) to rabbit eyes resulted in severe irritation with persistent corneal opacity, iris effects, and conjunctival irritation (MRID 00246769). Another test with rabbits found irritation and corneal opacity (MRID 00030350). Chlorothalonil is considered corrosive (Toxicity Category I).

In a dermal irritation study, slight erythema was seen in some rabbits at 72 hours with the effects clearing by day 4 (Toxicity Category IV) (MRID 00246843).

Chlorothalonil (96%) was not a dermal sensitizer in guinea pigs (MRID 00144112).

Subchronic Toxicity

Table 4 summarizes the subchronic toxicity data for chlorothalonil.

Table 4. Subchronic Toxicity of Technical Chlorothalonil

Test	Results (NOEL)	Effects Observed (summarized)	MRID#
Dietary, 13wk, mouse	2.1 mg/kg/day	hyperplasia, hyperkeratosis of epitheluim of forestomach	00138148, 00258769
Dietary, 13wk, rat	3.0 mg/kg/day	dilated renal tubules; epithelial hyperplasia, hyperkeratosis of nonglandular stomach	00127852, 00258768
Dietary, 90d, rat	<40 mg/kg/day	increased kidney wt., gastritis, changes in enzyme levels	00127850
Oral, 95-98d, beagle	15 mg/kg/day	body wt. gain, reduced alanine aminotransferase	43653602
Dermal, 21d, rat	dermal <60 mg/kg/day; systemic 600 mg/kg/day*	dermal irritation and lesions	44119101
Dermal, 21d, rabbit	50 mg/kg/day	slight erythema	00158254

* This NOEL was selected as the endpoint for the short- and intermediate-term occupational risk assessments.

Chlorothalonil (98%) was administered to CD-1 mice at dietary levels 0, 1.0, 2.1, 7.1, 39.3 or 107 mg/kg/day for 13 weeks. The NOEL was 2.1 mg/kg/day. The LOEL was 7.1 mg/kg/day based upon hyperplasia and hyperkeratosis of the epithelium of the forestomach (MRID 00138148 and 00258769).

Chlorothalonil (100%) was administered in the diet to Sprague Dawley rats at doses of 0, 1.5, 3, 10 or 40 mg/kg/day for 13 weeks. Dilated renal tubules and epithelial hyperplasia plus hyperkeratosis in the non-glandular portion of the stomach were found at 10 and 40 mg/kg/day. Microscopy studies of the rat renal lesions found hyperplasia of the tubules at 40 mg/kg/day. Based on these findings, the NOEL was 3.0 mg/kg/day and the LOEL in rats was 10.0 mg/kg/day (MRID 00127852 and 00258768).

In a 90-day study, CD rats were administered chlorothalonil (98%) in the diet at doses of 0, 40, 80, 175, 375, 750, or 1500 mg/kg/day. There were increases in relative kidney weights, gastritis, decreases in body weight and food consumption for males and females, and changes in enzyme levels, and urinary parameters at all dose levels. The NOEL was less than 40 mg/kg/day

(MRID 00127850).

In a subchronic toxicity study, chlorothalonil (97.9-98.2%) was administered orally by gelatin capsules to Marshall beagle dogs at doses of 0, 15, 150 or 500 (reduced from 750 on study day 5) mg/kg/day for 95-98 days. There was an increased incidence of emesis at 500 mg/kg/day (number of episodes for males was 25 versus 18 for controls and, for females, 42 versus 18 for controls). Body weight gains were decreased at 150 and 500 mg/kg/day in males and possibly at 500 mg/kg/day in females, and alanine aminotransferase values were reduced approximately 90% at these doses in all dosed animals compared with controls as well as with pretreatment levels. The NOEL was 15 mg/kg/day, and the LOEL was 150 mg/kg/day based on decreased body weight gain in males (MRID 43653602).

Chlorothalonil (98%) was administered dermally to male Fischer 344 rats at 0, 60, 100, 250 or 600 mg/kg/day, 6 hours/day for 5 days/week during a period of 21 days. Clinical signs at doses $\geq$ 100 mg/kg/day were limited to rough hair coat and colored material around the nose and/or eyes. Dermal irritation, characterized as erythema and desquamation, was observed at all doses. Histopathologically, dermal lesions were described as hyperkeratosis and hyperplasia of the squamous epithelium and were seen in all rats at all dose levels. For systemic toxicity, the NOEL was 600 mg/kg/day. For dermal toxicity, the NOEL was <60 mg/kg/day and the LOEL was 60 mg/kg/day (MRID 44119101). The systemic toxicity NOEL, representing the highest dose tested, was selected as the endpoint for the short- and intermediate-term occupational assessments.

In a 21-day dermal toxicity study, chlorothalonil technical was administered dermally at doses of 0, 0.1, 2.5 or 50 mg/kg/day, 6 hours/day, 5 days/week to New Zealand rabbits for a period of 21-22 days. The only effect was slight erythema in the mid- and high-dose groups. No systemic toxicity was observed at any dose. For systemic toxicity, the NOEL was 50 mg/kg/day and the LOEL was >50 mg/kg/day. For dermal toxicity, the NOEL was 50 mg/kg/day and the LOEL was > 50 mg/kg/day (MRID 00158254).

Chronic Toxicity/Carcinogenicity

Table 5 summarizes the chronic toxicity and carcinogenicity data for chlorothalonil.

Table 5. Chronic Toxicity/Carcinogenicity of Technical Chlorothalonil

TEST	RESULTS	EFFECTS OBSERVED (summarized)	MRID#
Carcinogenicity, mouse	NOEL<112 mg/kg/day	renal and stomach tumors	00127858
Carcinogenicity, mouse	NOEL=5.35 mg/kg/day	renal tubular hyperplasia; no evidence of carcinogenicity	40243701
Carcinogenicity, mouse	---	no evidence of carcinogenicity	00030286
Carcinogenicity, rat	NOEL<253 mg/kg/day	renal adenomas, carcinomas	00030286
Carcinogenicity, rat	NOEL<40 mg/kg/day[1]	renal adenomas, carcinomas; stomach papillomas	00146945
Carcinogenicity, rat	NOEL=2 mg/kg/day[2]	renal tubular adenomas, carcinomas; forestomach papillomas, carcinomas	41250502
Chronic toxicity, beagle	NOEL=1.8 mg/kg/day	increase in kidney vacuolated epithelium	00114034
Chronic toxicity, beagle	NOEL=150 mg/kg/day	decreased body wt. gains	43653603

[1] The Q_1* was derived from this study.
[2] The RfD for chronic non-cancer risk was derived from the NOEL in this study.

In a carcinogenicity study, chlorothalonil (97.7%) was administered to CD-1 mice at dietary levels of 0, 750, 1500 or 3000 ppm (equivalent to 0, 112.5, 225 or 450 mg/kg/day) for two years. Bone marrow and splenic red pulp hyperplasia, increased kidney weights with surface irregularities, pelvic dilation, cysts and nodules, and stomach/esophageal hyperplasia as well as hyperkeratosis were found at all dose levels. In males, the incidence of renal tumors was greater than in the control at all treatment levels reaching statistical significance ($p<0.05$) only at 750 ppm (112.5 mg/kg/day); whereas, in females, none were reported in any dose group. The incidence of stomach tumors in all treated males was slightly greater than in the control but was not statistically significant; whereas, in females, the increase was statistically significant ($p<0.01$) in the 1,500 and 3,000 ppm groups compared with the control group. The NOEL was less than 750 ppm (112.5 mg/kg/day) (MRID 00127858).

In another study, male CD-1 mice were given diets containing chlorothalonil (98.0%) at doses of 0, 10/15, 40, 175 or 750 ppm (0, 1.86, 5.35, 23.2 or 99.7 mg/kg/day), for two years. The NOEL was 40 ppm (5.35 mg/kg/day). The LOEL, based on the finding of renal tubular hyperplasia, was 175 ppm (23.2 mg/kg/day). There was no evidence of carcinogenicity in the

mice (MRID 40243701).

In a study conducted for the National Cancer Institute (NCI), chlorothalonil (98.0-98.5%) was administered in the diet to B6C3F1 mice at 0, 2688 or 5375 ppm (0, 384 or 768 mg/kg/day) to males and at 0, 3000 or 6000 ppm (0, 429 or 851 mg/kg/day) to females for 91-92 weeks. There was no evidence of carcinogenicity (MRID 00030286).

In a study conducted for NCI, chlorothalonil (98.0-98.5%) was administered in the diet at 0, 5063 or 10126 ppm (0, 253 or 506 mg/kg/day) for 110-111 weeks to male and female Osborne Mendel rats. Renal adenomas and carcinomas were seen in both sexes at both dose levels (MRID 00030286).

In a carcinogenicity study in Fischer 344 rats, chlorothalonil (98.1%) was administered in the diet at 0, 40, 80 or 175 mg/kg/day for 116 weeks to males and 129 weeks to females. There were body weight decreases in both sexes at the high and mid doses. The non-glandular stomach was eroded and ulcerated. Histologically, there were compound related effects on the kidneys, esophagus, stomach and duodenum. Chronic glomerulonephritis, hyperplasia of cortical tubules and pelvic/papillary epithelium, and tubular cysts were found at all dose levels. Renal adenomas and carcinomas as well as stomach papillomas were also present at all dose levels. The NOEL was <40 mg/kg/day. Female rat renal (adenoma and/or carcinoma) tumor rates were 0/60 in the controls, 2/60 at 40 mg/kg/day, 7/61 at 80 mg/kg/day, and 19/59 at 175 mg/kg/day. Female rats did not display statistically significant differential mortality. The 3/4 scaling factor was used to determine the Q_1* from the rat data. The carcinogenic potency factor (Q_1*) of 7.66×10^{-3} $(mg/kg/day)^{-1}$ was derived from this study. (MRID 00146945)

In a related study, chlorothalonil (98.3%) was administered in the diet to Fischer 344 rats at levels of 0, 2, 4, 15 or 175 mg/kg/day for 23-29 months. Renal tubular adenomas and carcinomas were seen in males at 15 and 175 mg/kg/day and in females only at 175 mg/kg/day. The incidence of forestomach papillomas and carcinomas was increased only at 175 mg/kg/day in males and at both 15 and 175 mg/kg/day in females. The NOEL was 2 mg/kg/day and the LOEL of 4 mg/kg/day was based on increased kidney weights and hyperplasia of the proximal convoluted tubules in the kidneys as well as ulcers and forestomach hyperplasia (MRID 41250502). The RfD used in estimating chronic non-cancer dietary risk was derived from the NOEL in this study.

In a chronic toxicity study, beagle dogs received chlorothalonil (97.6%) in the diet at 0, 60 or 120 ppm (0, 1.8 and 3.5 mg/kg/day) for two years. There was an increase in kidney vacuolated epithelium in males at 120 ppm (3.5 mg/kg/day) but only at the 12-month sacrifice. The NOEL was 60 ppm (1.8 mg/kg/day) and the LOEL was 120 ppm (3.5 mg/kg/day) based on the above mentioned kidney findings (MRID 00114034).

In another chronic toxicity study, chlorothalonil (98.3%) was administered orally by gelatin capsules to Marshall beagle dogs at doses of 0 (empty capsules), 15, 150 or 500

mg/kg/day for 52 weeks. There were decreases in body weight gains in males and females at 500 mg/kg/day. The NOEL was 150 mg/kg/day and the LOEL was 500 mg/kg/day, based on decreased body weight gains in both sexes (MRID 43653603).

Other studies relevant to the carcinogenicity of chlorothalonil are discussed below under "Mechanistic Data," "Metabolism," and "Classification of Carcinogenic Potential."

Mechanistic Data

GB Biosciences submitted several studies which address the mechanism of carcinogenicity of chlorothalonil. In a cell proliferation study, 28 male Fischer 344 rats received technical chlorothalonil (97.9% ai) in the diet at 175 mg/kg/day for up to 91 days. Scheduled sacrifices occurred on Days 7 (14 rats), 28 (7 rats), and 91 (7 rats) for the purpose of assessing the effect of chlorothalonil administration on cell proliferation in the kidney. Rats were implanted with Alzet minipumps containing bromodeoxyuridine 3.5 and 6.5 days prior to sacrifice (Day 7), or 3.5 days prior to sacrifice (Days 28 and 91). Mean labeling index was statistically increased in the kidneys of male rats treated with 175 mg/kg/day chlorothalonil at all scheduled sacrifice times. From Day 7 to Day 28, the increase in labeling index was relatively stable (approximately 10-fold over control), with a decrease to approximately 3.5-fold over control on Day 91. Increased cell proliferation correlated with histopathological lesions of degeneration of the proximal convoluted tubules and epithelial hyperplasia. The results of this study demonstrate a sustained cell proliferative response as a result of dietary administration of technical chlorothalonil at a dose of 175 mg/kg/day. The apparent lack of cytotoxicity compared to the hypertrophic response in this study is not readily explained by the available data (MRID 44223002). This study provided the acute dietary endpoint for this RED.

In another study, 96 male SPF rats were divided into test groups of 6 animals per group. Rats received technical chlorothalonil (98.98% a.i.) in the diet at dose levels of 0, 1.5, 15, or 175 mg/kg/day for either 7, 14, 21, or 28 days (total of 24 rats per time point). Histological examination of kidney and stomach tissue was performed for each group after the appropriate exposure. In addition, kidneys were subjected to PCNA staining and stomachs to BrdU staining, and the labeling index and labeling count of cell nuclei were performed. Duodenum was used as a negative control for PCNA and BrdU staining. Increased absolute and relative weight of the kidneys was observed at 175 mg/kg/day at all time points, and in one animal at 15 mg/kg/day on Day 28. Increased incidence of vacuolization of the epithelium of the proximal convoluted tubules was observed at all time points at 175 mg/kg/day and on Days 7, 14, and 21 at 15 mg/kg/day. PCNA immunostaining of the proximal convoluted tubule epithelial cells showed increased labeling of cells at the 175 mg/kg/day dose level at all time points, and increased labeling at 15 mg/kg/day on Days 7, 14, and 21. BrdU labeling of the rat forestomach showed marked labeling at 175 mg/kg/day at all time points, and increased labeling on Day 28 at 15 mg/kg/day. The results of this study demonstrate a toxic response of the kidney and forestomach to repeated dietary administration of chlorothalonil at doses of 15 and 175 mg/kg/day (MRID 44240901). This study was used to define the carcinogenic endpoint used in this RED to calculate the MOEs

for cancer risk.

Developmental Toxicity

In a developmental toxicity study, New Zealand white rabbits were administered 0, 5, 10 or 20 mg/kg/day of chlorothalonil (98.7%) by gavage on gestation days 7-19. For maternal toxicity the NOEL was 10 mg/kg/day and the LOEL was 20 mg/kg/day based upon reductions in body weight gain and food consumption during dosing. No developmental toxicity was seen. For developmental toxicity, the NOEL was 20 mg/kg/day, the highest dose tested (MRID 41250503).

In a developmental toxicity study, Sprague Dawley rats were given chlorothalonil (98%) at 0, 25, 100 or 400 mg/kg/day by gavage on gestation days 6-15. For maternal toxicity, the NOEL was 100 mg/kg/day and the LOEL was 400 mg/kg/day based on increased mortality and reduced body weight gain. For developmental toxicity, the NOEL was 100 mg/kg/day and the LOEL was 400 mg/kg/day based on an increase in total resorptions and resorptions per dam with a related increase in post-implantation loss. No decrease in litter size was reported (MRID 00130733).

Reproductive Toxicity

In a two-generation study, Sprague Dawley rats were administered chlorothalonil (98%) in the diet at levels of 0, 500, 1500 or 3000 ppm (0, 38, 115 and 234 mg/kg/day). For parental/systemic toxicity, the NOEL was less than 500 ppm (<38 mg/kg/day). The LOEL was 500 ppm (38 mg/kg/day) based on hyperplasia of renal and forestomach tissues. For offspring toxicity, the NOEL was 1500 ppm (115 mg/kg/day) and the LOEL was 3000 ppm (234 mg/kg/day) based on lower neonatal body weights by day 21 (MRID 41706201).

Mutagenicity

Overall, the data from the mutagenicity data base indicate that chlorothalonil is not mutagenic in bacteria or cultured mammalian cells and does not induce morphological transformation in rat embryo cells. A weak positive response was seen under nonactivated conditions in an *in vitro* cytogenetic CHO assay and in the subchronic phase of an *in vivo* bone marrow Chinese hamster cytogenetic assay. However, the relevance of both findings is questionable since genotoxicity was not demonstrated *in vitro* in the presence of metabolic activation and the *in vivo* results were not reproducible. In light of the considerable body of evidence from acceptable whole animal testing, it is concluded that chlorothalonil is also not clastogenic or aneugenic in rats, mice or Chinese hamsters.

Chlorothalonil was not mutagenic and did not interfere with DNA repair mechanisms in *S. typhimurium* either in the presence or absence of exogenous metabolic activation derived from Aroclor-induced rat livers and/or kidneys (MRID 00030288, 00030290 and 00147949). There was also no evidence that treatment with nonactivated or S9-activated chlorothalonil induced a

mutagenic response in either cultured Chinese hamster V 79 cells or BALB/3T3 mouse fibroblasts (MRID 00030289). Chlorothalonil did not cause phenotypic transformation in two rat embryo cell lines (F1706 and H4536 P+2), and these chlorothalonil-treated cell lines were not tumorigenic in newborn Fischer mice (MRID 00030291).

In an *in vitro* Chinese hamster (CHO) cell cytogenetic assay, chlorothalonil produced positive results at 0.15 and 0.3 µg/ml but only in the absence of metabolic activation (MRID 40559103). The compound was also weakly clastogenic in an *in vivo* bone marrow chromosome aberration assay following 5 consecutive daily oral gavage administrations of 50-250 mg/kg to Chinese hamsters (MRID 00147948). The inclusion of gaps in the incidence of aberrant cells, the lack of a dose response and the absence of an effect in the acute phase of the study with levels up to 5000 mg/kg was, however, noted. Additionally, the result was not reproduced in subsequent studies using a 5-day repeated dosing schedule with Chinese hamsters up to a lethal dose of 750 mg/kg (MRID 43700602) or with rats receiving chlorothalonil levels $\leq$2000 mg/kg (MRID 43700601). Negative results were also obtained in rats (MRID 00147947) and mice (MRID 00147946) receiving single high doses of 5000 or 2500 mg/kg, respectively. Further testing yielded negative results for chromosomal aberrations and micronuclei induction in either rats or Chinese hamsters administered gavage doses up to 5000 mg/kg once daily for 2 days or mice receiving 2500 mg/kg once daily for 2 consecutive days (MRID 00127853 and 00127854).

Metabolism

Disposition studies of chlorothalonil were conducted in male and female rats in which either single oral doses (5-200 mg/kg) or multiple oral doses (1.5-160 mg/kg/day for 5 days) of 14C-labeled chlorothalonil were used. Oral absorption of the test material was low (approximately 33% of the administered dose). Peak blood levels were observed between 2-9 hours post-dose and were considered low (i.e. less than 1% of the dose present in blood). Apparent saturation of kinetics occurred at doses between 5 and 50 mg/kg, with prolonged elimination and increased blood levels observed at higher dose levels. Chlorothalonil derived radioactivity was eliminated primarily by the gastrointestinal tract, with 80-90% of the administered dose observed in feces. Approximately 15-20% of the dose was observed in bile, with a reduced rate of biliary excretion observed at high doses. Tissue residues of chlorothalonil were highest in the gastrointestinal tract, blood, liver, and kidneys.

Available data on metabolism of chlorothalonil in rats and dogs indicates that the parent chemical is conjugated in liver to glutathione or cysteine-S-conjugates. These conjugates are then absorbed from the gastrointestinal tract. Cysteine-S-conjugates, glutathione conjugates, or mercapturic acids reaching the kidney come into contact with proximal tubular cells, where eventual "activation" of pre-mercapturic acids occurs through the action of cysteine conjugate DF-lyase, an enzyme found in the cytosol and mitochondria of the cells of the renal proximal tubules. Nephrotoxicity of cysteine-S-conjugates through activation to thiol metabolites is related to renal cortical mitochondrial dysfunction. Respiratory control has been shown to be disrupted by the di- and tri-thiol analogs of chlorothalonil. Osmotic changes occur within the renal cortical

tubular cells as a result of toxic insult by the thiol metabolites of chlorothalonil, resulting in vacuolar degeneration followed by cellular regeneration (MRID 44223002 and 44240901). This mechanism has been proposed to explain the carcinogenicity of chlorothalonil in rats, and formed the basis for the recent reconsideration of the carcinogenic potential of chlorothalonil.

Dermal Absorption

In a dermal absorption study, 1% ^{14}C chlorothalonil in latex base paint or in alkyd covering stain (0.1µg/cm^2) was applied to the back of male rats for periods of 8 hours (washed and terminated), 24 hours (washed and terminated) and 24 hours (washed and maintained for an additional 24 hours). For the paint, total recovery was 99-105% with 97-102% being in skin washes, 0.64-1.62% in skin and 0.58-0.99% absorbed (urine, feces, cage wash, blood and carcass). For the stain, total recovery was 89-96%, with 84-95% being in skin washes, 0.56-1.52% in skin and 0.78-2.97% absorbed (MRID 43600103).

In all other (non-paint and non-stain) scenarios that result in skin contact during the workday, an upper limit of 0.15% of chlorothalonil is estimated to be absorbed (MRID 44493601). This dermal absorption rate was calculated using the lowest LOEL from the subchronic oral dosing studies in rats, the oral absorption rate obtained from the rat metabolism study, and the LOEL from the 21-day dermal toxicity study (R.Zendzian, D244482, 3/30/98).

2. Toxicology of SDS-3701

SDS-3701 is the major metabolite of chlorothalonil and one for which some toxicology data are available.

There was no evidence of carcinogenicity for the SDS-3701 metabolite in either rats or mice. Therefore, it is included in the acute and chronic (non-cancer) assessments, but not the carcinogenic assessment. Residues of chlorothalonil *per se* are not expected to transfer from feed items to meat and milk, but residues of SDS-3701 have been shown to occur in these commodities. For the acute and chronic non-cancer dietary exposure assessments, residues of SDS-3701 were combined with residues of chlorothalonil and the sums compared to chlorothalonil endpoints (the LOEL for acute dietary risk and the RfD for chronic non-dietary risk).

Acute Toxicity

The acute oral LD_{50} of SDS-3701 for male rats was 422 mg/kg and for female rats was 242 mg/kg. These values were averaged for the combined sexes value of 332 mg/kg, Toxicity Category II (MRID 00047938, 00047939 and 00095783).

Subchronic Toxicity

In a 4-month feeding study in Sprague-Dawley rats, SDS-3701 was administered at 0, 10, 50, 100 or 200 ppm (approximately 0, 0.5, 2.5, 5 or 10 mg/kg/day). The NOEL was 5 mg/kg/day. The LOEL was 10 mg/kg/day based on depression of body weight and an increase in liver weight in males (MRID 00047936).

In another study, Sprague-Dawley rats of both sexes were administered SDS-3701 in the diet for 61-69 days at doses of 0, 10, 20, 40, 75, 125, 250, 500 or 750 mg/kg/day. Mortality occurred at ≥75 mg/kg/day. The NOEL was 20 mg/kg/day. The LOEL was 40 mg/kg/day based on decreased body weights compared with controls, anemia and renal cortical atrophy (MRID 00127847).

In a 3-month feeding study in beagle dogs, SDS-3701 was administered at 0, 50, 100 or 200 ppm (approximately 0, 1.25, 2.5 or 5.0 mg/kg/day). The NOEL was 2.5 mg/kg/day. The LOEL was 5.0 mg/kg/day based on renal tubular degeneration and vacuolation in males (MRID 00047940).

Chronic Toxicity and Carcinogenicity

In a 2-year feeding study in Sprague-Dawley rats, SDS-3701 was administered at doses of 0, 0.5, 3.0 or 15 (reduced to 10 at week 30) or 30 (reduced to 20 at week 30) mg/kg/day. The NOEL was 3.0 mg/kg/day. The LOEL was 10 mg/kg/day based on reduced body weight, microcytic anemia, hemosiderin and decreased serum potassium. There was no evidence of carcinogenicity in either sex (MRID 00127848 and 00137124).

In a 2-year feeding study in CD-1 mice, SDS-3701 was administered at nominal doses of 0, 375, 750 or 1500 ppm (approximately 0, 54, 107 or 214 mg/kg/day). A NOEL was not established; the LOEL was <54 mg/kg/day based on increased liver-to-body weight ratios in males. There was no evidence of carcinogenicity in either sex (MRID 00127849).

Developmental Toxicity

SDS-3701 was administered to pregnant female Dutch Belted rabbits at dose levels of 1, 2.5 or 5 mg/kg/day on gestation days six through fifteen. For maternal toxicity the NOEL was 1 mg/kg/day and the LOEL was 2.5 mg/kg/day based on a dose dependent increase in maternal death and abortion. For developmental toxicity the NOEL was 5 mg/kg/day; a LOEL was not established (MRID 00047944).

Reproductive Toxicity

In a 1-generation reproduction study in Sprague-Dawley CD rats, SDS-3701 was administered at 0, 10, 20, 30, 60, or 120 ppm (approximately 0, 0.5, 1.0, 1.5, 3.0 or 6.0 mg/kg/day). For parental systemic toxicity, the NOEL was 1.5 mg/kg/day and the LOEL was 3.0 mg/kg/day. For offspring toxicity, the NOEL was 6.0 mg/kg/day based on reduced weanling

body weights (MRID 00127845).

In a 3-generation reproduction study in Sprague-Dawley CD rats, SDS-3701 was administered at 0, 10, 60 or 125 ppm (approximately 0, 0.5, 3.0 or 6.25 mg/kg/day). The parental systemic NOEL was 0.5 mg/kg/day and the LOEL was 3.0 mg/kg/day based on a modest reduction in pup body weight. For reproductive toxicity the NOEL was 6.25 mg/kg/day (MRID 00127844).

Mutagenicity

Based on available data, the Agency concluded that the SDS-3701 metabolite of chlorothalonil was positive for clastogenic activity in cultured mammalian cells; however, damage to chromosomes was not expressed in either the somatic or germinal cells of whole animals. Hence, the concern for genotoxic potential is lessened.

The SDS-3701 metabolite of chlorothalonil did not cause DNA damage in *S. typhimurium* or induce a mutagenic response in this microbial species or in cultured Chinese hamster V 79 cells or BALB/3T3 mouse fibroblasts. No evidence of mutagenesis was found in a host mediated assay using *S. typhimurium* tester strains and mice exposed daily for 5 days to 6.5 mg/kg/day of the compound (MRID 00030288, 00030289, 00030290 and 00030291). Phenotypic transformation was not observed in rat embryo cells treated with concentrations of the metabolite up to 10 µg/ml; however, F1706 cells treated with 10 µg/ml did induce late tumors in newborn Fischer rats. The latter finding was considered inconclusive since the more sensitive cell line (H4536 P+2) was not tumorigenic under similar conditions (MRID 00127846).

The S9-activated SDS-3701 metabolite at 260-520 µg/ml induced reproducible, significant and dose-related increases in the yield of cells with abnormal chromosome morphology (MRID 44022201). Clastogenic activity was, however, not uncovered in bone marrow cytogenetic assays conducted in Chinese hamsters receiving a single oral administration of 500 mg/kg (MRID 44022202) or in mice receiving a single oral dose of 6.5 mg/kg (MRID 00044728). Mouse and rat dominant lethal assays were also negative using either a subchronic 5-day exposure to 6.5 mg/kg (mice) or an acute and subchronic experimental design with treatment levels up to 8 mg/kg/day in rats (MRID 00047941 and 00047942).

3. Toxicology of Hexachlorobenzene

Hexachlorobenzene (HCB) is an impurity present in chlorothalonil and other pesticide products. Endpoints for the risk assessment of HCB were obtained from the IRIS database. The RfD for HCB is 0.0008 mg/kg/day based on a NOEL of 0.08 mg/kg/day in a 130-week feeding study in rats. Effects observed were hepatic centrilobular basophilic chromogenesis. An uncertainty factor of 100 was used to account for inter-species extrapolation and intra-species variability.

HCB is classified as a B2 or probable human carcinogen, based on data which show significant increases in tumor incidences in two species: hamsters and rats. The Q_1* for HCB is 1.02 $(mg/kg/day)^{-1}$ based on a 3/4 scaling factor (as described in a June 21, 1995 memo by W. Burnam/SAB).

The dermal penetration factor is estimated to be 26%, based on a previous assessment performed for DCPA, another pesticide which is contaminated with HCB (MRID 42651501).

4. Special Sensitivity of Infants and Children and FQPA Safety Factor

FQPA directs the Agency to "ensure that there is a reasonable certainty that no harm will result to infants and children" from aggregate exposure to a pesticide chemical residue in setting and reassessing tolerances. The law further states that in the case of threshold effects, for purposes of providing this reasonable certainty of no harm, "an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. Notwithstanding such requirement for an additional margin of safety, the Administrator may use a different margin of safety for the pesticide residue only if, on the basis of reliable data, such margin will be safe for infants and children."

In determining what safety factor is appropriate for assessing risks to infants and children, EPA considers all available reliable data and makes a decision using a weight-of-evidence approach. This approach takes into account the completeness and adequacy of the toxicity and exposure data bases, the nature and severity of the effects observed in pre- and post-natal studies, and other information such as epidemiological data.

The developmental and reproductive data for chlorothalonil indicate that there is no evidence of an increased sensitivity to chlorothalonil from pre- or post-natal exposures. In the rat developmental toxicity study, the developmental NOEL and LOEL were based on an increase in total resorptions and resorptions per dam with a related increase in post-implantation loss. These observations occurred at a dose (400 mg/kg/day) which produced increased mortality and reduced body weight gain in the maternal animals. No developmental toxicity was observed (at any dose level) in the rabbit developmental toxicity study, and no maternal toxicity was observed at the highest dose tested (20 mg/kg/day).

Based on the considerations outlined above, the Agency concludes the ten-fold safety factor applied according to FQPA to account for special sensitivity to infants and children is not warranted for the chlorothalonil risk assessment, and therefore should be removed. No reproductive effects were observed in any study. Developmental effects occurred only in the presence of significant maternal toxicity.

HCB was not considered in this evaluation of the special sensitivity of infants and children.

HCB will be considered at a future date when the Agency is better equipped to understand the implications of FQPA for HCB, which is a common contaminant of at least nine other pesticides and which also enters the environment from non-pesticidal sources.

5. Toxicological Endpoints of Concern Identified for Use in the Chlorothalonil Risk Assessment

Reference Dose (RfD) for Chlorothalonil

An RfD of 0.02 mg/kg/day was determined based on the NOEL of 2 mg/kg/day established in a 2-year dietary study in rats and using an uncertainty factor of 100. The LOEL of 4 mg/kg/day was based on increased kidney weights and hyperplasia of the proximal convoluted tubules in the kidneys as well as ulcers and forestomach hyperplasia (MRID 41250502, discussed under "Chronic Toxicity/Carcinogenicity" above).

Classification of Carcinogenic Potential for Chlorothalonil

On September 4, 1987, the Agency classified chlorothalonil as a Group B2 or probable human carcinogen. This classification was based on statistically significant increases in the incidence of renal adenomas and carcinomas in male and female Fisher 344 rats, a statistically significant increase in combined renal adenomas/carcinomas in male and female Osborne-Mendel rats, and statistically significant increases in carcinomas of the forestomach in male and female CD-1 mice, as well as a positive dose-related trend for combined renal adenomas/carcinomas in male mice. The Scientific Advisory Panel on July 20, 1988 concurred with the Agency's classification of chlorothalonil as a Group B2 carcinogen.

A carcinogenic potency factor (Q_1*) of 7.66 x 10^{-3} $(mg/kg/day)^{-1}$ was calculated based upon female rat renal (adenoma and/or carcinoma) tumor rates. The dose levels used in the rat study were 0, 40, 80 and 175 mg/kg chlorothalonil. Corresponding tumor rates in female rats were 0/60, 2/60, 7/61 and 19/59, and female rats did not display statistically significant differential mortality. The 3/4 scaling factor was used to determine the Q_1* from the rat data.

On June 11, 1997, the Agency evaluated the weight-of-the-evidence on chlorothalonil in reference to its carcinogenic potential and additional mechanistic data submitted by the registrant in support of the request for re-classification of the carcinogenicity of this chemical. In considering the weight of the evidence for classification of the carcinogenicity of chlorothalonil, the Agency utilized its " Proposed Guidelines for Carcinogen Risk Assessment" (April 23, 1996). In accordance with these proposed guidelines, the Agency agreed that the weight of the evidence supported a classification of chlorothalonil as "likely" to be a human carcinogen by all routes of exposure. This conclusion was based on the evidence of increased incidence of renal adenomas, carcinomas, and adenomas/carcinomas combined in rats and mice following chronic administration of chlorothalonil at doses of 15 and 175 mg/kg/day, as well as increased incidence of forestomach carcinomas in CD-1 mice and papillomas and/or carcinomas combined in Fisher

344 rats. The Agency further concluded that the renal tumor type is rare, there is evidence that precursor lesions occur in the kidney at doses just below those producing tumors, and that steps in that mechanism (for production of renal tumors) are present in humans but not to the same degree.

The Agency concluded that the cell proliferation data supported a non-linear mechanism of action for induction of forestomach tumors and that precursor lesions to these tumors (including cell proliferation, hyperplasia, and hyperkeratosis) occur at doses and/or exposure times just below those producing tumors. Based on the discussion of the mode of action for production of renal and forestomach tumors by chlorothalonil, the Agency concluded that chlorothalonil met the risk assessment criteria for non-linearity, and that the Margin of Exposure (MOE) approach should be used for the purposes of this risk assessment (MRID 44240901, 44223002, discussed under "Mechanistic Data" above).

The Scientific Advisory Panel met on July 30, 1998 to consider the mechanism for the formation of renal and forestomach tumors associated with chlorothalonil. The Panel subsequently reported that the data appear to indicate that the proposed mode of action for chlorothalonil is plausible and likely to be valid, but acknowledged that data gaps exist that prevent definitive understanding of the mechanism. The Panel further reported that if the mode of action is as proposed, then a non-linear MOE approach would be warranted. The Panel recommended that additional analyses of the data be conducted to determine whether the data points followed a linear or non-linear pattern. The Panel's report is provided in Appendix F.

For the purposes of this risk assessment, the MOE has been determined using the 1.5 mg/kg/day dose as the "point of departure," as no tumor response or cell proliferation response was observed at this dose level. Tumor response in the kidney as well as cell proliferation was observed at the next higher dose level tested (15 mg/kg/day).

In this document, the results of both the linear (Q_1* approach) and non-linear models (MOE approach) are presented together. While the results of both models are presented in this RED, the additional work needed to confirm the validity of the non-linear model has not been performed, and the policy implications, methodology, and appropriateness of using the MOE approach in regulatory decision-making have not yet been fully developed by the Agency. Until these issues are resolved, the Agency will regulate chlorothalonil based on the results of the Q_1* approach.

NOELs Determined by Other Organizations

For renal tumorigenicity in the rat, the following NOELs were determined by others:

Health Canada.....NOEL = 15 mg/kg/day
World Health Organization.....NOEL = 3.0 mg/kg/day
United Kingdom.....NOEL = 4.0 mg/kg/day

For renal tumorigenicity in the mouse, the following NOELs were determined by others:

Health Canada.....NOEL = 21.3 mg/kg/day
World Health Organization.....NOEL = 21.0 mg/kg/day

Dermal Absorption Rate for Chlorothalonil

As discussed previously, an upper limit of 0.15% of chlorothalonil that contacts the skin during a workday is estimated to be absorbed (MRID 44493601). Except when estimating risk from short- and intermediate-term exposures (where the endpoint was derived from a dermal study) and when estimating risk in scenarios with paints and stains containing chlorothalonil, the Agency used the 0.15% dermal absorption rate. For scenarios with paints and stains containing chlorothalonil, a 1.22% dermal absorption rate (8 hour period) for latex based paints and a 1.34% dermal absorption rate (8 hour period) for alkyl-based stains were used. These values are based on the total dermal absorption rate for washed and unwashed skin (0.58+0.64=1.22 for latex; 0.78+0.56=1.34 for alkyd) (MRID 43600103). The 8-hour rate was selected since it is assumed professional painters wash with soap and water at the end of a working day.

Acute Dietary LOEL for Chlorothalonil

A LOEL of 175 mg/kg/day will be used for acute assessment of chlorothalonil (MRID 44223002). Because a LOEL instead of a NOEL was used for the chlorothalonil acute dietary risk assessment, an extra safety factor of 3 was added, and the safety margin is 300 instead of 100 (S. Makris and M. VanGemert memo, 8/12/94).

Short-Term (1-7 days) and Intermediate-Term (1 week to several months) Occupational and Residential NOEL for Chlorothalonil

A NOEL of equal to or greater than 600 mg/kg/day will be used for this risk assessment (MRID 44119101). An MOE of 100 is required.

Chronic (Life-Time) Dietary NOEL, Non-cancer, for Chlorothalonil

A NOEL of 2 mg/kg/day was used for non-cancer effects. The LOEL was based on increased kidney weights and hyperplasia of the proximal convoluted tubules in the kidneys as well as forestomach hyperplasia and ulcers at 4 mg/kg/day in a 2-year dietary study (MRID 41250502). An RfD of 0.02 mg/kg/day was determined based on the NOEL of 2 mg/kg/day and using an uncertainty factor of 100.

Chronic (Life-Time) Dietary, Occupational, and Residential (several months to lifetime) Carcinogenic Potency Factor for Chlorothalonil

A carcinogenic potency factor (Q_1*) of 7.66 x 10^{-3} $(mg/kg/day)^{-1}$ was calculated based

upon female rat renal (adenoma and/or carcinoma) tumor rates (MRID 00146945). A 3/4 scaling factor was applied to the Q_1*.

Chronic (Life-Time) Dietary, Occupational, and Residential (several months to lifetime) NOEL, Cancer for Chlorothalonil

A NOEL of 1.5 mg/kg/day was used in the risk assessment for the carcinogenic endpoint (MRID 44240901, discussed under "Mechanistic Data"). This NOEL is used to calculate MOEs for cancer risk.

Inhalation NOEL (Any Time Period) for Chlorothalonil

Except for an acute inhalation toxicity study, no inhalation toxicity studies were available for this assessment. The NOEL selected for assessing inhalation risk comes from an oral study with a NOEL of 2 mg/kg/day (MRID 41250502). Therefore, the inhalation exposure (in mg/kg/day) using a 100% absorption rate (default value) is converted to an oral exposure (in mg/kg/day). This exposure is then compared to the oral NOEL of 2 mg/kg/day to calculate the inhalation Margin of Exposure (MOE_I). Separate risk calculations are made for inhalation and dermal exposures since doses and endpoints have been identified for separate (i.e. dermal and inhalation) risk assessments.

Toxicological Endpoints of Concern Identified for Use in the Assessment of SDS-3701

There is no evidence of carcinogenicity for the SDS-3701 metabolite in either rats or mice. For the acute and chronic non-cancer dietary exposure assessments, residues of SDS-3701 were combined with residues of chlorothalonil and the sums compared to chlorothalonil endpoints (the LOEL for acute dietary risk and the RfD for chronic non-dietary risk).

Toxicological Endpoints of Concern Identified for Use in the Assessment of HCB

The RfD for HCB is 0.0008 mg/kg/day. The Q_1* for HCB is 1.02 $(mg/kg/day)^{-1}$ based on a 3/4 scaling factor (IRIS).

6. Exposure Assessment

Dietary Exposure From Food

OPPTS GLN 860.1300 (Plant Metabolism, formerly Guideline 171-4a): The qualitative nature of the residues in plants is adequately understood based on metabolism studies with carrots, celery, lettuce, snap beans, and tomatoes. The residues of concern are chlorothalonil and its 4-hydroxy metabolite (SDS-3701). Chlorothalonil comprised approximately 90% of the total radioactive residues (TRR) in lettuce harvested 1-21 days following four foliar applications of

[^{14}C]chlorothalonil. Chlorothalonil, at 70-95% of TRR, and SDS-3701, at 2-8% of TRR, were the major residues identified in carrots harvested 1-21 days and tomatoes harvested 1-14 days following three foliar applications of [^{14}C]chlorothalonil. Chlorothalonil, at 20-31% of TRR, was the only residue identified in snap beans harvested 7 days following the last of four foliar applications of [^{14}C]chlorothalonil at about the maximum registered single application rate. Chlorothalonil, at 24.1-76.9% of TRR, was also the only residue identified in celery foliage and stalks harvested 7 and 21 days following the last of 12 foliar applications of [^{14}C]chlorothalonil at about the maximum registered single application rate. Although no polar metabolites were conclusively identified in the celery study, the data suggested that these residues were glutathione conjugates of chlorothalonil and related compounds in which the glutathione moiety had undergone further transformation.

In December 1995, the Agency considered whether to continue to regulate chlorothalonil residues as the combined residues of parent and SDS-3701 or to remove SDS-3701 from the tolerance expression. The Agency subsequently concluded that since available toxicological data indicate that SDS-3701 can contribute to the non-cancer dietary risk from uses of chlorothalonil on food and feed commodities, it should remain in the tolerance expression.

OPPTS GLN 860.1300 (Animal Metabolism, formerly Guideline 171-4b): The qualitative nature of the residue in animals is adequately understood. The residue of concern in meat and milk is SDS-3701. Chlorothalonil, per se, has been shown to be so unstable in ruminant tissues that it is impractical to establish tolerances that include the parent. Tolerances are needed on meat and milk for SDS-3701. Little metabolism of SDS-3701 occurs in ruminants and the unchanged test substance accounted for 88-99% of the TRR in milk and edible tissues. The metabolic fate of chlorothalonil and SDS-3701 in ruminants is adequately understood based on goat metabolism studies. The proposed pathway for chlorothalonil metabolism in ruminants involves substitution of one or more of the chlorine atoms with glutathione. These complexes may undergo further modification of the glutathione side chains to yield a variety of products.

Tolerances are not required for residues of either chlorothalonil or SDS-3701 in poultry. Poultry metabolism studies using [^{14}C]chlorothalonil and 4-hydroxy-[^{14}C]chlorothalonil indicate that there is no significant transfer of chlorothalonil to poultry tissues or eggs, and that the levels of transfer of SDS-3701 are too low to require feeding studies or tolerances for poultry commodities.

OPPTS GLN 860.1340 (Residue Analytical Methods, Plants and Animals, formerly Guidelines 171-4c,d: Adequate residue analytical methods are available for purposes of reregistration. The Pesticide Analytical Manual (PAM) Vol. II lists Method I, a GC method with electron capture detection (ECD), for the enforcement of tolerances for plant commodities. Residue data for plant commodities were collected using methods based on the enforcement method. The establishment of tolerances for residues of SDS-3701 on meat and milk was made contingent upon receipt of an acceptable enforcement method for these commodities. The registrant proposed a GC/ECD method for enforcement of tolerances for peanuts, potatoes, and

tomatoes which is a modification of the current enforcement method. This method underwent successful validation by the Agency and was accepted in 1997. It was forwarded to FDA for publication in PAM, Vol II.

The FDA PESTDATA database dated 1/94 (PAM Vol. I, Appendix I) indicates that chlorothalonil is completely recovered (>80%) using multiresidue methods PAM Vol. I Sections 303 (Mills, Onley, Gaither method) and 304 (Mills fatty food method) and has a low recovery (<50%) using Section 302 (Luke method).

OPPTS GLN 860.1380 (Storage Stability, formerly Guideline 171-4e): All data pertaining to storage stability have been evaluated and deemed adequate. The existing evidence indicates that residues of chlorothalonil, SDS-3701 and HCB are generally stable during frozen storage for up to 6 years. The data support the trial data used in establishing tolerances.

OPPTS GLN 860.1480 (Magnitude of the Residue in Meat, Milk, Poultry, and Eggs, formerly Guideline 171-4j): A 28-day ruminant feeding study has been reviewed and accepted by the Agency. The establishment of tolerances for SDS-3701 in meat and milk are required contingent upon satisfactory validation of an enforcement analytical method for SDS-3701 residues in these commodities. The requirement for a poultry feeding study was waived based on the results of the poultry metabolism study.

The requirements for additional HCB poultry and ruminant feeding studies from the July 31, 1991 DCI have been waived. HCB feeding studies available to the Agency indicate that residues of HCB accumulate only in fatty matrices.

OPPTS GLN 860.1300 (Magnitude of the Residue in Plants, formerly Guideline 171-4a): The reregistration requirements for magnitude of the residue in plants are fulfilled for the following commodities: apricots; asparagus; beans, dry and succulent; blueberries; carrots; celery; cherries; field corn; field corn fodder; sweet corn (K+CWHR); sweet corn fodder; sweet corn forage; cranberries; cucumbers; filberts; garlic; grass seed screenings; melons; mint; mushrooms; nectarines; onions, dry bulb; papayas; parsnips; passion fruit; peaches; peanuts; plums; fresh prunes; potatoes; pumpkins; soybeans; squash, summer and winter; and tomatoes. An increased tolerance is necessary for green onions.

Negotiations with technical registrants of chlorothalonil based on assessments detailed in this document will result in revisions to product labels so that for many food crops, maximum individual application rates, minimum intervals between applications, and maximum seasonal application rates, which have been approved by the Agency, will be explicitly stated. Many of these treatment regimens represent application rate reductions.

The July 31, 1991 DCI required residue data for HCB from field trials on eight representative crops for the purposes of risk assessment. The Agency is waiving these data requirements. The Agency has concluded that residues of HCB on crops are often below the limit

of detection of the analytical method, and that dietary risk from HCB as a contaminant in chlorothalonil should be based on an assumption that residues of HCB in treated commodities are present in the same proportion to chlorothalonil residues as HCB is present in the formulation applied to the crop.

The Agency will allow labels to be amended to permit chlorothalonil-treated plant parts remaining after harvest of seed to be fed to livestock once the appropriate tolerances have been established.

OPPTS GLN 860.1520 (Magnitude of the Residue in Processed Food/Feed, formerly Guideline 171-4l: All data for magnitude of the residue in processed food/feed have been evaluated and deemed adequate. No tolerances for processed commodities are required for chlorothalonil.

OPPTS GLN 860.1560 (Reduction in Residues, formerly Guideline 171-7): All data pertaining to reduction in residues have been evaluated and deemed adequate. No additional data are required (see "Anticipated Residues" section below).

OPPTS GLN 860.1850 (Confined/Field Rotational Crops, formerly 165-1): All data pertaining to rotational crops have been evaluated and deemed adequate. In response to Agency evaluations of confined rotational crop data, the registrant established a 12-month rotational crop restriction on all pertinent product labels and submitted several rotational crop studies. These data indicated that the only residue that was detected in rotated crops was the soil metabolite 3-carbamyl-2,4,5-trichlorobenzoic acid (SDS-46851). Because of the low toxicity of this metabolite, an exemption for the requirement of a tolerance for residues of SDS-46851 as inadvertent residues in rotated crops has been established (40 CFR §180.1110). In addition, the registrant's request to delete rotational crop restrictions from chlorothalonil labels was approved.

The following assumptions were used in estimating anticipated residues:

- Although chlorothalonil and SDS-3701 are both regulated, only chlorothalonil is considered to be a probable human carcinogen by the Agency. Therefore, SDS-3701 residues (present only in meat and milk) are not included in the cancer risk calculations.

- HCB, which is a B2 carcinogen, is present as an impurity in chlorothalonil formulations and is considered to be a residue of concern on chlorothalonil-treated crops. In the absence of actual HCB residue measurements, anticipated residues of HCB on plant food commodities have been estimated by assuming that residues are present in chlorothalonil-treated commodities at a level proportional to the maximum level certified to be present in chlorothalonil formulations. The present maximum certified limit of HCB is 0.05%, so anticipated residues of HCB on a plant commodity have been estimated as 0.0005 x the anticipated residues of chlorothalonil on that commodity, for the assessment of risks from HCB in chlorothalonil alone. Adjustments to this contamination level have been included

in the HCB aggregate risk assessment summarized elsewhere in this document, and are clearly noted.

GB Biosciences has reduced the level of HCB in its technical formulations to 0.004%. To evaluate the potential reduction in anticipated residues if all registrants committed to the lower level of contamination, the values in Table 7 can be multiplied by a factor of 0.08.

The Agency has concluded that residues of chlorothalonil *per se* will not transfer to meat, milk, poultry and eggs; therefore, only anticipated residues for HCB on these commodities are provided.

Table 6 shows the anticipated residues of chlorothalonil and HCB from chlorothalonil on food and feed crops used in the cancer risk assessment. All anticipated residue values have been adjusted for the indicated % crop treated. For commodities with tolerances (established or pending) not listed on this table, the Agency assumed tolerance level residues and 100% crop treated. Dietary exposure estimates (from DRES) incorporate the indicated processing factors.

Table 6. Anticipated Residues of Chlorothalonil and HCB from Chlorothalonil on Food or Feed Crops Used to Calculate Cancer Risk

Commodity	Processing factors	Anticipated Residues (ppm)		% crop treated
		Chlorothalonil	HCB	
apricots	None	0.0078	3.9×10^{-6}	35
banana pulp	None	0.0005	0.3×10^{-6}	10
beans, dry	None	0.0087	4.4×10^{-6}	2
beans, snap	0.05 for all cooked, canned or frozen beans	0.0133	6.7×10^{-6}	40
broccoli	None	0.0015	0.8×10^{-6}	15
Brussels sprouts	None	0.0135	6.8×10^{-6}	42
cabbage	0.2 for all food forms	0.0137	6.9×10^{-6}	50
cabbage, Chinese	0.2 for all food forms	0.0116	5.8×10^{-6}	100
cocoa	0.1 for all food forms	0.05	2.5×10^{-6}	100
cantaloupe	None	0.0191	9.6×10^{-6}	30
carrots	0.005 for all cooked or processed food forms	0.0036	1.8×10^{-6}	35
cauliflower	None	0.0115	5.8×10^{-6}	20
celery	None	0.0874	43.7×10^{-6}	85
cherries	0.05 for all processed food forms	0.002	1×10^{-6}	40
cranberries	None	0.4125	206×10^{-6}	60
coffee	O.1 for all food forms	0.20	1×10^{-4}	100
corn, sweet	None	0.0002	0.1×10^{-6}	5
cucumbers	0.2 for cold-canned pickles; 0.04 for hot-canned pickles	0.0062	3.1×10^{-6}	35
garlic	None	0.0005	0.3×10^{-6}	10
honeydew	None	0.0033	1.7×10^{-6}	20

Commodity	Processing factors	Anticipated Residues (ppm)		% crop treated
		Chlorothalonil	HCB	
nectarines	None	0.00175	0.9×10^{-6}	35
onions, bulb	None	0.0033	1.7×10^{-6}	65
onions, green & leeks	None	0.0262	13.1×10^{-6}	65
papayas	None	0.005	2.5×10^{-6}	100
parsnips	None	0.0052	2.6×10^{-6}	10
passion fruit	None	3	1.5×10^{-3}	100
peaches	0.02 for all cooked or canned food forms	0.0018	0.9×10^{-6}	35
peanuts	0.5 for peanut oil	0.0045	2.3×10^{-6}	90
plums	0.33 for dried prunes	0.0005	0.3×10^{-6}	10
potatoes	None	0.0030	1.5×10^{-6}	30
pumpkins	0.002 for raw pumpkin	0.0065	3.3×10^{-6}	30
soybeans	0.5 for soybean oil	0.00005	2.5×10^{-8}	1
squash	None for summer squash; 0.002 for raw winter squash; 0.001 for cooked winter squash	0.0058	2.9×10^{-6}	15
tomatoes	0.25 for juice; 0.02 for paste, puree & catsup	0.0716	35.8×10^{-6}	70
watermelon	None	0.0228	11.4×10^{-6}	55
Residues in Animal Commodities				
Cattle fat		0	1.65×10^{-4}	-
meat		0	1.24×10^{-5}	-
liver		0	8×10^{-6}	-
kidney		0	8×10^{-6}	
Poultry fat		0	2.2×10^{-6}	-

Commodity	Processing factors	Anticipated Residues (ppm)		% crop treated
		Chlorothalonil	HCB	
meat		0	3.7×10^{-8}	-
liver		0	7.3×10^{-7}	-
Milk		0	1.7×10^{-6}	-
Egg-white only		0	1.5×10^{-9}	-
Egg-yolk only		0	7.3×10^{-7}	-
Eggs-whole (36.55 yolk)		0	2.7×10^{-7}	-

The dietary exposure analysis also includes pending uses on pistachios, asparagus, mangoes, almonds, and non-bell peppers.

Dietary Exposure from Drinking Water

Exposure to chlorothalonil in drinking water is derived from the monitoring data discussed below. The Agency assumes that children weighing 10 kg consume one liter of drinking water per day while adults weighing 70 kg consume two liters.

Groundwater Exposure: The groundwater database for chlorothalonil as presented here is not necessarily complete or up-to-date, and the risk assessment for groundwater represents a worst-case scenario.

The metabolites of chlorothalonil have been found in groundwater in Long Island, New York, and have been attributed to potato use. These metabolites (SDS-46851, SDS-47525, SDS-3701, and SDS-19221) were measured at a combined concentration of approximately 16 ppb in Suffolk County, Long Island in 1981. Chlorothalonil and the two isomeric metabolites SDS-47523/SDS-4752 were not detected. Chlorothalonil itself has been detected in the States of California, Florida, Massachusetts, and Maine at levels typically below 1 ppb. These observations are predictable based on laboratory mobility studies and evidence of metabolite persistence.

It is not clear how the use of chlorothalonil in New York compares to use in other areas, although Long Island is traditionally an area where potatoes are grown, and potatoes are a major use site for chlorothalonil. It is expected that the levels of chlorothalonil metabolites detected in

the groundwater in New York are relatively high compared to the country as a whole, because 1) they were the highest values reported in the database, 2) potatoes are a major crop on Long Island, and 3) Long Island groundwater is generally shallow and vulnerable. We have used the Long Island values to represent a high-end potential exposure.

A prospective small-scale groundwater monitoring study which was precipitated by the presence of chlorothalonil degradates (metabolites) in groundwater has recently been completed, and should provide the Agency with a more quantitative measure of groundwater contamination potential. When these data are reviewed, a refined drinking water risk assessment may be conducted, including, if necessary, a cancer risk assessment.

In the absence of data demonstrating otherwise, this assessment is based on the conservative assumption that the detected metabolites of chlorothalonil have the same toxicity as the parent. As indicated above, this assessment relies on other conservative factors. Based on this assumption and worst-case parameters, the following conclusions can be drawn about exposure and risk from groundwater-based drinking water.

The Agency used the combined 16 ppb metabolite concentration from New York to calculate an acute (one day) and chronic non-cancer exposure estimate for chlorothalonil. Since it is assumed that the metabolites of chlorothalonil are not of carcinogenic concern, a cancer risk assessment for groundwater was not calculated.

The Agency assumes that children weighing 10 kg consume one liter of drinking water per day while adults weighing 70 kg consume two liters. Based on the highest combined metabolite concentration (16 ppb), estimated exposure for children is 0.0016 mg/kg/day, and for adults, 0.00046 mg/kg/day. With most groundwater sources, there are no known predictable seasonal or longer-term trends in concentrations of pesticide contaminants, so these exposure values were used to calculate both acute and chronic risk.

Surface Water Exposure: Chlorothalonil can contaminate surface water at application via spray drift or after application through runoff and erosion. The intermediate soil/water partitioning of chlorothalonil indicates that its concentration in suspended and bottom sediment will be substantially greater than its concentration in water. The major degradate of chlorothalonil in the soil under aerobic conditions is SDS-3701. SDS-3701 appears to be more persistent and mobile than chlorothalonil, based on groundwater detections. Substantial amounts of SDS-3701 could be available for runoff for longer periods than chlorothalonil, and SDS-3701 may be more persistent in water/sediment systems than chlorothalonil. The apparent greater mobility of SDS-3701 suggests that it exhibits lower soil/water partitioning than chlorothalonil. Therefore, the ratio of SDS-3701 runoff loss via dissolution in runoff to runoff loss via adsorption to eroding soil for SDS-3701 may be greater than for chlorothalonil. In addition, the ratios of concentrations dissolved in the water column to concentrations adsorbed to suspended and bottom sediment may be higher for SDS-3701 than for chlorothalonil. The Agency was unable to calculate drinking water risk for SDS-3701 in surface water because no monitoring data were available.

The South Florida Water Management District (SFWMD; Miles and Pfeuffer 1994) summarized chlorothalonil detections in samples collected every two to three months from 27 surface water sites within the SFWMD from November 1988 through November 1993. Approximately 810 samples (30 sampling intervals X 27 sites sampled/interval) were collected during that time. Chlorothalonil was detected in 25 samples at concentrations ranging from 0.003 ppb to 0.035 ppb. Six of the samples had concentrations $\geq$ 0.01 ppb. The detection limits generally ranged from 0.001 to 0.006 ppb; and the quantification limit was approximately 0.2 ppb.

The Agency assumes that children weighing 10 kg consume one liter of drinking water per day, while adults weighing 70 kg drink two liters a day. Based on the highest measured concentration (0.035 ppb, exposure to children is 0.0000035 mg/kg/day and exposure to adults is 0.000001 mg/kg/day. These exposure values were used to calculate both acute and chronic risk.

Occupational and Residential Exposure

Handler Exposures & Assumptions: EPA has determined that there is potential for mixers, loaders, applicators, or other handlers to be exposed to chlorothalonil and HCB during use patterns associated with chlorothalonil. The daily exposure for handlers is calculated using the following formula:

Daily exposure (mg ai/kg bw/day) =

$$\frac{\text{unit exp.(mg ai/lb ai used) X lb ai/A X A/day}}{\text{body weight (70 kg for males, 60 kg for females)}}$$

Handler exposure scenarios for chlorothalonil include:

- Large scale mixing/loading and applying chlorothalonil for air-assisted, ground-boom, and aerial application equipment;
- Mixing/loading chlorothalonil for applications through irrigation equipment;
- Mixer/loader and applicator exposure while using hand-held equipment such as backpack sprayers, hose-end sprayers and granular spreaders;
- Flaggers supporting aerial applications;
- Painting with airless sprayers and paint brushes using paints and stains containing chlorothalonil;
- Mixing liquid chlorothalonil into paints.

These scenarios are not directly applicable to determining potential handler exposures for

several non-agricultural uses of chlorothalonil, including uses on fresh cut lumber to control sapstain and molds (dip vats and sprayed-on), pressure treatment of wood, uses in caulks, sealants, and grout. Exposure data for wood treatment uses are needed. The Agency considers the application of paints and stains containing chlorothalonil to have greater potential for exposure than the use of chlorothalonil in caulks, sealants, and grout, so risks from these uses are assumed to be lower.

Mixer/loader/applicator (M/L/A) exposure data were required during Phase IV of the reregistration process. Additional M/L/A data were required in 1991 for painters and greenhouse applicators. The following handler exposure monitoring studies have been submitted to support the reregistration of chlorothalonil:

- a mixer, applicator, and mower exposure study with chlorothalonil for golf course maintenance [MRID 42433810];

- potential exposure of workers to chlorothalonil when handling and applying paint containing chlorothalonil [MRID 43600102];

- chlorothalonil worker exposure during backpack sprayer application of Daconil 2787 flowable fungicide in greenhouses [MRID 43623201].

Surrogate data (unit exposures) provided in the Pesticide Handlers Exposure Database (PHED) are also available for estimating other handler exposure scenarios. These scenarios include handling tasks associated with the use of aerial, chemigation, airblast, ground-boom, and hand-held equipment. Where appropriate, the data from handler exposure monitoring studies submitted by the registrant (such as those cited above) have been merged with data contained in PHED. These scenarios are shown in Tables 10-18. The clothing and PPE scenarios for each type of exposure reflect the clothing and PPE worn in the study from which the unit exposure values were derived. The crops listed with each exposure scenario are the crops with the higher application ranges representing reasonable and high end exposure scenarios.

Exposure data on professional lawn care applications to residential turf are very limited. An "Assessment of Lawn Care Worker Exposure to Dithiopyr" is available in the open literature (Cowell, J.E., Lottman, C.M., and Manning, M.J. 1991. Arch. Environ. Contam. Toxicol. 21:195-201). In this study, applicator exposure was measured using biological monitoring techniques. Since the dermal absorption rates of both dithiopyr and chlorothalonil are known, an estimation of exposure to handlers using chlorothalonil can be made using these surrogate data.

Post-Application Exposures and Assumptions: As a non-systemic fungicide applied to plant tissues, chlorothalonil is strongly bound to leaf and stem cuticular waxes. According to GB Biosciences, dissipation is influenced primarily by rainfall and irrigation. In the absence of rain or irrigation, dissipation is influenced primarily by leaf expansion. Repeated applications are made to many crops because chlorothalonil is used as a preventative treatment rather than curative

treatment. Chlorothalonil is applied to several crops requiring hand-labor, presenting a significant potential for workers to be exposed to treated foliage. For many crops, frequent applications are made up-to, and throughout the harvest period.

Post-application exposure may be mitigated by the establishment of restricted entry intervals (REI) for occupational uses. REIs allow field residues to dissipate to levels that result in acceptable MOEs for reentry workers (100 or greater). REIs and post-application exposure for chlorothalonil were calculated by using the following data submitted by GB Biosciences:

- Determination of Dislodgeable Foliar Residues of Chlorothalonil and HCB from Bravo 720 Treated Cherry Leaves [MRID 42875902];

- Determination of Dislodgeable Foliar Residues of Chlorothalonil and HCB from Bravo 720 Treated Broccoli Plants [MRID 42875903];

- Determination of Dislodgeable Foliar Residues of Chlorothalonil and HCB from Bravo 720 Treated Cucumber Plants [MRID 42875904];

- A Tomato Harvester Exposure Study with Chlorothalonil [MRID 470025045];

- A Golfer Exposure Study with Chlorothalonil Used for Golf Course Maintenance [MRID 42433811];

- A Mixer, Applicator, and Mower Exposure Study with Chlorothalonil for Golf Course Maintenance [MRID 42433810].

Except for the tomato study, the above-referenced dislodgeable foliar residue studies were conducted without concurrently monitoring worker exposure, so worker exposure (µg/hr) to dislodgeable foliar residues (µg/cm^2) was calculated using estimated transfer factors (cm^2/hr). Transfer factors bridge various worker exposures/tasks to field-measured dislodgeable foliar residues. The estimated transfer factors used in this risk assessment are based on professional judgment and discussions with personnel at the California Department of Pesticide Regulation. Generic transfer factors corresponding to agricultural reentry exposures are presently being developed by the Agricultural Reentry Task Force (ARTF). GB Biosciences and Sipcam Agro USA, Inc. are members of the task force.

The studies submitted by the registrant do not address post-application exposure to treated turfgrass in residential situations. Although two of the studies address post-application exposure of golfers and mowers following chlorothalonil treatments to golf courses, no measurements of foliar dislodgeable residues were made. By measuring human exposure and available dislodgeable foliar residues concurrently, transfer factors can be calculated. Residential exposure to treated turfgrass will be addressed by the Outdoor Residential Exposure Task Force (ORETF) of which GB Biosciences and Sipcam Agro USA, Inc. are members. Data for reentry

to turfgrass treated with chlorothalonil were required in a March 1995 DCI for products registered on turfgrass. These data are due to the Agency in October 1999.

Post-application/reentry daily exposure (mg/kg/day) is calculated as follows:

$$\frac{\text{DFR } (\mu g/cm^2) \text{ x transfer factor } (cm^2/hr) \text{ x 8 hours/day x dermal absorption}}{\text{body weight (in kg)}}$$

The Agency's default value for worker body weight is 70 kg, but for post-application risk to workers in greenhouses and in a conifer nursery scenario, a body weight of 60 kg was used to account for the lower body weight of women, who form a significant part of the greenhouse and nursery workforce.

Occupational and Residential Exposure to HCB: The Agency did not conduct an extensive handler and post-application exposure evaluation for HCB as a contaminant in chlorothalonil were evaluated through a qualitative because a preliminary investigation indicated that the risks associated with these exposures would be negligible. The potential risk posed by HCB in these situations was estimated by comparison to a high-end occupational exposure scenario--a mixer/loader using a wettable powder to support aerial applications to celery. For this scenario, a risk of 2.8×10^{-5} was estimated. Risks from HCB exposure in a post-application scenario are expected to be lower. The estimate is for HCB in chlorothalonil at a contamination level of 0.05% HCB; formulations with lower contamination levels would pose correspondingly lower risk.

7. Risk Characterization

Dietary Risk

Food uses evaluated in the DRES (Dietary Risk Evaluation System) analysis were the published uses of chlorothalonil listed in 40 CFR §180.275 and the Tolerance Index System (TIS) and pending uses. The chronic non-cancer analysis for chlorothalonil and HCB used anticipated residues and the results were compared to the RfD for chlorothalonil and HCB, respectively. Residues of chlorothalonil *per se* are not expected to transfer from feed items to meat and milk. Residues of SDS-3701 can occur in meat and milk, but SDS-3701 is not carcinogenic, so there is no carcinogenic risk attributable to chlorothalonil from its use on livestock feed items or its presence in meat and milk. Monitoring data were not used for estimating exposure to SDS-3701. The upper bound carcinogenic risk from chlorothalonil was calculated using both the Q_1* and Margin of Exposure (MOE) approaches. The Agency's reasoning in estimating carcinogenic risk using the two approaches is discussed below. The upper bound carcinogenic risk from HCB was calculated using the Q_1* approach.

Reassessed Tolerances: Tolerances for chlorothalonil are adequate for reregistration. Currently there are no tolerances for chlorothalonil on cattle, goat, hogs, horse and sheep meat, fat and meat

byproducts, milk, poultry or eggs. Tolerances are not required for poultry and eggs for the reregistration of chlorothalonil. A 28-day ruminant feeding study has been reviewed and accepted by the Agency. Tolerances are required for SDS-3701 in meat and milk. All of these animal commodities are considered in the risk assessment for HCB since secondary residues of HCB are found in meat, milk, and eggs at low levels.

Pending Tolerances: Tolerances on pecans (0.02 ppm), pistachios (0.2 ppm), asparagus (0.1 ppm), mangoes (1 ppm), almonds (0.05 ppm), almond hulls (1 ppm), and non-bell peppers (5 ppm) have been included in the risk analysis as pending tolerances. Anticipated residues were used for pistachios (0.068 ppm), mangoes (0.3 ppm), and asparagus (0.03 ppm). Anticipated residues for blueberries (1 ppm) and filberts (0.1 ppm) are set at tolerance levels. Residues for mushrooms were set at 7 ppm, the level proposed at the time of the analysis. A tolerance of 1 ppm has since been established for mushrooms based on an altered use pattern. Imported snow peas from Guatemala have not been included in the analysis but have been assessed by the Agency in the past.

Anticipated Residues and Percent Crop Treated Information: Anticipated residues (ARS) have been provided for the purpose of dietary risk analysis. There is one set of residues values for chlorothalonil and another for residues of the contaminant, HCB. U.S. FDA monitoring data (1988-1993), USDA PDP survey data (1992-1994 partial), and field trial data are types of anticipated residue data provided for HCB and chlorothalonil. Percent Crop Treated information for some of the food crops was provided from sources mentioned previously and other sources cited in the anticipated residue analysis (W. Smith memo, D208333, 6/13/95).

The FQPA amendments to section 408(b)(2)(F) of the FFDCA require that if a tolerance relies on percent crop-treated data, that the Agency make a determination as to the reliability of the data. The percent crop treated estimates used by EPA are derived from Federal and private market survey data. Typically, the Agency considers the range of percent crop treated data from a period of several years, and uses the upper end of this range for estimating dietary exposure. In so doing, the Agency is reasonably certain that exposure is not understated for any major population sub-group. The Agency will provide for the periodic evaluation of these estimates of percent crop treated, as long as the tolerances for chlorothalonil remain in force.

Residues of HCB in plant commodities were estimated to be present at 0.05% of the residues of chlorothalonil. This level is equivalent to the maximum level of HCB that is allowed in formulations of chlorothalonil. In meat products, ARs were estimated based on HCB feeding studies (W.Smith memo, 6/13/95). ARs were used to calculate both chronic and carcinogenic dietary exposure.

Table 7 summarizes sources of dietary exposure data and toxicity test endpoints used in the dietary risk assessments for chlorothalonil, chlorothalonil and SDS-3701 combined, and HCB from chlorothalonil.

Table 7. Residue Sources and Toxicity Values used for Dietary Risk Calculations

Risk Assessment	Residue Source	For **Chlorothalonil** Risk, Compare to:	For **HCB** Risk, Compare to:
Acute Dietary (chlorothalonil = parent + SDS-3701)	TMRC or ARs -- All commodities[1]	LOEL for chlorothalonil: 175 mg/kg/day (for MOE>300)	N/A: no acute dietary endpoint for HCB
Chronic Non-Cancer Dietary (chlorothalonil = parent + SDS-3701)	For Chlorothalonil: TMRC with PCT -- All commodities	RfD for chlorothalonil: 0.02 mg/kg/day (for %RfD)	N/A
	For HCB: ARs for HCB in 6/13/95 (tolerances X 0.0005 except MMPE[2])	N/A	RfD for HCB:0.0008 mg/kg/day
Dietary Cancer (chlorothalonil = parent only)	For Chlorothalonil: ARs excluding MMPE[2]	Q_1* = 7.66 x 10^{-3} $(mg/kg/day)^{-1}$; NOEL = 1.5 mg/kg/day (for MOE approach);	N/A
	For HCB: ARs -- All commodities	N/A	Q_1* for HCB: 1.02 $(mg/kg/day)^{-1}$

[1] "All Commodities" includes meat and milk, eggs and poultry.
[2] MMPE = meat, milk, poultry and eggs

Acute Dietary Risk from Chlorothalonil and SDS-3701 Combined: The Agency employed the computerized modeling system DRES to estimate dietary risk. The DRES detailed acute exposure analysis for chlorothalonil estimates the distribution of single-day exposures for the overall U.S. population and certain subgroups. The analysis evaluates individual food consumption as reported by respondents in the USDA 1977-1978 Nationwide Food Consumption Survey (NFCS) and accumulates exposure to chlorothalonil for each commodity. Each analysis assumes uniform distribution of chlorothalonil in the commodity supply.

Since the toxicological effects to which high-end exposure is being compared in this analysis are renal and gastric lesions (found in the kidneys and stomach), all standard DRES subgroups are of concern. The analysis includes the general US population in 48 states and four subgroups: infants (<1 year), children (1-6 years), females (13+years) and males (13+years).

The Margin of Exposure (MOE) is a measure of how close the high-end exposure comes to the NOEL (the highest dose at which no effects were observed in the laboratory test), and is calculated as the ratio of the NOEL to the exposure (NOEL/exposure = MOE). When the endpoint is taken from an animal study, as in this case, the Agency is not generally concerned unless the MOE is below 100. As noted previously for chlorothalonil, a NOEL could not be determined, so the LOEL is used, and the safety margin is 300 instead of 100 (S. Makris and M. VanGemert memo, 8/12/94). In this case, an MOE of less than 300 could be a cause for concern.

The analysis included tolerances being recommended through reregistration for chlorothalonil, pending tolerances, and tolerances for meat and milk.

The analysis calculated the exposure of the most highly exposed individual for the U.S. population in the distribution and compared the exposure to the LOEL of 175 mg/kg bwt/day from the subchronic study in rats (MRID 40243702). The table below provides the calculated MOEs for the general population and the four most highly exposed subgroups. The percent of the population which consumes at least one of the commodities for which chlorothalonil is registered is 92-99% of all persons in the food survey.

Table 8 captures acute dietary risk estimates for residues of chlorothalonil and SDS-3701 combined, using supported and pending tolerances for chlorothalonil.

Table 8. Acute Dietary Risk Estimates for Chlorothalonil and SDS-3701

DRES Subgroup	MOE (=NOEL/Exposure)
U.S. population (48 states)	1166
Infants<1 year old	875
Children (1-6 years)	875
Females (13+ years)	1750
Males (13+ years)	1750

The Agency has concluded that acute dietary risk estimates for the general population and these four subgroups from combined residues of chlorothalonil and SDS-3701 do not exceed our level of concern.

Chronic Non-Cancer Risk from Combined Residues of Chlorothalonil and SDS-3701:
Tolerance level residues were used in the analysis to calculate a Theoretical Maximum Residue Contribution (TMRC). The analysis was further refined by considering percent of crop treated information. These exposure estimates were then compared to the RfD for chlorothalonil for chronic dietary risk. Exposures at less than 100% of the Reference Dose are not generally of concern.

Using Tolerance level Residues: The TMRC for the overall U.S. population and the subgroup with the highest estimated risk from all currently published and pending chlorothalonil tolerances and proposed meat and milk tolerances are listed below.

Subgroup	Exposure(mg/kg/day)	%Reference Dose
U.S. population	0.013868	77
Children (1-6)	0.025800	143

The % RfD is a risk estimate for chronic non-cancer risk from combined residues of chlorothalonil and SDS-3701.

Using Tolerance level Residues Corrected for Percent Crop Treated Information: Exposure and risk estimates for the overall U.S. population and the subgroup with the highest estimated risk from all published and pending uses and proposed meat and milk tolerances are listed below.

Subgroup	Exposure(mg/kg/day)	%Reference Dose
U.S. population	0.006474	32
Non-nursing Infants (<1year old)	0.012059	60

The risk estimate for the subgroup Children (1-6) is similar to that for the Non-nursing Infant subgroup. This more refined analysis shows that combined residues of chlorothalonil and SDS-3701 do not present chronic non-cancer risk estimates of concern for the general population or the most highly exposed subgroup.

Chronic Non-Cancer Risk from HCB: Tolerance level residues corrected for 0.05% HCB in the formulation were used in the analysis to calculate a TMRC. The analysis was further refined by considering percent of crop treated information for the ARC. These exposure estimates were then compared to the RfD for HCB (0.0008 mg/kg/day) for chronic dietary risk.

The ARC for HCB for the overall U.S. population and the subgroup with the highest estimated risk from all currently published and pending chlorothalonil and proposed meat and milk tolerances are listed below.

Subgroup	Exposure(mg/kg/day)	%Reference Dose
U.S. population	0.0000002	0.029
Children (1-6 years)	0.0000004	0.050

HCB in chlorothalonil does not present chronic non-cancer risk estimates of concern for the general population or the most highly exposed subgroup.

Carcinogenic Risk from Chlorothalonil, *per se*: Dietary carcinogenic risk from chlorothalonil was estimated using two approaches. These two approaches represent two different ways of looking at the dose-carcinogenic response relationship, and their origins are discussed above under "Classification of Carcinogenic Potential for Chlorothalonil." The Agency has explored both linear and non-linear models for estimating the carcinogenic risk of chlorothalonil. The SAP recommended that additional work is necessary before a definitive conclusion can be reached about the validity of the non-linear model. This work has not been completed or reviewed, and so

the issues which have been raised about chlorothalonil's mechanism of carcinogenicity are not yet resolved. In addition, the non-linear model yields a measure of risk outside of our usual regulatory experience, i.e., an MOE for cancer risk. The Agency has not determined the appropriate MOE at which to regulate cancer risk.

In this document, the results of both the linear (Q_1* approach) and non-linear models (MOE approach) are presented together. While the results of both models are presented in this RED, the additional work needed to confirm the validity of the non-linear model has not been performed, and the policy implications, methodology, and appropriateness of using the MOE approach in regulatory decision-making have not yet been fully developed by the Agency. Until these issues are resolved, the Agency will regulate chlorothalonil based on the results of the Q_1* approach.

Q_1* Approach: The upper bound carcinogenic risk from food uses of chlorothalonil for the general U.S. population was calculated using the following equation:

$$\text{Chlorothalonil Cancer Risk} = \text{Dietary Exposure (ARC)} \times Q_1^*$$

The dietary exposure anticipated residue contribution used for this risk assessment incorporated not only refinement in terms of percent crop treated, but additional refinement based on anticipated residues for all the published, pending and new uses for chlorothalonil. These anticipated residues were obtained from field trial data or monitoring data. As was previously noted, chlorothalonil per se is not found in meat or milk. The refined exposure estimate for the U.S. Population is 0.000158 mg/kg/day. Based on a Q_1^* of 0.00766 $(mg/kg/day)^{-1}$, the upper bound cancer risk was calculated to be **1.2×10^{-6}.** This figure is at a level which the Agency considers negligible for excess lifetime cancer risk estimates.

MOE Approach: The carcinogenic risk from food uses of chlorothalonil for the general U.S. population was calculated by comparing the dietary exposure from chlorothalonil to the NOEL identified for use with the cancer risk assessment. The NOEL of 1.5 mg/kg/day comes from a somatic cell proliferation study in mice (MRID 44223002). The following equation was used to determine dietary cancer risk:

Cancer Risk = NOEL/ Dietary Exposure (ARC) in mg/kg/day

Chronic dietary exposure is again estimated at 0.000158 mg/kg/day, based on the ARC. Based on the cancer NOEL of 1.5 mg/kg/day, the cancer risk was calculated as an MOE of **9500** for the general population, contributed through all the published, pending and new uses for chlorothalonil. At this point in time, the Agency is not able to conclusively determine that chlorothalonil is a non-linear carcinogen nor to apply approved policy determinations on non-linear carcinogens to chlorothalonil, and so cannot determine whether the MOE of 9500 represents an excess lifetime cancer risk.

Carcinogenic Risk from HCB in Chlorothalonil: The upper bound carcinogenic risk from food uses of HCB for the general U.S. population was calculated using the following equation:

HCB Upper Bound Cancer Risk = Dietary Exposure (ARC) x Q_1^*

Based on a Q_1^* of 1.02 $(mg/kg/day)^{-1}$, the upper bound cancer risk was calculated to be 2.4×10^{-7}, contributed through all the published, pending and new uses for chlorothalonil.

The upper bound risk for HCB in chlorothalonil is in the range the Agency generally considers negligible for excess lifetime cancer risk. The exposure assessment for carcinogenic risk from HCB in chlorothalonil includes many assumptions and uncertainties which impact the Agency's confidence in the calculated risk.

HCB is also a contaminant in several other pesticides, and an aggregate risk assessment for HCB from chlorothalonil and these other sources has been conducted. The exposure assessment for aggregate risk is subject to the same kinds of uncertainties and assumptions as the risk assessment for HCB in chlorothalonil. For some of the individual pesticide contributors, these limitations impact the assessment to an even greater extent.

Dietary Cancer Risk from HCB and Pentachlorobenzene in all Pesticidal Sources: Four pesticides that are used on food/feed crops have been assessed for cancer risk due to contamination with HCB--chlorothalonil, dacthal, picloram, and pentachloronitrobenzene (PCNB). Pentachlorobenzene (PCB) is also present in PCNB, and the Agency has concluded that the carcinogenic potential of PCB is comparable to HCB, based on the similarities of the chemical structures and toxicities of HCB and PCB. In estimating dietary risk from HCB in these four pesticides, the Q_1^* for PCB is assumed to be equal to that for HCB.

HCB is also present in pentachlorophenol, but pentachlorophenol is not a food-use pesticide and so the contaminant in pentachorolphenol does not contribute to aggregate dietary risk (the contribution to drinking water risk is discussed below). HCB and/or PCB is present in five other food-use pesticides, but at low levels which do not significantly add to the aggregate dietary exposure.

The estimated aggregate dietary cancer risk for HCB from all known pesticidal sources is 1.34×10^{-6}. An additional 0.46×10^{-6} may be attributed to PCB for a total of 1.8×10^{-6}. Table 9 documents the estimated dietary cancer risk contributions from the pesticidal sources of HCB and PCB.

Table 9. Estimated Dietary Carcinogenic Risk of the Pesticide Impurities, HCB and PCB.

Source Pesticide	Carcinogenic Risk		
	HCB	PCB	Combined
Chlorothalonil	2.4×10^{-7}	None	2.4×10^{-7}
PCNB	1.6×10^{-7}	4.3×10^{-7}	5.9×10^{-7}
Picloram	1.5×10^{-7}	None	1.5×10^{-7}
Dacthal	7.1×10^{-7}	None	7.1×10^{-7}
Five Other Chemicals*	7.5×10^{-8}	2.8×10^{-8}	1.0×10^{-7}
Total	**1.3×10^{-6}**	**4.6×10^{-7}**	**1.8×10^{-6}**

*Endosulfan, chlorpyrifos-methyl, atrazine, simazine, and clopyrilid

The Agency generally views dietary carcinogenic risks at or below 10^{-6} not to be of concern. The aggregate HCB/PCB dietary risk as estimated in this assessment is at the lower end of the range of concern. These findings must be viewed in light of several factors. Most notably, HCB is generally present in food commodities at levels that are below the limit of detection of analytical methods. For the most part in this assessment, the assumption was made that the impurities would occur on food commodities at the same ratio to the active ingredient as was present in the formulation applied to crops. It is assumed that the impurity would dissipate from the food commodity at an equal or greater rate than the active ingredient. The Agency believes this is a reasonable assumption because there are some data available from exaggerated use rate studies of chlorothalonil, picloram, and dacthal which support this approach.

For the four most significant contributors to HCB aggregate risk, the residue data on which the HCB inputs were based are a mixture of anticipated residues and tolerances. For three of the four major contributors, when levels of HCB in formulated products were used to estimate levels of HCB in residues of the parent compounds on food and feed items, the levels of HCB which were used were the maximum certified limits the registrants are required not to exceed. For PCNB only, the analysis was based on a higher, historic level of HCB contamination. These certified limits and the level used for PCNB are:

Pesticide	Certified Limit	Assessment level
Chlorothalonil	0.05%	same
PCNB	0.05% (0.01% for PCB)	0.1% HCB (0.01% for PCB]
Picloram	0.01%	same
Dacthal	0.3 %	same

Adjustments to these limits are possible, and in fact, GB Biosciences has certified that the level of HCB in its chlorothalonil products does not exceed 0.004%. GB Biosciences has agreed

to reduce the level of HCB in dacthal. The two producers of technical grade PCNB have certified that levels of HCB will not exceed 0.05% and that levels of PCB will not exceed 0.01%.

Risks associated with the five chemicals containing only small amounts of the impurities are based on a first cut screening assessment from DRES with no refinement for anticipated residues. Such refinements would not significantly affect the assessment because the levels of HCB and PCB in these pesticides are much lower than the levels found in picloram, PCNB, chlorothalonil, and dacthal.

Drinking Water Risk

This risk assessment covers both groundwater and surface water sources of drinking water. For chlorothalonil in groundwater, acute and chronic non-cancer risks are assessed. Cancer risk was not calculated because available groundwater monitoring data show predominantly detections of metabolites of chlorothalonil, rather than chlorothalonil itself. These metabolites have not been shown to be carcinogenic. Acute drinking water risk from HCB (in either groundwater or surface water) was not estimated because there is no acute dietary endpoint for HCB, Cancer risk from HCB in groundwater was not calculated because, lacking other data, HCB exposure could only be based on chlorothalonil detections.

For surface water, the acute, chronic non-cancer, and cancer risks of chlorothalonil are assessed. Chronic non-cancer and cancer risks are also assessed for HCB in chlorothalonil. HCB is present in drinking water from the use of other pesticides in addition to chlorothalonil, and also from non-pesticidal and historic use. Aggregate drinking water risk from HCB from all sources is addressed elsewhere in this document.

Acute drinking water risk was calculated by dividing the LOEL identified for acute dietary risk assessment by the exposure from drinking water sources. As discussed previously, an MOE of at least 300 is considered adequate for acute risk because a NOEL could not be determined in the subject study. Chronic non-cancer risk for drinking water was calculated by comparing exposure through drinking water sources to the appropriate RfD. Carcinogenic risk from drinking water sources of chlorothalonil for the general U.S. population was calculated in two ways, that is, by:

- multiplying the drinking water exposure from chlorothalonil times the Q_1* to express cancer risk as a probability.

AND

- dividing the NOEL (1.5 mg/kg/day) by the drinking water exposure from chlorothalonil to express cancer risk as an MOE.

Chlorothalonil is not currently regulated under the Safe Drinking Water Act (SDWA).

Therefore no MCL has been established for it and water supply systems are not required to sample and analyze for it. No lifetime HAL has been established for it. EPA has assigned a Health Advisory (HA) Drinking Water Equivalent Level (DWEL) of 500 ppb (U.S. EPA, 1994). The intermediate soil/water partitioning of chlorothalonil should make the primary treatment processes employed by most surface water source supply systems at least partially effective in removing it.

Chlorothalonil Acute Drinking Water Risk from Groundwater: In order to calculate acute drinking water risk for chlorothalonil, the highest combined metabolite concentration in groundwater was compared to the acute dietary exposure LOEL of 175 mg/kg/day. Acute drinking water risk for chlorothalonil was estimated as:

MOE for Children = 110,000; MOE for Adults = 380,000

As noted previously, an MOE of 300 or more is considered adequate for acute risk because a NOEL could not be determined in the subject study.

Chlorothalonil Chronic Non-Cancer Drinking Water Risk from Groundwater: For chronic non-cancer risk, the highest combined metabolite concentration was compared to the RfD for chlorothalonil (0.02 mg/kg/day). For children, 8% of the RfD for chlorothalonil was occupied; for adults, 2% of the RfD was occupied.

HCB (originating in chlorothalonil) Chronic Non-Cancer Drinking Water Risk from Groundwater: Assuming HCB is present in drinking water at 0.05% of the chlorothalonil level, then <1% of the RfD is occupied for children and the general US population. The RfD for HCB is 0.0008 mg/kg/day, children's exposure is 8×10^{-7} mg/kg/day, and the exposure of the general US Population is 2×10^{-7} mg/kg/day.

Chlorothalonil Acute Drinking Water Risk from Surface Water: To calculate acute drinking water risk, the highest detected concentration of 0.035 ppb (or 0.035 µg/L) was compared to the acute dietary exposure LOEL of 175 mg/kg/day for chlorothalonil.

MOE for Children = 50,000,000; MOE for Adults = 175,000,000

As noted previously, an MOE of 300 or more is considered adequate for acute risk because a NOEL could not be determined in the subject study.

Chlorothalonil Chronic Non-Cancer Drinking Water Risk from Surface Water: For chronic non-cancer risk, the highest detected concentration of 0.035 ppb (or 0.035 µg/L) was compared to the RfD for chlorothalonil (0.02 mg/kg/day). For both children and adults, < 1% of the RfD for chlorothalonil was occupied.

Chlorothalonil Drinking Water Cancer Risk from Surface Water: Based on adult exposure of 0.000001 mg/kg/day and a Q_1^* of 0.00766 $(mg/kg/day)^{-1}$, the upper bound cancer risk for

chlorothalonil was calculated to be 8×10^{-9}. This figure is well below the level which the Agency considers negligible for excess life time cancer risk estimates.

Based on the highest detected concentration of 0.035 ppb (or 0.035 µg/L) compared to the dietary cancer NOEL for chlorothalonil of 1.5 mg/kg/day, the MOE for cancer risk is > 1.5 million.

HCB (originating in chlorothalonil) Chronic Non-Cancer Drinking Water Risk from Surface Water: Chlorothalonil was assumed to be contaminated with HCB at 0.05%. The estimated concentration of HCB was compared to the RfD for HCB (0.0008 mg/kg/day) for the non-cancer chronic risk. For both children and adults, < 1% of the RfD was occupied.

HCB (originating in chlorothalonil) Drinking Water Cancer Risk from Surface Water: The estimated concentration of HCB was compared to the cancer potency factor for HCB, $1.02\ (mg/kg/day)^{-1}$, to estimate the cancer risk for adults at 5×10^{-9}.

Based on these assessments, the Agency has determined that chlorothalonil, its degradates, and HCB originating with chlorothalonil do not represent drinking water risks of concern.

Aggregate Drinking Water Carcinogenic Risk from HCB and Pentachlorobenzene from all Pesticidal Sources: HCB and pentachlorobenzene are present in groundwater and surface water from sources other than current usage of contaminated pesticides, including manufacture of solvents and tires, incineration of wastes, and coal combustion. Both are persistent and relatively immobile in the environment; the major route of dissipation is through sorption to soil, sediment, and suspended particulates in water.

HCB and PCB contamination of groundwater resources is relatively unlikely due to the high binding potential of both compounds. Detections of HCB in groundwater generally have ranged between 0.00002 to 0.100 µg/L. PCB levels in groundwater at a hazardous waste site ranged from 0.001 to 62.1 µg/L.

Based on monitoring data and fate properties, it seems unlikely that long-term HCB and PCB concentrations in surface water would exceed 10 ppt (0.01 µg/L). Surface water detections show much more variability than concentrations in groundwater and have been measured at up to 750 µg/L. These high values appear to include sorbed HCB. The HCB concentrations which actually appear to be dissolved in the water are generally less than 0.001 µg/L. Great Lakes region concentrations generally ranged from 0.00002 to 0.0001 µg/L. When concentrations exceeded this range, they appeared to be related to industrial areas or areas of historic contamination (more than 20 years ago). Concentrations of PCB in surface water have ranged between 0.00002 and 0.0001 µg/L. Concentrations of HCB and PCB in drinking water can be greatly reduced through treatment with activated granular charcoal.

Higher concentrations of HCB and PCB have been reported in surface and groundwater,

but tend to be related to hazardous waste, landfill sites, and suspended sediment. The US Department of Health and Human Services in 1996 estimated that the average exposure in the United States from drinking HCB contaminated water is 0.00085 µg/kg/year (~ 0.000082 µg/L). Since potential exposures are generally so low, and because pesticides are just one source of HCB and PCB in drinking water, the Agency concluded that there were insufficient data to quantify risk and that drinking water risk estimates from HCB in pesticides did not exceed the Agency's level of concern.

Occupational and Residential Risk Assessment for Handlers

Handlers are individuals who mix, load, or apply chlorothalonil or are involved in flagging operations to support aerial applications of chlorothalonil. Risks for the dermal and inhalation routes of exposure are presented in Tables 10-18. No chemical specific data were submitted. These tables were developed using the Pesticide Handlers Exposure Database (PHED) Version 1.1 surrogate data as estimated in the PHED Surrogate Exposure Guide (May, 1997). The PHED was developed by Health Canada, The American Crop Protection Association, and EPA. PHED was initially released for public use in 1992. PHED is a generic/surrogate exposure database containing a large number of measured values of dermal and inhalation exposure for pesticide workers (e.g., mixers, loaders, and applicators) involved in handling and applying pesticides. The database currently contains data for over 2000 monitored exposure events. Use of surrogate or generic data is appropriate since it is generally believed that the physical parameters of the handling and application process (e.g., the type of formulation used, the method of application, and the type of clothing worn), not the chemical properties of the pesticide, control the amount of dermal and inhalation exposure. Thus, PHED typically allows exposure and risk assessments to be conducted with a much larger number of observations than are normally available from a single exposure study.

PHED also contains algorithms that allow the user to complete surrogate task-based exposure assessments beginning with one of the four main data files contained in the system (i.e., mixer/loader, applicator, flagger, and mixer/loader/applicator). Users select data from each file and construct exposure scenarios that are representative of the use of the chemical. The Agency, in conjunction with the PHED task force, has evaluated all of the data currently in PHED, and developed a surrogate exposure table that contains a series of standard exposure estimates for various scenarios. These standard unit exposure values are the basis for this assessment. The standard exposure values (i.e., the unit exposure values included in the exposure and risk tables) are based on the "best fit" values calculated by PHED. PHED calculates "best fit" exposure values by assessing the distributions of exposures for each body part included in data sets selected for the assessments (e.g., chest or forearm) and then calculates a composite exposure value representing the entire body. PHED categorizes distributions as normal, lognormal, or "other". Generally, most data contained in PHED are lognormally distributed or fall into the PHED "other" distribution category. If the distribution is lognormal, the geometric mean for the distribution is used in the calculation of the "best fit" exposure value. If the data are an "other" distribution, the median value of the data set is used in the calculation of the "best fit" exposure value. As a

result, the surrogate unit exposure values that serve as the basis for this assessment generally range from the geometric mean to the median of the selected data set.

The Agency's first step in performing a handler exposure assessment is to complete a baseline exposure assessment. The baseline scenario generally represents a handler wearing long pants, a long-sleeved shirt, and no chemical-resistant gloves. If the level of concern is met or exceeded, then increasing levels of risk mitigation, such as PPE (personal protective equipment) and engineering controls, are used to recalculate the MOE's until exposure is sufficiently reduced to achieve an appropriate margin of exposure.

Risk from Short-Term and Intermediate-Term Exposures: For the purposes of this assessment, short-term exposures are of 1-7 days duration and intermediate-term exposures are of 1 week to several months duration. Because the endpoints are the same, short- and intermediate-term risk estimates are derived from the same daily (short/intermediate-term) exposures. Short- and intermediate-term handler risk estimates are presented along with the dermal and inhalation exposures in Tables 10-13.

Risk from Short-Term and Intermediate-Term Dermal Exposures: Short-term and intermediate-term dermal margins of exposure for occupational and residential handlers are calculated as follows:

$$MOE_D = \frac{NOEL}{Dose} = \frac{600 \text{ mg/kg/day}}{\text{Daily Dermal Exposure (mg/kg/day)}}$$

Risk From Short-Term and Intermediate-Term Inhalation Exposure: Except for an acute inhalation toxicity study, no inhalation toxicity studies were available for this assessment. The dose identified for determining inhalation risk is from an oral toxicity study (i.e., an oral NOEL). The inhalation exposure component was converted to an equivalent oral exposure using a 100% default value inhalation absorption rate and the default respiratory volume of 29 L/minute, which is the value used for estimation of dose from PHED, Version 1.1. This exposure can then be compared to the oral NOEL of 2 mg/kg/day to calculate the inhalation Margin of Exposure (MOE_I). As indicated previously, while the inhalation endpoint is taken from an oral study, the inhalation and dermal endpoints are different, so separate risk calculations are made for inhalation and dermal exposures. Short-term and intermediate-term inhalation margins of exposure for occupational and residential handlers are calculated as follows:

$$MOE_I = \frac{NOEL_{oral}}{Dose} = \frac{2.0 \text{ mg/kg/day}}{\text{Inhalation Exposure (mg/kg/day)}}$$

Daily Exposure/Short- and Intermediate-Term Risk Tables (Tables 10-13) for Occupational and Residential Handlers follow. Exposure estimates in these tables are based on a 70 kg default body weight.

Table 10. Estimated Short- and Intermediate-Term Exposure and Risk for Mixer/loaders Using Chlorothalonil (Occupational)

Exposure Scenario	Clothing and PPE Parameters	Unit Dermal Exposure (mg/lb ai)	Unit Inhalation Exposure (mg/lb ai)	Application Rate (lb ai/cycle)	Area Treated per Day	Daily Dermal Dose (mg/kg/day)	Daily Inhalation Dose (mg/kg/day)	Dermal Margin of Exposure (MOE)	Inhalation Margin of Exposure (MOE)
Wettable Powder-Open Bag (Aerial and Chemigation Applications to Tomatoes)	Long-sleeved shirt, long pants, gloves	0.1737	0.0434	1.04 - 2.08	350 acres	0.90 - 1.8	0.23 - 0.45	660 - 300	8.9 - 4.4
Wettable Powders-Open Bag (Aerial and Chemigation Applications to Celery)	Long-sleeved shirt, long pants, gloves	0.1737	0.0434	0.78 - 2.21	350 acres	0.68 - 1.9	0.17 - 0.48	890 - 310	12 - 4.2
Wettable Powders-Open Bag (Ground Applications to Tomatoes)	Long-sleeved shirt, long pants, gloves	0.1737	0.0434	1.04 - 2.08	50 acres	0.13 - 0.26	0.032 - 0.64	4,600 - 2,300	62 - 31
Wettable Powders-Open Bag (Ground Applications to Celery)	Long-sleeved shirt, long pants, gloves	0.1737	0.0434	0.78 - 2.21	50 acres	0.097 - 0.27	0.024 - 0.069	6,200 - 2,200	83 - 29
Wettable Powders-Open Bag (Ground Applications to Stone Fruits)	Long-sleeved shirt, long pants, gloves	0.1737	0.0434	2.34 - 4.16	20 acres	0.12 - 0.21	0.029 - 0.052	5,200 - 2,900	69 - 39
Liquid Flowable-Open Pour (Aerial and Chemigation Applications to Tomatoes)	Long-sleeved shirt, long pants, gloves	0.047	0.0012	1.04 - 2.08	350 acres	0.24 - 0.49	0.0062 - 0.012	2,500 - 1,200	320 - 160
Liquid Flowable-Open Pour (Aerial and Chemigation Applications to Celery)	Long-sleeved shirt, long pants, gloves	0.047	0.0012	0.78 - 2.21	350 acres	0.18 - 0.52	0.0047 - 0.013	3,300 - 1,200	430 - 150
Liquid Flowable-Open Pour (Aerial and Chemigation Applications to Christmas Trees)	Long-sleeved shirt, long pants, gloves	0.047	0.0012	1.04 - 4.16	100 acres	0.070 - 0.28	0.0018 - 0.0071	8,600 - 2,100	1,100 - 280

Exposure Scenario	Clothing and PPE Parameters	Unit Dermal Exposure (mg/lb ai)	Unit Inhalation Exposure (mg/lb ai)	Application Rate (lb ai/cycle)	Area Treated per Day	Daily Dermal Dose (mg/kg/day)	Daily Inhalation Dose (mg/kg/day)	Dermal Margin of Exposure (MOE)	Inhalation Margin of Exposure (MOE)
Liquid Flowable-Open Pour (Ground Applications to Stone Fruits and Christmas Trees)	Long-sleeved shirt, long pants, gloves	0.047	0.0012	1.04 - 4.16	20 acres	0.014 - 0.056	0.00036 - 0.0014	43,000 - 11,000	5,600 - 1,400
Liquid Flowable-Open Pour (Ground Applications to Tomatoes)	Long-sleeved shirt, long pants, gloves	0.047	0.0012	1.04 - 2.08	50 acres	0.035 - 0.070	0.00089 - 0.0018	17,000 - 8,600	2,200 - 1,100
Liquid Flowable-Open Pour (Ground Applications to Celery)	Long-sleeved shirt, long pants, gloves	0.047	0.0012	0.78 - 2.21	50 acres	0.026 - 0.074	0.00067 - 0.0019	23,000 - 8,100	3,000 - 1,100
Liquid Flowable-Open Pour (Ground Applications to Golf Courses)	Long-sleeved shirt, long pants, gloves	0.047	0.0012	2.08 - 12.51	40 acres	0.056 - 0.34	0.0014 - 0.0086	11,000 - 1,800	1,400 - 230
Liquid Flowable-Open Pour (Ground Applications to Sod Farms)	Long-sleeved shirt, long pants, gloves	0.047	0.0012	2.08 - 12.51	100 acres	0.14 - 0.84	0.0036 - 0.021	4,300 - 710	560 - 93
Dry Flowable-Open Pour (Aerial and Chemigation Applications to Tomatoes)	Long-sleeved shirt, long pants, gloves	0.08	0.0008	1.04 - 2.08	350 acres	0.042 - 0.83	0.0042 - 0.0083	1,400 - 720	480 - 240
Dry Flowable-Open Pour (Aerial and Chemigation Applications to Celery)	Long-sleeved shirt, long pants, gloves	0.08	0.0008	0.78 - 2.21	350 acres	0.31 - 0.88	0.0031 - 0.0088	1,900 - 680	640 - 230
Dry Flowable-Open Pour (Aerial and Chemigation Applications to Christmas Trees)	Long-sleeved shirt, long pants, gloves	0.08	0.0008	1.04 - 4.16	100 acres	0.12 - 0.48	0.0012 - 0.0048	5,000 - 1,300	1,700 - 420

Exposure Scenario	Clothing and PPE Parameters	Unit Dermal Exposure (mg/lb ai)	Unit Inhalation Exposure (mg/lb ai)	Application Rate (lb ai/cycle)	Area Treated per Day	Daily Dermal Dose (mg/kg/day)	Daily Inhalation Dose (mg/kg/day)	Dermal Margin of Exposure (MOE)	Inhalation Margin of Exposure (MOE)
Dry Flowable-Open Pour (Ground Applications to Stone Fruits and Christmas Trees)	Long-sleeved shirt, long pants, gloves	0.08	0.0008	1.04 - 4.16	20 acres	0.024 - 0.095	0.00024 - 0.00095	25,000 - 6,300	8,400 - 2,100
Dry Flowable-Open Pour (Ground Applications to Tomatoes)	Long-sleeved shirt, long pants, gloves	0.08	0.0008	1.04 - 2.08	50 acres	0.059 - 0.12	0.00059 - 0.0012	10,000 - 5,000	3,400 - 1,700
Dry Flowable-Open Pour (Ground Applications to Celery)	Long-sleeved shirt, long pants, gloves	0.08	0.0008	0.78 - 2.21	50 acres	0.045 - 0.13	0.00045 - 0.0013	13,000 - 4,800	4,500 - 1,600
Dry Flowable-Open Pour (Ground Applications to Golf Courses)	Long-sleeved shirt, long pants, gloves	0.08	0.0008	2.08 - 12.51	40 acres	0.095 - 0.57	0.00095 - 0.0057	6,300 - 1,000	2,100 - 350
Dry Flowable-Open Pour (Ground Applications to Sod Farms)	Long-sleeved shirt, long pants, gloves	0.08	0.0008	2.08 - 12.51	100 acres	0.24 - 1.4	0.0024 - 0.014	2,500 - 420	840 - 140
Granulars - Tractor Drawn Spreader Applications to Golf Course Turf	Long-sleeved shirt, long pants, no gloves	0.0084	0.0017	8 - 25.5	40 acres	0.038 - 0.12	0.0078 - 0.025	16,000 - 4,900	260 - 81
Granulars - Tractor Drawn Spreader Applications to Sod Farms	Long-sleeved shirt, long pants, no gloves	0.0084	0.0017	8 - 25.5	100 acres	0.096 - 0.31	0.019 - 0.062	6,300 - 2,000	100 - 32
Pressure Treating Wood (closed system)	Long-sleeved shirt, long pants, gloves, closed system	0.0086	0.000083	0.41	5,000 gallons	0.25	0.024	2,400	82

Table 11. Estimated Short- and Intermediate-Term Exposure and Risk for Applicators Using Chlorothalonil (Occupational and Residential)

Exposure Scenario	Clothing and PPE Parameters	Unit Dermal Exposure (mg/lb ai)	Unit Inhalation Exposure (mg/lb ai)	Application Rate (lb ai/cycle)	Area Treated per Day	Daily Dermal Dose (mg/kg/day)	Daily Inhalation Dose (mg/kg/day)	Dermal Margin of Exposure (MOE)	Inhalation Margin of Exposure (MOE)
Occupational									
Aerial Applications to Tomatoes	Long-sleeved shirt, long pants, no gloves	0.009	not a significant route of exposure	1.04 - 2.08	350 acres	0.047 - 0.094	--	13,000 - 6,400	--
Aerial Applications to Celery	Long-sleeved shirt, long pants, no gloves	0.009	not a significant route of exposure	0.78 - 2.21	350 acres	0.035 - 0.099	--	17,000 - 6,000	--
Aerial Applications to Christmas Trees	Long-sleeved shirt, long pants, no gloves	0.009	not a significant route of exposure	1.04 - 4.16	100 acres	0.013 - 0.053	--	45,000 - 11,000	--
Ground-Boom Applications to Tomatoes (Open Cab)	Long-sleeved shirt, long pants, no gloves	0.017	0.0007	1.04 - 2.08	50 acres	0.013 - 0.025	0.00052 - 0.001	48,000 - 24,000	3,800 - 1,900
Ground-Boom Applications to Celery (Open Cab)	Long-sleeved shirt, long pants, no gloves	0.017	0.0007	0.78 - 2.21	50 acres	0.0095 - 0.027	0.00039 - 0.0011	63,000 - 22,000	5,100 - 1,800

Exposure Scenario	Clothing and PPE Parameters	Unit Dermal Exposure (mg/lb ai)	Unit Inhalation Exposure (mg/lb ai)	Application Rate (lb ai/cycle)	Area Treated per Day	Daily Dermal Dose (mg/kg/day)	Daily Inhalation Dose (mg/kg/day)	Dermal Margin of Exposure (MOE)	Inhalation Margin of Exposure (MOE)
Airblast Applications to Stone Fruits and Christmas Trees (Open Cab)	Long-sleeved shirt, long pants, no gloves	0.4	0.0045	1.04 - 4.16	20 acres	0.12 - 0.48	0.0013 - 0.0053	5,000 - 1,300	1,500 - 370
Specialty air-assisted equipment applications to Golf Courses (Open Cab)	Long-sleeved shirt, long pants, no gloves	1.71	0.001	2.08 - 12.51	40 acres	2.0 - 12	0.0012 - 0.0071	300 - 49	1,700 - 280
Ground-Boom Applications to Sod Farms (Open Cab)	Long-sleeved shirt, long pants, no gloves	0.017	0.0007	2.08 - 12.51	100 acres	0.051 - 0.3	0.0021 - 0.013	12,000 - 2,000	960 - 160
Ground-Boom Applications to Golf Courses (Open Cab)	Long-sleeved shirt, long pants, no gloves	0.075	0.002	2.08 - 12.51	40 acres	0.089 - 0.54	0.0024 - 0.014	6,700 - 1,100	840 - 140
Granulars - Tractor Drawn Spreader Applications to Golf Course Turf	Long-sleeved shirt, long pants, no gloves	0.0099	0.0012	8 - 25.5	40 acres	0.045 - 0.14	0.0055 - 0.017	13,000 - 4,200	360 -110
Granulars - Tractor Drawn Spreader Applications to Sod Farms	Long-sleeved shirt, long pants, no gloves	0.0099	0.0012	8 - 25.5	100 acres	0.11 - 0.36	0.014 - 0.044	5,300 - 1,700	150 - 46

Exposure Scenario	Clothing and PPE Parameters	Unit Dermal Exposure (mg/lb ai)	Unit Inhalation Exposure (mg/lb ai)	Application Rate (lb ai/cycle)	Area Treated per Day	Daily Dermal Dose (mg/kg/day)	Daily Inhalation Dose (mg/kg/day)	Dermal Margin of Exposure (MOE)	Inhalation Margin of Exposure (MOE)
Residential									
Applying Granulars with Bellygrinder to Turf	Short Pants, Short Sleeved Shirt, No Gloves	.110	0.062	8.7 - 15.7	0.5 acres	6.8 - 12	0.0039 - 0.007	88 - 49	520 - 290
Applying Granulars with Push Type Spreader to Turf	Short Pants, Short Sleeved Shirt, No Gloves	3	0.0063	8.7 - 15.7	0.5 acres	0.19 -0.34	0.00039 - 0.00071	3,200 - 1,800	5,100- 2,800
Applying Spray with Garden Hose-end Sprayer to Turf	Short Pants, Short Sleeved Shirt, No Gloves	30	0.0095	8.7 - 15.7	0.5 acres	1.9 - 3.4	0.00059 - 0.0011	320 - 180	3,400 - 1,900
Applying Spray with Garden Hose-end Sprayer to ornamentals and vegetables	Short pants, short sleeved shirt, no gloves	30	0.0095	0.183 - 8.7	0.25 acres	0.020 - 0.93	6.2E-6 - 0.00030	31,000 - 640	320,000 - 6,800
Applying Spray with Backpack Sprayer to Turf	Short Pants, Short Sleeved Shirt, No Gloves	5.1	0.030	8.7 - 15.7	0.5 acres	0.32 - 0.57	0.0019 - 0.0034	1,900 - 1,000	1,100 - 590
Applying Spray with Backpack Sprayer to ornamentals and vegetables	Short pants, short sleeved shirt, no gloves	5.1	0.030	0.183 - 8.7	0.25 acres	0.0033 - 0.16	2.0E-5 - 0.00093	180,000 - 3,800	100,000 - 2,100

Exposure Scenario	Clothing and PPE Parameters	Unit Dermal Exposure (mg/lb ai)	Unit Inhalation Exposure (mg/lb ai)	Application Rate (lb ai/cycle)	Area Treated per Day	Daily Dermal Dose (mg/kg/day)	Daily Inhalation Dose (mg/kg/day)	Dermal Margin of Exposure (MOE)	Inhalation Margin of Exposure (MOE)
Mixing/Loading/ Applying Spray with Low Pressure Hand Wand to Turf	Short Pants, Short Sleeved Shirt, No Gloves	100 (liquid)	0.030	8.7 - 15.7	0.5 acres	6.2 - 11	0.0019 - 0.0034	97 - 54	1,100 -590
Mixing/Loading/ Applying Spray with Low Pressure Hand Wand to turf	Short Pants, Short Sleeved Shirt, No Gloves	250 (liquid)	1.1	8.7 - 15.7	0.5 acres	16 - 28	0.069 - 0.12	39 - 21	29 - 16
Mixing/Loading/Applying Spray with Low Pressure Hand Wand to ornamentals and vegetables	Short pants, short sleeved shirt, no gloves	100	0.030	0.183 - 8.7	0.25 acres	0.065 - 3.1	2.0E-5 - 0.00093	9,200 - 190	100,000 - 2,100
Applying RTU* with Low Pressure Handwand to ornamentals and vegetables	Short pants, short sleeved shirt, no gloves	100	0.030	0.0085 lb ai/gal	2 gallons	0.024	7.3E-6	25,000	270,000
Loading/Applying RTU with a Backpack Sprayer to ornamentals and vegetables	Short pants, short sleeved shirt, no gloves	5.1	0.030	0.0085 lb ai/gal	2 gallons	0.0012	7.3E-6	480,000	270,000

Exposure Scenario	Clothing and PPE Parameters	Unit Dermal Exposure (mg/lb ai)	Unit Inhalation Exposure (mg/lb ai)	Application Rate (lb ai/cycle)	Area Treated per Day	Daily Dermal Dose (mg/kg/day)	Daily Inhalation Dose (mg/kg/day)	Dermal Margin of Exposure (MOE)	Inhalation Margin of Exposure (MOE)
Applying Dust with a Handheld Duster to turf, ornamentals, and vegetables (PHED surrogate = applying granules by hand)	Short pants, short sleeved shirt, no gloves	430	0.470	0.05 lb ai/container	1 container	0.31	0.00034	2,000	6,000
Applying Wood Treatment with a Paintbrush	Short pants, short sleeved shirt, no gloves	230	0.280	0.068 lb ai/gallon	2 gallons	0.45	0.00054	1,300	3,700
Applying Wood Treatment with a Roller	Short pants, short sleeved shirt, no gloves	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data
Applying Wood Treatment with an Airless Sprayer	Short pants, short sleeved shirt, no gloves	79	0.830	0.068 lb ai/gallon	5 gallons	0.38	0.0040	1,600	500
Dipping Wood into Liquid Wood Treatment	Short pants, short sleeved shirt, no gloves	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data

* RTU = Ready-to-use formulation

Table 12. Estimated Short- and Intermediate-Term Exposure and Risk for Mixer/Loader/Applicators Using Chlorothalonil (Occupational and Residential)

Exposure Scenario	Clothing and PPE Parameters	Unit Dermal Exposure (mg/lb ai)	Unit Inhalation Exposure (mg/lb ai)	Application Rate (lb ai/cycle)	Area treated per Day	Daily Dermal Dose (mg/kg/day)	Daily Inhalation Dose (mg/kg/day)	Dermal Margin of Exposure (MOE)	Inhalation Margin of Exposure (MOE)
Occupational									
Backpack Sprayer (Greenhouse Application)	Long-sleeved shirt, long pants, gloves, respirator	2.19	0.006	1.04 - 4.16	2 acres	0.065 - 0.26	0.00018 - 0.00071	9,200 - 2,300	11,000 - 2,800
Backpack Sprayer (Outdoor Applications) - Forestry and Nursery Uses	Long-sleeved shirt, long pants, gloves	2.19	0.06	1.04 - 4.16	2 acres	0.065 - 0.26	0.0018 - 0.0071	9,200 - 2,300	1,100 - 280
Handgun Sprayer using Water Dispersible Granules - Forestry and Nursery Uses	Long-sleeved shirt, long pants, no gloves	0.35	0.001	1.04 - 4.16	2 acres	0.01 - 0.042	0.00003 - 0.00012	58,000 - 14,000	67,000 - 17,000
Indoor Painting Using an Airless Sprayer - Interior Latex	Long-sleeved shirt, long pants, no gloves	36.22	2.35	0.048 lb ai/gallon	40 gallons	0.99	0.064	600	31
Indoor Painting Using an Airless Sprayer - Interior Latex	Long-sleeved shirt, long pants, gloves	12	2.35	0.048 lb ai/gallon	40 gallons	0.33	0.064	1,800	31
Outdoor Painting Using an Airless Sprayer - Exterior Alkyd	Long-sleeved shirt, long pants, no gloves	33.33	0.433	0.11 lb ai/gallon	40 gallons	2.1	0.027	290	73
Outdoor Painting Using an Airless Sprayer - Exterior Alkyd	Long-sleeved shirt, long pants, gloves	8.87	0.433	0.11 lb ai/gallon	40 gallons	0.56	0.027	1,100	73

Exposure Scenario	Clothing and PPE Parameters	Unit Dermal Exposure (mg/lb ai)	Unit Inhalation Exposure (mg/lb ai)	Application Rate (lb ai/cycle)	Area treated per Day	Daily Dermal Dose (mg/kg/day)	Daily Inhalation Dose (mg/kg/day)	Dermal Margin of Exposure (MOE)	Inhalation Margin of Exposure (MOE)
Outdoor Painting w/ Airless Sprayer - Exterior Latex	Long shirt and pants, no gloves	33.33	0.433	0.096 lb ai/gallon	40 gallons	1.8	0.024	330	84
Outdoor Painting w/ Airless Sprayer - Ext. Stain/Wood Preservative	Long-sleeved shirt, long pants, gloves	33.33	0.433	0.068 lb ai/gallon	40 gallons	1.3	0.017	460	120
Applying onto Paint Film with an Airless Sprayer	Long-sleeve shirt & pants, no gloves	36.22	2.35	3.9 lb ai/gallon	40 gallons	81	5.2	7.4	0.38
Residential									
Homeowner Push-Type Granular Spreader	Long shirt and pants, no gloves	4.7	0.006	1 - 1.8 lb ai/ 5,000 sq.ft	5,000 sq.ft	0.067 - 0.12	0.000086 - 0.00015	8,900 - 5,000	23,000 - 13,000
Homeowner Garden Hose-End Sprayer	Total deposition	39.1	0.002	1-1.8 lb ai/ 5,000 sq.ft	5,000 sq.ft	0.56 - 1.0	0.000029 - 0.000051	1,100 - 600	70,000 - 39,000
Paint Brush Application with treated paint - Interior Latex	Long-sleeved shirt, long pants, no gloves	290	0.507	0.048 lb ai/gallon	2 gallons	0.40	0.00070	1,500	2,900
Paint Brush Application with treated paint- Exterior Latex	Long-sleeved shirt, long pants, no gloves	290	0.507	0.096 lb ai/gallon	2 gallons	0.80	0.0014	750	1,400
Paint Brush Application with treated paint- Exterior Alkyd	Long-sleeved shirt, long pants, no gloves	290	0.507	0.11 lb ai/gallon	2 gallons	0.91	0.0016	660	1,300
Brush Application with Ext./Wood Preservative	Longshirt, long pants, no gloves	290	0.507	0.068 lb ai/gallon	2 gallons	0.56	0.00099	1,100	2,000

Exposure Scenario	Clothing and PPE Parameters	Unit Dermal Exposure (mg/lb ai)	Unit Inhalation Exposure (mg/lb ai)	Application Rate (lb ai/cycle)	Area treated per Day	Daily Dermal Dose (mg/kg/day)	Daily Inhalation Dose (mg/kg/day)	Dermal Margin of Exposure (MOE)	Inhalation Margin of Exposure (MOE)
Applying onto Paint Film with a Paintbrush	Long-sleeved shirt, long pants, no gloves	290	0.507	3.9 lb ai/gallon	2 gallons	32	0.056	19	35

Table 13. Estimated Short- and Intermediate-Term Exposure and Risk for Flaggers Exposed to Chlorothalonil Sprays (Occupational)

Exposure Scenario	Clothing and PPE Parameters	Unit Dermal Exposure (mg/lb ai)	Unit Inhalation Exposure (mg/lb ai)	Application Rate (lb ai/acre)	Daily Amt. Treated	Daily Dermal Dose (mg/kg/day)	Daily Inhalation Dose (mg/kg/day)	Dermal Margin of Exposure (MOE)	Inhalation Margin Of Exposure (MOE)
Flaggers	Long-sleeved shirt, long pants	0.011	0.0003	0.78 - 2.21	350 acres	0.043 - 0.12	0.0012 - 0.0033	14,000 - 4,900	1,700 - 600

Carcinogenic Risk to Handlers: In this assessment, the Agency has estimated handler risk from prolonged exposure to chlorothalonil. These risks are associated with chronic non-cancer and cancer effects, but this assessment only addresses cancer risk. As discussed previously, the Agency has used two approaches for quantifying chlorothalonil cancer risk. The MOE approach to occupational or residential exposures can be used exposures are chronic, e.g., six months or more of continuous exposure in a year. The Agency has determined that exposure to residential and occupational handlers of chlorothalonil is not of sufficient duration for application of the MOE approach. Chronic exposures are not a requisite for calculating cancer risk under the Q_1* paradigm, which is based on lifetime average daily exposures. Cancer risk assessments for occupational and residential handlers have been performed using the Q_1*. Carcinogenic risk estimates for occupational and residential handler exposure appear in Tables 14-18. Risk estimates in these tables are based on a default body weight of 70 kg, a dermal absorption factor of 0.15%, and 35 years of exposure out of a 70 year lifetime.

It is possible that chronic exposure, representing several months or more per year of exposure, may apply to pesticide handlers in the cut flower industry, especially for cut flowers grown in greenhouses, because such crops can be continuously grown throughout the year. It is not clear how frequently and continuously individual workers may treat cut flower crops with chlorothalonil. It would seem prudent from a pest management standpoint to treat these crops with a variety of fungicides to prevent disease resistance. If alternate fungicides are used, then it is likely that handler exposure is of a short-term or intermediate-term nature. In contrast to handlers of chlorothalonil in cut flower crops, the Agency believes that workers who reenter treated areas to perform hand-labor tasks on cut flowers, particularly in greenhouses, may be chronically exposed to chlorothalonil. (The Agency's thinking on the carcinogenic risk to these hand-laborers is detailed in Tables 26 and 27.)

Carcinogenic Risk Tables for Occupational and Residential Handlers follow.

Table 14. Estimated Lifetime Exposure and Carcinogenic Risk for Mixer/Loaders Using Chlorothalonil (Occupational)

Exposure Scenario	Clothing and PPE Parameters	Unit Dermal Exposure (mg/lb ai)	Unit Inhalation Exposure (mg/lb ai)	Application Rate (lb ai/acre)	Daily Amt. Treated	Absorbed Daily Dermal Dose (mg/kg/day)	Daily Inhalation Dose (mg/kg/day)	Combined Daily Dermal and Inhalation Dose (mg/kg/day)	Days worked per year	Lifetime Average Daily Exposure (mg/kg/day)	Cancer Risk (Q_1* approach)
Wettable Powder-Open Bag (Aerial and Chemigation Applications to Tomatoes)	Long-sleeved shirt, long pants, gloves	0.1737	0.0434	1.04 - 2.08	350 acres	1.4E-3 - 2.7E-3	0.23 - 0.45	0.23 - 0.45	80	0.025 - 0.05	1.9E-4 - 3.8E-4
Wettable Powders-Open Bag (Aerial and Chemigation Applications to Celery)	Long-sleeved shirt, long pants, gloves	0.1737	0.0434	0.78 - 2.21	350 acres	1.0E-3 - 2.9E-3	0.17 - 0.48	0.17 - 0.48	80	0.019 - 0.053	1.4E-4 - 4.1E-4
Wettable Powders-Open Bag (Ground Applications to Tomatoes)	Long-sleeved shirt, long pants, gloves	0.1737	0.0434	1.04 - 2.08	50 acres	1.9E-04 - 3.9E-4	0.032 - 0.064	0.032- 0.65	20	8.9E-4 - 1.8E-3	6.8E-6 - 1.4E-5
Wettable Powders-Open Bag (Ground Applications to Celery)	Long-sleeved shirt, long pants, gloves	0.1737	0.0434	0.78 - 2.21	50 acres	1.5E-4 - 4.1E-4	0.024 - 0.069	0.024 - 0.069	20	6.7E-4 - 1.9E-3	5.1E-6 - 1.5E-5
Wettable Powders-Open Bag (Ground Applications to Stone Fruits)	Long-sleeved shirt, long pants, gloves	0.1737	0.0434	2.34 - 4.16	20 acres	1.7E-4 - 3.1E-4	0.029 - 0.052	0.029 - 0.052	3	1.2E-4 - 2.1E-4	9.2E-7 - 1.6E-6
Liquid Flowable-Open Pour (Aerial and Chemigation Applications to Celery)	Long-sleeved shirt, long pants, gloves	0.047	0.0012	0.78 - 2.21	350 acres	2.7E-4 - 7.8E-4	0.0047 - 0.013	0.005 - 0.014	80	5.4E-4 - 1.5E-3	4.2E-6 - 1.2E-5

Exposure Scenario	Clothing and PPE Parameters	Unit Dermal Exposure (mg/lb ai)	Unit Inhalation Exposure (mg/lb ai)	Application Rate (lb ai/acre)	Daily Amt. Treated	Absorbed Daily Dermal Dose (mg/kg/day)	Daily Inhalation Dose (mg/kg/day)	Combined Daily Dermal and Inhalation Dose (mg/kg/day)	Days worked per year	Lifetime Average Daily Exposure (mg/kg/day)	Cancer Risk (Q_1* approach)
Liquid Flowable-Open Pour (Aerial Applications to Christmas Trees)	Long-sleeved shirt, long pants, gloves	0.047	0.0012	1.04 - 4.16	100 acres	1.0E-4-4.2E-4	0.0018 - 0.0071	0.0019 - 0.0076	20	5.2E-5 - 2.1E-4	4.0E-7 - 1.6E-6
Liquid Flowable-Open Pour (Ground Applications to Stone Fruits and Christmas Trees)	Long-sleeved shirt, long pants, gloves	0.047	0.0012	1.04 - 4.16	20 acres	2.1E-5 - 8.4E-5	0.00036 - 0.0014	0.00038 - 0.0015	3	1.6E-6 - 6.2E-6	1.2E-8 - 4.8E-8
Liquid Flowable-Open Pour (Ground Applications to Tomatoes)	Long-sleeved shirt, long pants, gloves	0.047	0.0012	1.04 - 2.08	50 acres	5.2E-5 - 1.0E-4	0.00089 - 0.0018	0.00094 - 0.0019	20	2.6E-5 - 5.2E-5	2.0E-7 - 4.0E-7
Liquid Flowable-Open Pour (Ground Applications to Celery)	Long-sleeved shirt, long pants, gloves	0.047	0.0012	0.78 - 2.21	50 acres	3.9E-5 - 1.1E-4	0.00067 - 0.0019	0.00071 - 0.002	20	1.9E-5 - 5.5E-5	1.5E-7 - 4.2E-7
Liquid Flowable-Open Pour (Ground Applications to Golf Courses)	Long-sleeved shirt, long pants, gloves	0.047	0.0012	2.08 - 12.51	40 acres	8.4E-5 - 5.0E-4	0.0014 - 0.0086	0.0015 - 0.0091	20	4.1E-5 - 2.5E-4	3.2E-7 - 1.9E-6
Liquid Flowable-Open Pour (Ground Applications to Sod Farms)	Long-sleeved shirt, long pants, gloves	0.047	0.0012	2.08 - 12.51	100 acres	2.1E-4 - 1.3E-3	0.0036 - 0.021	0.0038 - 0.023	20	1.0E-4 - 6.2E-4	8.0E-7 - 4.8E-6

Exposure Scenario	Clothing and PPE Parameters	Unit Dermal Exposure (mg/lb ai)	Unit Inhalation Exposure (mg/lb ai)	Application Rate (lb ai/acre)	Daily Amt. Treated	Absorbed Daily Dermal Dose (mg/kg/day)	Daily Inhalation Dose (mg/kg/day)	Combined Daily Dermal and Inhalation Dose (mg/kg/day)	Days worked per year	Lifetime Average Daily Exposure (mg/kg/day)	Cancer Risk (Q_1* approach)
Dry Flowable-Open Pour (Aerial and Chemigation Applications to Tomatoes)	Long-sleeved shirt, long pants, gloves	0.08	0.0008	1.04 - 2.08	350 acres	6.2E-04 - 1.2E-3	0.0042 - 0.0083	0.0048 - 0.0096	80	5.2E -4 - 1.0E-3	4.0E-6 - 8.1E-6
Dry Flowable-Open Pour (Aerial and Chemigation Applications to Celery)	Long-sleeved shirt, long pants, gloves	0.08	0.0008	0.78 - 2.21	350 acres	4.7E-4 - 1.3E-3	0.0031 - 0.0088	0.0036 - 0.01	80	3.9E-4 - 1.1E-3	3.0E-6 - 8.6E-6
Dry Flowable-Open Pour (Aerial Applications to Christmas Trees)	Long-sleeved shirt, long pants, gloves	0.08	0.0008	1.04 - 4.16	100 acres	1.8E-4 - 7.1E-4	0.0012 - 0.0048	0.0014 - 0.0056	20	3.7E-5 - 1.5E-4	2.9E-7 - 1.2E-6
Dry Flowable-Open Pour (Ground Applications to Stone Fruits and Christmas Trees)	Long-sleeved shirt, long pants, gloves	0.08	0.0008	1.04 - 4.16	20 acres	3.6E-5 - 1.4E-4	2.4E-4 - 9.5E-4	2.7E-4 - 1.1E-3	3	1.1E-6 - 4.5E-6	8.7E-9 - 3.8E-8
Dry Flowable-Open Pour (Ground Applications to Tomatoes)	Long-sleeved shirt, long pants, gloves	0.08	0.0008	1.04 - 2.08	50 acres	8.9E-5 - 1.8E-4	0.00059 - 0.0012	0.00068 - 0.0014	20	1.9E-5 - 3.7E-5	1.4E-7 - 2.9E-7
Dry Flowable-Open Pour (Ground Applications to Celery)	Long-sleeved shirt, long pants, gloves	0.08	0.0008	0.78 - 2.21	50 acres	6.7E-5 - 1.9E-4	0.00045 - 0.0013	0.00051 - 0.0015	20	1.4E-5 - 4.0E-5	1.1E-7 - 3.1E-7

Exposure Scenario	Clothing and PPE Parameters	Unit Dermal Exposure (mg/lb ai)	Unit Inhalation Exposure (mg/lb ai)	Application Rate (lb ai/acre)	Daily Amt. Treated	Absorbed Daily Dermal Dose (mg/kg/day)	Daily Inhalation Dose (mg/kg/day)	Combined Daily Dermal and Inhalation Dose (mg/kg/day)	Days worked per year	Lifetime Average Daily Exposure (mg/kg/day)	Cancer Risk (Q_1* approach)
Dry Flowable-Open Pour (Ground Appl'n/ Golf Courses)	Long-sleeved shirt, long pants, gloves	0.08	0.0008	2.08 - 12.51	40 acres	1.4E-4 - 8.6E-4	0.00095 - 0.0057	0.0011- 0.0066	20	3.0E-5 - 1.8E-4	2.3E-7 - 1.4E-6
Mixing/Loading Tractor-Drawn Granule Spreader on Golf Course Turf	Long-sleeved shirt, long pants, no gloves	0.0084	0.0017	8 - 25.5	40 acres	5.8E-5 - 1.8E-4	0.0078 - 0.025	0.0078 - 0.025	20	2.1E-4 - 6.8E-4	1.7E-6 - 5.3E-6
Mixing/Loading Tractor- Drawn Granule Spreader on Sod Farms	Long-sleeved shirt, long pants, no gloves	0.0084	0.00017	8 - 25.5	100 acres	1.4E-4 - 4.5E-4	0.019 - 0.062	0.021 - 0.062	20	6.2E-4 - 1.7E-3	4.7E-6 - 1.3E-5
Pressure Treating Wood (closed system)	Long-sleeved shirt, long pants, gloves	0.0086	0.000083	0.41	5,000 gallons[k]	3.8e-04	0.024	0.025	20	6.8E-4	5.2E-6
Dry flowable-Open Pour (Ground Applications to Sod)	Long-sleeved shirt, long pants, gloves	0.08	0.0008	2.08 - 4.16	100 acres	3.6E-4 - 7.1E-4	0.0024 - 0.0048	0.0027 - 0.0055	20	7.5E-5 - 1.5E-4	5.8E-7 - 1.2E-6

Exposure Scenario	Clothing and PPE Parameters	Unit Dermal Exposure (mg/lb ai)	Unit Inhalation Exposure (mg/lb ai)	Application Rate (lb ai/acre)	Daily Amt. Treated	Absorbed Daily Dermal Dose (mg/kg/day)	Daily Inhalation Dose (mg/kg/day)	Combined Daily Dermal and Inhalation Dose (mg/kg/day)	Days worked per year	Lifetime Average Daily Exposure (mg/kg/day)	Cancer Risk (Q_1* approach)
Wettable Powders-Open Bag (Aerial and Chemigation Applications to Tomatoes)	Long-sleeved shirt, long pants and gloves and a dust/mist mask (80% reduction)	0.1737	0.0087 (With PPE)	1.04 -2.08	350 acres	1.4E-3 - 2.7E-3	0.045 - 0.09	0.047 - 0.093	80	5.1E-3 - 1.0E-2	3.9E-5 - 7.9E-5
Wettable Powders-Open Bag (Aerial and Chemigation Applications to Celery)	Long-sleeved shirt, long pants and gloves and a dust/mist mask (80% reduction)	0.1737	0.0087 (With PPE)	0.78 - 2.21	350 acres	1.0E-3 - 2.9E-3	0.034 - 0.096	0.035 - 0.099	80	3.8E-3 - 1.1E-2	2.9E-5 - 8.4E-5

Table 15. Estimated Lifetime Exposure and Carcinogenic Risk for Applicators Using Chlorothalonil (Occupational)

Exposure Scenario	Clothing and PPE Parameters	Unit Dermal Exposure (mg/lb ai)	Unit Inhalation Exposure (mg/lb ai)	Application Rate (lb ai/acre)	Daily Amt. Treated	Absorbed Daily Dermal Dose (mg/kg/day)	Daily Inhalation Dose (mg/kg/day)	Combined Daily Dermal and Inhalation Dose (mg/kg/day)	Days worked per year	Lifetime Average Daily Exposure (mg/kg/day)	Cancer Risk
Aerial Applications to Tomatoes	Long-sleeved shirt, long pants, no gloves	0.009	--	1.04 - 2.08	350 acres	7.0E-5 - 1.4E-4	--	7.0E-5 - 1.4E-4	80	7.7E-6 - 1.5E-5	5.9E-8 - 1.2E-7
Aerial Applications to Celery	Long-sleeved shirt, long pants, no gloves	0.009	--	0.78 - 2.21	350 acres	5.3E-5 - 1.5E-4	--	5.3E-5 - 1.5E-4	80	5.8E-6 - 1.6E-5	4.4E-8- 1.3E-7
Aerial Applications to Christmas Trees	Long-sleeved shirt, long pants, no gloves	0.009	--	1.04 - 4.16	100 acres	2.0E-5 - 8.0E-5	--	2.0E-5 - 8.0E-5	20	5.5E-7 - 2.2E-6	4.2E-9 - 1.7E-8
Ground-Boom Applications to Tomatoes (Open Cab)	Long-sleeved shirt, long pants, no gloves	0.017	0.0007	1.04 - 2.08	50 acres	1.9E-5 - 3.8E-5	0.00052 - 0.001	0.00054 - 0.0011	20	1.5E-5 - 3.0E-5	1.1E-7 - 2.3E-7
Ground-Boom Applications to Celery (Open Cab)	Long-sleeved shirt, long pants, no gloves	0.017	0.0007	0.78 - 2.21	50 acres	1.4E-5 - 4.0E-5	0.00039 - 0.0011	0.0004 - 0.0011	20	1.1E-5 - 3.1E-5	8.5E-8 - 2.4E-7

Exposure Scenario	Clothing and PPE Parameters	Unit Dermal Exposure (mg/lb ai)	Unit Inhalation Exposure (mg/lb ai)	Application Rate (lb ai/acre)	Daily Amt. Treated	Absorbed Daily Dermal Dose (mg/kg/day)	Daily Inhalation Dose (mg/kg/day)	Combined Daily Dermal and Inhalation Dose (mg/kg/day)	Days worked per year	Lifetime Average Daily Exposure (mg/kg/day)	Cancer Risk
Airblast Applications to Stone Fruits and Christmas Trees (Open Cab)	Long-sleeved shirt, long pants, no gloves	0.4	0.0045	1.04 - 4.16	20 acres	1.8E-4 - 7.1E-4	0.0013 - 0.0053	0.0014 - 0.0061	20	6.2E-6 - 2.5E-5	4.8E-8 - 1.9E-7
Specialty Air-assisted Equipment Applications to Golf Courses (Open Cab)	Long-sleeved shirt, long pants, no gloves	1.71	0.001	2.08 - 12.51	40 acres	3.0E-3 - 1.8E-2	0.0012 - 0.0072	0.0042 - 0.025	20	1.2E4 - 7.0E-4	8.9E-7 - 5.4E-6
Ground-Boom Applications to Golf Courses (Open Cab)	Long-sleeved shirt, long pants, no gloves	0.075	0.002	2.08 - 12.51	40 acres	1.3E-4 - 8.0E-4	0.0024 - 0.014	0.0025 - 0.015	20	6.9E-5 - 4.1E-4	5.3E-7 - 3.2E-6
Ground-Boom Applications to Sod Farms (Open Cab)	Long-sleeved shirt, long pants, no gloves	0.017	0.0007	2.08 - 12.51	100 acres	7.9E-5 - 4.6E-4	0.0021 - 0.013	0.0022 - 0.013	20	5.9E-5 - 3.6E-4	4.5E-7 - 2.7E-6
Granulars - Tractor Drawn Spreader Applications to Golf Course Turf	Long-sleeved shirt, long pants, no gloves	0.0099	0.0012	8 - 25.5	40 acres	6.8E-5 - 2.2E-4	0.0056 - 0.018	0.0056 - 0.018	20	1.5E-4 - 4.8E-4	1.2E-6 - 3.7E-6

Exposure Scenario	Clothing and PPE Parameters	Unit Dermal Exposure (mg/lb ai)	Unit Inhalation Exposure (mg/lb ai)	Application Rate (lb ai/acre)	Daily Amt. Treated	Absorbed Daily Dermal Dose (mg/kg/day)	Daily Inhalation Dose (mg/kg/day)	Combined Daily Dermal and Inhalation Dose (mg/kg/day)	Days worked per year	Lifetime Average Daily Exposure (mg/kg/day)	Cancer Risk
Granulars - Tractor Drawn Spreader Applications to Sod Farms	Long-sleeved shirt, long pants, no gloves	0.0099	0.0012	8 - 25.5	100 acres	1.7E-4 - 5.4E-4	0.014 - 0.044	0.014 - 0.044	20	3.8E-4 - 1.2E-3	2.9E-6 - 9.3E-6

Table 16. Estimated Lifetime Exposure and Carcinogenic Risk for Applicators Using Chlorothalonil on Turf (Residential)

Exposure Scenario	Clothing and PPE Parameters	Unit Dermal Exposure (mg/lb ai)	Unit Inhalation Exposure (µg/lb ai)	Application Rate (lb ai/acre)	Daily Amt. Treated	Absorbed Daily Dermal Dose (mg/kg/day)	Daily Inhalation Dose (mg/kg/day)	Combined Daily Dermal/ Inhalation Dose (mg/kg/day)	Days worked per year	Lifetime Average Daily Exposure (mg/kg/day)	Cancer Risk
Applying Granulars with Bellygrinder to turf	Short Pants, Short Sleeved Shirt, No Gloves	110	62	8.7 - 15.7	0.5 acres	0.01 - 0.019	0.0039 - 0.007	0.014 - 0.025	5	9.7E-5 - 1.7E-4	7.4E-6 - 1.3E-7
Applying Granulars with Push Spreader to turf	Short Pants, Short Sleeved Shirt, No Gloves	3.0	6.3	8.7 - 15.7	0.5 acres	0.00028-0.0005	0.00039 - 0.00071	0.00067 - 0.0012	5	4.6E-6 - 8.3E-6	3.5E-8 - 6.4E-8
Applying Spray with Garden Hose-end Sprayer to turf	Short Pants, Short Sleeved Shirt, No Gloves	30	9.5	8.7 - 15.7	0.5 acres	0.0028 - 0.005	0.00059 - 0.0011	0.0034 - 0.0061	5	2.3E-5 - 4.2E-5	1.8E-7 - 3.2E-7
Applying Spray with Garden Hose-end Sprayer to ornamentals, vegetables	Short Pants, Short Sleeved Shirt, No Gloves	30	0.0095	0.183 - 8.7	0.25 acres	2.9E-5 - 0.0014	6.2E-6 - 3.0E-4	3.6E-5 - 0.0017	5	2.4E-7 - 1.2E-5	1.9E-9 - 8.9E-8
Applying Spray with Backpack Sprayer to turf	Short Pants, Short Sleeved Shirt, No Gloves	5.1	30	8.7 - 15.7	0.5 acres	0.00048 - 0.00086	0.0019 - 0.0034	0.00059 - 0.0011	5	1.6E-5 - 2.9E-5	1.2E-7 - 2.2E-7

Exposure Scenario	Clothing and PPE Parameters	Unit Dermal Exposure (mg/lb ai)	Unit Inhalation Exposure (µg/lb ai)	Application Rate (lb ai/acre)	Daily Amt. Treated	Absorbed Daily Dermal Dose (mg/kg/day)	Daily Inhalation Dose (mg/kg/day)	Combined Daily Dermal/ Inhalation Dose (mg/kg/day)	Days worked per year	Lifetime Average Daily Exposure (mg/kg/day)	Cancer Risk
M/L/A Spray with Backpack Sprayer to ornamentals, vegetables	Short Pants, Short Sleeved Shirt, No Gloves	5.1	0.030	0.183 - 8.7	0.25 acres	5.0E-6 - 2.4E-4	2.0E-5 - 9.3E-4	2.5E-5 - 0.0012	5	1.7E-7 - 8.0E-6	1.3E-9 - 6.2E-8
M/L/As Spraying with Low Pressure Handwand to turf	Short Pants, Short Sleeved Shirt, No Gloves	100 (liquid)	30	8.7 - 15.7	0.5 acres	0.0093 - 0.017	0.0019 - 0.0034	0.011 - 0.02	5	7.7E-5 - 1.4E-4	5.9E-7 - 1.1E-6
M/L/As spraying with Low Pressure Handwand to turf	Short Pants, Short Sleeved Shirt, No Gloves	250 (Wettable Powder)	1,100	8.7 - 15.7	0.5 acres	0.023 - 0.042	0.069 - 0.12	0.069 - 0.12	5	6.4E-4 - 1.1E-3	4.9E-6- 8.8E-6
M/L/As Spraying with Low Pressure Handwand ornamentals, vegetables	Short Pants, Short Sleeved Shirt, No Gloves	100	0.030	0.183 - 8.7	0.25 acres	9.8E-5 - 4.7E-3	1.9E-5 - 9.3E-4	0.00012 - 0.0056	5	8.1E-7 - 3.8E-5	6.2E-9 - 2.9E-7

Exposure Scenario	Clothing and PPE Parameters	Unit Dermal Exposure (mg/lb ai)	Unit Inhalation Exposure (µg/lb ai)	Application Rate (lb ai/acre)	Daily Amt. Treated	Absorbed Daily Dermal Dose (mg/kg/day)	Daily Inhalation Dose (mg/kg/day)	Combined Daily Dermal/ Inhalation Dose (mg/kg/day)	Days worked per year	Lifetime Average Daily Exposure (mg/kg/day)	Cancer Risk
Applying RTU with Low Pressure Handwand ornamentals, vegetables	Short Pants, Short Sleeved Shirt, No Gloves	100	0.030	0.0085 lb ai/gallon	2 gallons	3.6E-5	7.3E-6	0.000044	5	3.0E-7	2.3E-9
Loading/Applying RTU with a Backpack Sprayer to ornamentals, vegetables	Short Pants, Short Sleeved Shirt, No Gloves	5.1	0.030	0.0085 lb ai/gallon	2 gallons	1.9E-6	7.3E-6	9.1E-6	5	6.3E-8	4.8E-10
Applying Dust with a Handheld Duster to turf, ornamentals, vegetables (PHED surrogate = applying granules by hand)	Short Pants, Short Sleeved Shirt, No Gloves	430	0.470	0.05 lb ai/container	1 box or bag	0.00046	0.00034	0.00080	5	5.5E-6	4.2E-8
Applying Wood Treatment with a Paintbrush	Short Pants, Short Sleeved Shirt, No Gloves	230	0.280	0.068 lb ai/gallon	2 gallons	0.00067	0.00054	0.0012	2	3.3E-6	2.6E-8

Exposure Scenario	Clothing and PPE Parameters	Unit Dermal Exposure (mg/lb ai)	Unit Inhalation Exposure (µg/lb ai)	Application Rate (lb ai/acre)	Daily Amt. Treated	Absorbed Daily Dermal Dose (mg/kg/day)	Daily Inhalation Dose (mg/kg/day)	Combined Daily Dermal/ Inhalation Dose (mg/kg/day)	Days worked per year	Lifetime Average Daily Exposure (mg/kg/day)	Cancer Risk
Applying Wood Treatment with an Airless Sprayer	Short Pants, Short Sleeved Shirt, No Gloves	79	0.830	0.068 lb ai/gallon	5 gallons	0.00058	0.0040	0.0046	2	1.3E-5	9.7E-8

Table 17. Estimated Lifetime Exposure and Carcinogenic Risk for Mixer/Loader/Applicators Using Chlorothalonil (Occupational and Residential)

Exposure Scenario	Clothing and PPE Parameters	Unit Dermal Exposure (mg/lb ai)	Unit Inhalation Exposure (mg/lb ai)	Application Rate (lb ai/acre)	Daily Amt. Treated	Absorbed Daily Dermal Dose (mg/kg/day)	Daily Inhalation Dose (mg/kg/day)	Combined Daily Dermal and Inhalation Dose (mg/kg/day)	Days worked per year	Lifetime Average Daily Exposure (mg/kg/day)	Cancer Risk
Occupational											
Backpack Sprayer (Greenhouse Application)	Long-sleeved shirt, long pants, gloves, respirator	2.19	0.006	1.04 - 4.16	2 acres	9.8E-5 - 3.9E-4	1.8E-4 - 7.1E-4	2.8E-4 - 1.1E-3	30	1.1E-5 - 4.5E-5	8.7E-8 - 3.5E-7
Backpack Sprayer (Outdoor Applications) - Forestry & Nursery	Long-sleeved shirt, long pants, gloves	2.19	0.06	1.04 - 4.16	2 acres	9.8E-5 - 3.9E-4	0.0018-0.0071	0.0019-0.0075	20	5.2E-5 - 2.1E-4	4.0E-7 - 1.6E-6
Handgun Sprayer using Water Dispersible Granules - Forestry & Nursery	Long-sleeved shirt, long pants, no gloves	0.35	0.001	1.04 - 4.16	2 acres	1.6E-5 - 6.2E-5	3.0E-5 - 1.2E-4	4.5E-5 - 1.8E-4	20	1.2E-6 - 5.0E-6	9.6E-9 - 3.8E-8
Indoor Painting Using an Airless Sprayer - Interior Latex	Long-sleeved shirt, long pants, no gloves	36.22	2.35	0.048 lb ai/gallon	40 gallons	1.5E-3	0.064	0.066	10	9.0E-4	7.0E-6
Indoor Painting Using an Airless Sprayer - Interior Latex	Long-sleeved shirt, long pants, gloves	12	2.35	0.048 lb ai/gallon	40 gallons	4.9E-4	0.064	0.065	10	8.9E-4	6.9E-6
Outdoor Painting Using an Airless Sprayer - Exterior Alkyd	Long-sleeved shirt, long pants, no gloves	33.33	0.433	0.11 lb ai/gallon	40 gallons	3.1E-3	0.027	0.03	10	4.2E-4	3.2E-6

Exposure Scenario	Clothing and PPE Parameters	Unit Dermal Exposure (mg/lb ai)	Unit Inhalation Exposure (mg/lb ai)	Application Rate (lb ai/acre)	Daily Amt. Treated	Absorbed Daily Dermal Dose (mg/kg/day)	Daily Inhalation Dose (mg/kg/day)	Combined Daily Dermal and Inhalation Dose (mg/kg/day)	Days worked per year	Lifetime Average Daily Exposure (mg/kg/day)	Cancer Risk
Outdoor Painting Using an Airless Sprayer - Exterior Latex	Long-sleeved shirt, long pants, no gloves	33.33	0.433	0.096 lb ai/gallon	40 gallons	2.7E-3	0.024	0.026	10	3.6E-4	2.8E-6
Outdoor Painting Using an Airless Sprayer - Exterior Alkyd	Long-sleeved shirt, long pants, no gloves	8.87	0.433	0.11 lb ai/gallon	40 gallons	8.4E-4	0.027	0.028	10	3.8E-4	3.0E-6
Outdoor Painting Using an Airless Sprayer - Exterior Stain/Wood Preservative	Long-sleeved shirt, long pants, no gloves	33.33	0.433	0.068 lb ai/gallon	40 gallons	0.0019	0.017	0.019	10	2.6E-4	2.0E-6
Applying onto Paint Film with an Airless Sprayer	Long-sleeved shirt, long pants, no gloves	36.22	2.35	3.9 lb ai/gallon	40 gallons	0.12	5.2	5.4	10	7.3E-2	5.7E-4
Residential											
Homeowner Push-Type Granular Spreader	Long-sleeves shirt, long pants, no gloves	4.7	0.006	1 - 1.8 lb ai/5,000 sq.ft	5,000 sq.ft	1.0E-4 - 1.8E-4	8.6E-5 - 1.5E-4	1.9E-4 - 3.4E-4	5	1.3E-6 - 2.3E-6	9.8E-9 - 1.8E-8
Homeowner Hose-End Sprayer	Total deposition	39.1	0.002	1 - 1.8 lb ai/5,000 sq.ft	5,000 sq.ft	8.4E-4 - 1.5E-3	2.9E-5 - 5.1E-5	8.7E-4 - 1.6E-3	5	5.9E-6 - 1.1E-5	4.6E-8 - 8.2E-8

Exposure Scenario	Clothing and PPE Parameters	Unit Dermal Exposure (mg/lb ai)	Unit Inhalation Exposure (mg/lb ai)	Application Rate (lb ai/acre)	Daily Amt. Treated	Absorbed Daily Dermal Dose (mg/kg/day)	Daily Inhalation Dose (mg/kg/day)	Combined Daily Dermal and Inhalation Dose (mg/kg/day)	Days worked per year	Lifetime Average Daily Exposure (mg/kg/day)	Cancer Risk
Paint Brush Application - Interior Latex	Long-sleeved shirt, long pants, no gloves	290	0.507	0.048 lb ai/gallon	2 gallons	6.0E-4	0.00070	0.0013	10	1.8E-5	1.4E-7
Paint Brush Application- Exterior Latex	Long-sleeved shirt, long pants, no gloves	290	0.507	0.096 lb ai/gallon	2 gallons	1.2E-3	0.0014	0.0026	10	3.5E-5	2.7E-7
Paint Brush Application - Exterior Alkyd	Long-sleeved shirt, long pants, no gloves	290	0.507	0.11 lb ai/gallon	2 gallons	1.4E-3	0.0016	0.0030	10	4.1E-5	3.1E-7
Painting Using a Paintbrush - Exterior Stain/Wood Preservative	Long-sleeved shirt, long pants, no gloves	290	0.507	0.068 lb ai/gallon	2 gallons	0.00085	0.00099	0.0018	10	2.5E-5	1.9E-7
Applying onto Paint Film with a Paintbrush	Long-sleeved shirt, long pants, no gloves	290	0.507	3.9 lb ai/gallon	2 gallons	0.048	0.056	0.10	10	1.4E-3	1.1E-5

Table 18. Estimated Lifetime Exposure and Carcinogenic Risk for Flaggers Exposed to Chlorothalonil Sprays

Exposure Scenario	Clothing and PPE Parameters	Unit Dermal Exposure (mg/lb ai)	Unit Inhalation Exposure (mg/lb ai)	Application Rate (lb ai/acre)	Daily Amt. Treated	Absorbed Daily Dermal Dose (mg/kg/day)	Daily Inhalation Dose (mg/kg/day)	Combined Daily Dermal and Inhalation Dose (mg/kg/day)	Days worked per year	Lifetime Average Daily Exposure (mg/kg/day)	Cancer Risk
Flaggers	Long-sleeved shirt, long pants	0.011	0.0003	0.78-2.21	350 acres	6.4E-5 - 1.8E-4	0.0012-0.0033	0.0012-0.0035	80	1.4E-4 - 3.8E-4	1.0E-6 - 3.0E-6

Exposure and Risk for Handlers of Specialty Products, Additional Turf Products, and in Miscellaneous Use Patterns: In January 1997, the Agency completed an exposure assessment for proposed new uses of chlorothalonil as an additive containing 40.4 % a.i. for use in caulks, sealants, polymer lattices, grouts, joint compounds, and paper coatings. All relevant occupational and residential exposure scenarios were considered for the application rates proposed by the registrant. Based on exposure data submitted by the Chemical Manufacturer's Association (MRIDs 41412201, 41742601, 41761201 & 42587501), and relevant toxicological endpoints, primary occupational application risk estimates appear to be within the range that the Agency generally considers negligible for workers. However, data were not available to estimate exposure and risk for post-application exposure to primary and secondary occupational handlers, neither were data available to estimate application and post-application exposure and risk for primary or secondary homeowner exposure. Primary occupational and homeowner exposure occurs in individuals who use or install chlorothalonil-containing materials; secondary occupational and secondary residential exposures occur when other individuals work and live in places where chlorothalonil-containing materials have been used. For these exposures, no risk assessment could be conducted, but the Agency believes that secondary and homeowner exposures to these products by themselves are generally lower than primary occupational application exposures.

There are limited surrogate data available to address application of chlorothalonil to turf by professional lawn care operators (LCO). While data on these exposures are being developed by the Outdoor Residential Exposure Task Force (ORETF), a study is available in the literature that measured LCO exposure to dithiopyr using biomonitoring techniques. Biomonitoring studies can be used as surrogates to estimate exposure for other chemicals if the dermal absorption rates for both chemicals are known. The ratio of the absorption rates and the ratio between the two chemical application rates can be used to estimate exposure for LCOs using chlorothalonil. The dermal absorption rate of dithiopyr is reportedly 0.08% and the dermal absorption rate of chlorothalonil is 0.15%. The absorbed dose from the published dithiopyr study is 4.6×10^{-5} mg/kg/pound active ingredient handled. The absorbed dose of chlorothalonil from a similar application using dithiopyr can be estimated as follows:

$$\frac{0.000046 \text{ mg/kg/lb ai} \times 12.5 \text{ lb ai/A Chlorothalonil} \times 2\text{A/da}}{1 \text{ lb ai/A dithiopyr} \times 0.08\% \text{ dermal absorption (da)}} =$$

$$= 1.44 \text{ mg/kg/day}$$

$$= 0.00216 \text{ mg/kg/day when corrected for 0.15\% dermal absorption}$$

This exposure level is in the same range as exposures to mixer/loaders of liquid flowable-open pour for aerial and chemigation applications to celery (working 80 days/year, treating 350 acres/day) or flaggers (working 80 days/year, treating 350 acres/day). Neither of these two scenarios with comparable exposures result in short- and intermediate-term or cancer (Q_1*-based) risk estimates above the Agency's typical levels of concern. Although in the absence of specific

data for lawn care operators, there is uncertainty about the actual level of risk. The assessment of post-application risks to residents from treatment of home lawns has resulted in risk mitigation which will also reduce risk for professional lawn care operators.

There is one registered ignitable fogger product containing chlorothalonil. No data are available to assess exposures to handlers using this product or to workers who may be exposed to its residues post-application. The Agency relied on experience with other chlorothalonil products and other smoke generators and fumigants to devise an appropriate risk control strategy. The basis for this strategy and the specific control measures are discussed in Chapter IV.

One product containing chlorothalonil is registered as a dust for application with a hand-held duster to ornamentals and vegetables. The Agency lacks formulation-specific data on potential exposures to the dust, and a surrogate assessment based on potential exposures from granulars applied by hand was used. The surrogate assessment, which resulted in amply protective risk estimates, would tend to underestimate exposure, especially through the inhalation route. For other scenarios where use-specific data were not available, the Agency relied on reasonable surrogates and has cited data needed to support continued registration of the subject products. These data are detailed in Chapter V.

Handler Exposure and Risk from HCB: An extensive handler risk assessment was not performed for HCB as a contaminant in chlorothalonil because there are no data available to allow an handler exposure assessment. The Agency conducted a rudimentary assessment in which exposures were based on the contamination of chlorothalonil with HCB at 500 ppm, using an aerial celery application scenario to represent a high-end handler exposure.

Carcinogenic risk from lifetime exposure to HCB was calculated as follows:

$$\text{Daily exposure} \times \frac{\text{days exposure/yr}}{365 \text{ days}} \times \frac{\text{35 years exposure} \times Q_1^*}{75 \text{ years}}$$

Under this scenario, cancer risk from HCB in chlorothalonil is estimated at 2.8×10^{-5}. This risk estimate is below the level that the Agency typically considers to be of concern. Actual risk is assumed to be lower for other handler and occupational post-application exposures.

Incident Information for Handlers of Chlorothalonil: California is the only state that requires physicians to report the treatment of illnesses related to pesticide exposure. Between 1982 and 1992, 133 incident case reports involving chlorothalonil were received by the California Pesticide Illness Surveillance Program. In these reports, adverse health effects were attributed to exposure to chlorothalonil or chlorothalonil used in combination with other pesticides. In most cases, the incidents involved mixer/loaders and applicators and were the result of accidents such as splashes or carelessness such as not wearing protective eyewear. The reported symptoms attributed to chlorothalonil were primarily eye irritations and skin rashes.

According to EPA's Recognition and Management of Pesticide Poisonings (March 1989), chlorothalonil has caused skin irritation and irritation of mucous membranes of the eye and respiratory tract. Dermal sensitization is reportedly rare and no cases of human systemic poisoning have been reported.

Handler Risk Summary: Among the scenarios the Agency assessed for short- and intermediate-term handler risk, several resulted in concerns for inhalation risk:

- For mixer/loaders, wettable powder-open bag, for aerial and chemigation applications to tomatoes and celery; and for ground applications to tomatoes, celery, and stone fruits.

- For mixer/loader/applicators, indoor painting using an airless sprayer with interior latex paint and outdoor painting using an airless sprayer with exterior alkyd paint.

Among the scenarios the Agency assessed for short- and intermediate-term handler risk was one that resulted in concerns for dermal risk:

- For applicators using specialty air-assisted equipment on golf courses (open cab), at higher application rates.

Among the scenarios the Agency assessed for cancer risks for handlers, several resulted in risk concerns under the Q_1* approach:

- For mixer/loaders, wettable powder-open bag, for aerial and chemigation applications to tomatoes and celery.

- For residents applying granulars to turf with a belly-grinder.

- For residents applying wettable powders to turf with a low pressure hand wand.

Post-Application Exposure and Risk to Chlorothalonil

Current Restricted-Entry Interval: The current restricted-entry interval (REI) for chlorothalonil is 48-hours, the default (interim) REI set by the Worker Protection Standard (WPS). WPS interim REIs are determined based on the acute toxicity of the technical grade active ingredient (TGAI). For chlorothalonil, the interim REI of 48 hours is based on chlorothalonil's potential for primary eye irritation (Acute Toxicity Category 1). REIs do not apply to post-application exposure from treatment of residential lawns or golf courses.

Post-Application Exposures of Concern: In this assessment, the Agency has estimated post-application occupational and residential risks associated with exposure to chlorothalonil. The Agency believes that post-application exposures to chlorothalonil should be compared to the

endpoints selected for short-term and intermediate-term periods (1 to 7 days and 1 week to several months exposure, respectively), and to the cancer endpoints associated with the Q_1*.

As discussed previously, the Agency has used two approaches for quantifying chlorothalonil cancer risk. The Agency can apply the MOE approach to post-application exposures when they result in chronic exposures--six months or more of continuous exposure in a year. The Agency has determined that most post-application exposures to chlorothalonil are not of sufficient duration to be considered chronic, and do not warrant application of the MOE approach. The Agency believes that chronic exposure may occur in workers who reenter treated areas to perform hand-labor tasks on cut flowers, particularly in greenhouses, and so cancer MOEs are calculated for this cohort in Tables 26 and 27 below.

Dermal exposure is the primary route of post-application exposure, and the basis of the risk estimates in the tables which follow. Adverse eye effects are also a concern.

There are limited data to address inhalation exposure to chlorothalonil, although in most cases, it does not appear that this is a significant route of exposure for most reentry workers. However, in a study in which tomato harvesters were monitored while hand-harvesting tomatoes (MRID 47002545), inhalation exposure was 0.82 µg/kg/day. This scenario, which represents significant worker exposure, results in a short- and intermediate-term MOE of greater than 10,000, and does not represent a risk of concern. California Department of Pesticide Regulation personnel measured worker exposure to dusts contaminated with chlorothalonil during the mechanical harvesting of bush tomatoes (Spencer *et al.*, 1992). In that study, inhalation exposure was 0.02 mg/person per 8- hour day resulting in a short- and intermediate-term MOE greater than 40,000. To demonstrate the relationship between these two exposure values, if the California exposure figure is adjusted for a 75.9 kg male weight default value, it is equivalent to 0.26 µg/kg/8-hour day. Based on these data, the Agency does not believe that post-application inhalation risk estimates are likely to exceed levels which are typically considered to be of concern.

Post-Application Exposure and Risk Tables: Tables 19-31 show risk estimates for dermal exposure of post-application/reentry workers for agricultural and horticultural scenarios, for golfers and persons mowing fairways and greens on golf courses, and for those who are exposed after home lawns are treated with chlorothalonil.

In calculating post-application cancer risk, dermal exposures have been corrected for 0.15% dermal absorption. Because the endpoints are the same, short- and intermediate-term risk estimates are derived from the same daily (short/intermediate-term) exposures.

Table 19 presents the daily and lifetime average daily exposures and risk estimates for workers reentering treated stone fruit orchards, conifer nurseries (not seedlings), and Christmas tree plantations. Applications to stone fruits are made primarily early in the season (at early bloom and shuck-split), although cherries are treated after harvest. Hand-labor tasks for stone-fruits are pruning and topping cherry trees; for conifers, pruning, balling, and burlapping; for Christmas trees, pruning. This assessment is based on 8-hour work days, 30 days a year, 35 years of exposure out of a 70-year lifetime, dislodgeable foliar residue data from a cherry study, application rates of 2.34 - 4.16 lb ai/acre, a transfer factor of 3,800 cm^2/hr, and a body weight of 70 kg.

Table 19. Estimated Post-application Exposure and Risk for Workers Re-entering Treated Cherry Orchards, Conifer Nurseries, and Christmas Tree Plantations

Days after application	Field residue ($\mu g/cm^2$)	Daily exposure (mg/kg/day)	Short- and Intermediate-term MOE	LADD* (mg/kg/day)	Cancer risk (based on Q_1*)
0	1.81	0.79	>760	4.9E-5	3.7E-7
1	1.48	0.64		4.0E-5	3.1E-7
2	1.20	0.52		3.2E-5	2.5E-7
3	0.98	0.43		2.6E-5	2.0E-7
4	0.80	0.35		2.1E-5	1.7E-7
5	0.65	0.28		1.7E-5	1.3E-7

* Lifetime average daily dose

One incident is associated with the stone fruit orchard use pattern. In 1990, a possible case of eye irritation was reported for a worker thinning nectarines for three days in an area that had been treated with chlorothalonil and triforine.

Table 20 presents daily and lifetime average daily exposures and risk estimates for workers reentering treated tomato fields to hand-harvest tomatoes and stake tomato plants. The assessment is based on 8-hour work days, 120 days a year, 35 years of exposure out of a 70-year lifetime, dislodgeable foliar residue data from a tomato study, application rates of 1.04 - 2.08 lb ai/acre, a transfer factor of 1,300 cm^2/hr from a tomato harvester study, and a body weight of 70 kg. There is no preharvest interval for tomatoes.

Table 20. Estimated Post-application Exposure and Risk for Workers Re-entering Treated Tomato Fields

Days after application	DFR ($\mu g/cm^2$)	Daily exposure (mg/kg/day)	Short- and intermediate-term MOE	LADD* (mg/kg/day)	Cancer risk (based on Q_1*)
0	4.19	0.62	>960	1.5E-4	1.2E-6
1	4.01	0.60		1.5E-4	1.1E-6
2	3.83	0.57		1.4E-4	1.1E-6
3	3.66	0.54		1.3E-4	1.0E-6
4	3.50	0.52		1.3E-4	9.9E-7
5	3.34	0.50		1.2E-4	9.4E-7
6	3.19	0.47		1.2E-4	9.0E-7
7	3.05	0.45		1.1E-4	8.6E-7
14	2.22	0.33		8.1 E-4	6.3 E-7

* Lifetime average daily dose

There are several incidents associated with this use pattern. In 1989, one possible case was reported of a worker suffering from conjunctivitis. The worker had been hoeing weeds in a field treated with chlorothalonil, sulfur, and metalaxyl. In 1990, one possible case was reported of a worker who got a rash while harvesting tomatoes treated 12 days prior with an adjuvant, chlorothalonil, esfenvalerate, methomyl, and sulfur. Also in 1990, one worker developed a rash on a forearm while moving tomato vines in a field treated with an adjuvant, chlorothalonil, esfenvalerate, methomyl, and sulfur.

Table 21 presents daily and lifetime average daily exposures and risk estimates for workers reentering treated cucurbit and snap bean fields. For cucurbits, the hand-labor tasks are hand harvesting, vine turning, and covering watermelons with vines to prevent sunburn; and for snap beans, hand harvesting. The assessment is based on 8-hour work days, 120 days a year, 35 years of exposure out of a 70-year lifetime, dislodgeable foliar residue data from a cucumber study, application rates of 1.17 - 2.2 lb ai/acre, a transfer factor of 1,000 cm^2/hr, and a 70 kg body weight. There is no preharvest interval for cucumbers and a 7-day preharvest interval for snap beans.

Table 21. Estimated Post-Application Exposure and Risk for Workers Re-entering Cucurbit and Snap Bean Fields

Days after application	DFR (µg/cm^2)	Daily exposure (mg/kg/day)	Short- and intermediate-term MOE	LADD* (mg/kg/day)	Cancer risk (based on Q_1*)
0	7.74	0.88	>680	2.2E-4	1.7E-6
1	5.95	0.68		1.7E-4	1.3E-6
2	4.58	0.52		1.3E-4	9.9E-7
3	3.52	0.40		9.9E-5	7.6E-7
4	2.71	0.31		7.6E-5	5.9E-7
5	2.09	0.24		5.9E-5	4.5E-7
7	1.23	0.14		3.5E-5	2.7E-7

* Lifetime average daily dose

There is one incident associated with these use patterns. In 1989, a possible case was reported of a worker developing a rash while picking cucumbers. The rash occurred when the worker removed the plastic picking glove which some workers routinely wear because the fuzz on cucumbers can cause skin irritation. The field was treated with chlorothalonil and oxydemeton-methyl.

Table 22 presents daily and lifetime average daily exposures and risk estimates for workers reentering treated cole crop fields. Hand-labor tasks are hand-harvesting (cutters and packers) for cole crops in general; for Brussels sprouts, terminal point removal and leaf removal; and for cauliflower, head wrapping. This assessment is based on an 8-hour work day, 120 days a year, 35 years of exposure out of a 70-year lifetime, dislodgeable foliar residue data from a broccoli study, application rates of 1.17 - 1.43 lb ai/acre, a transfer factor of 700 cm^2/hr, and a body weight of 70 kg. Chinese cabbage and Chinese broccoli have a 7-day preharvest interval. The broccoli study from which these data are taken was considered supplemental because it rained on the day following the last application. The potential reduction in foliar residues decreases worker exposure and so this assessment represents a best case scenario.

Table 22. Estimated Post-Application Exposure and Risk for Workers Re-entering Treated Cole Crop Fields

Days after application	DFR (µg/cm^2)	Daily exposure (mg/kg/day)	Short- and intermediate-term MOE	LADD* (mg/kg/day)	Cancer risk (based on Q_1*)
0	1.84	0.15	>4,100	3.6E-5	2.8E-7
1	1.51	0.12		3.0E-5	2.3E-7
2	1.25	0.10		2.5E-5	1.9E-7
3	1.03	0.080		2.0E-5	1.6E-7
4	0.84	0.067		1.7E-5	1.3E-7
5	0.69	0.055		1.4E-5	1.1E-7
7	0.47	0.038		9.3E-6	7.1E-8

* Lifetime average daily dose

There are two incidents associated with these use patterns. In 1985, one possible case was reported for a worker who developed a rash while harvesting cauliflower in a field that had been treated with chlorothalonil, oxydemeton-methyl, and mevinphos. In 1988, one possible case was reported for a worker who developed hives. The field was treated with chlorothalonil and metalaxyl.

Table 23 presents daily and lifetime average daily exposure and risk estimates for workers reentering treated corn fields. Tasks for sweet corn are hand-harvesting; tasks for corn grown for seed include removing tassels. This assessment is based on an 8-hour work day, 60 work days a year, 35 years of exposure out of a 70-year lifetime, dislodgeable foliar residue data from the cucumber study adjusted for an application rate of 0.59 - 1.43 lb ai/acre, a transfer factor of 1,000 cm^2/hr, and a body weight of 70 kg. Sweet corn has a 14-day preharvest interval.

Table 23. Estimated Post-Application Exposure and Risk for Workers Re-entering Treated Corn Fields

Days after application	DFR (µg/cm^2)	Daily exposure (mg/kg/day)	Short- and intermediate-term MOE	LADD* (mg/kg/day)	Cancer risk (based on Q_1*)
0	5.16	0.59	>1,000	7.3E-5	5.6E-7
1	3.97	0.45		5.6E-5	4.3E-7
2	3.05	0.35		4.3E-5	3.3E-7
3	2.35	0.27		3.3E-5	2.6E-7
4	1.81	0.21		2.6E-5	2.0E-7
5	1.39	0.16		2.0E-5	1.5E-7
14	0.13	0.015		1.8E-6	1.4E-8

* Lifetime average daily dose

There are no incidents reported for this use pattern.

Table 24 presents daily and lifetime average daily exposures and risk estimates for workers reentering treated celery fields. Hand-labor tasks are cutting, field packing, and moving irrigation pipe. This assessment is based on an 8-hour work day, 120 work days per year, 35 years of exposure out of a 70-year lifetime, dislodgeable foliar residue data from a cucumber study, application rates of 1.17 - 2.2 lb ai/acre, a transfer factor of 700 cm^2/hr, and a 70 kg body weight. Celery has a 7-day preharvest interval. Packer exposure is expected to be lower than cutter exposure.

Table 24. Estimated Post-Application Exposure and Risk for Workers Re-entering Treated Celery Fields

Days after application	DFR (µg/cm^2)	Daily exposure (mg/kg/day)	Short- and intermediate-term MOE	LADD* (mg/kg/day)	Cancer risk (based on Q_1*)
0	7.75	0.62	>970	1.5E-4	1.2E-6
1	5.96	0.48		1.2E-4	9.1E-7
2	4.58	0.37		9.0E-5	7.0E-7
3	3.52	0.28		6.9E-5	5.4E-7
4	2.71	0.22		5.4E-5	4.1E-7
5	2.08	0.17		4.1E-5	3.2E-7
6	1.60	0.13		3.2E-5	2.4E-7
7	1.23	0.098		2.4E-5	1.9E-7

* Lifetime average daily dose

There is one incident associated with this use pattern. In 1987, one possible case was reported for an irrigation worker getting dizzy and feeling itchy around the neck. The worker was wearing rubber pants, jacket, and gloves and had entered the field 2 hours after it was treated with bacillus thuringiensis, chlorothalonil, mevinphos, and permethrin.

Table 25 presents daily and lifetime average daily exposure and risk estimates for workers reentering treated conifer nurseries (seedlings). Hand-labor tasks are packing and moving irrigation equipment. This assessment is based on 8-hour work days, 120 work days per year, 35 years of exposure out of a 70-year lifetime, dislodgeable foliar residue data from a cherry study, application rates of 2.34 - 4.16 lb ai/acre, a transfer factor of 700 cm^2/hr, and a body weight of 60 kg. This reduced body weight reflects risks to females since many nursery workers are women.

Table 25. Estimated Post-Application Exposure and Risk for Workers Re-entering Treated Conifer Nurseries (seedlings)

Days after application	DFR (µg/cm^2)	Daily exposure (mg/kg/day)	Short- and intermediate-term MOE	LADD* (mg/kg/day)	Cancer risk (based on Q_1*)
0	1.81	0.17	>3,600	4.2E-5	3.2E-7
1	1.48	0.14		3.4E-5	2.6E-7
2	1.20	0.11		2.7E-5	2.1E-7
3	0.98	0.090		2.3E-5	1.7E-7
4	0.80	0.070		1.8E-5	1.4E-7
5	0.65	0.060		1.5E-5	1.2E-7

* Lifetime average daily dose

There is one incident associated with this use pattern. In 1989, a probable case was reported for a nursery worker handling treated conifer seedlings damp from recent irrigation. The worker was wearing gloves, but during unloading, some seedlings brushed against the worker's face. The seedlings had been treated with chlorothalonil, and 300 ppm of chlorothalonil was detected on the seedlings. The worker's symptoms were not reported.

Table 26 presents daily and lifetime average daily exposures and risk estimates for field and greenhouse workers following the use of chlorothalonil at a high application rate (2.4 lb a.i./acre). This assessment is based on a study by Brouwer *et al.*, in which chlorothalonil was applied at 0.6 lb ai/80 - 100 gallons of water/0.25 acre to carnation sprays and carnations grown for cut flowers. Exposure for reentry workers was 14.4 mg/hour and a transfer factor of 5800 cm^2/hour was calculated. Based on Brouwer *et al.*, dislodgeable residues in that study are estimated at 4.97 µg/cm^2, single sided (2.5 µg/cm^2 double sided). These measurements were taken from sampling conducted 35 hours after treatment. Brouwer *et al.* reported that the chlorothalonil residues did not dissipate during this time. Hand-labor tasks were cutting, bundling, transplanting, and pruning field and greenhouse grown flowers. For estimating worker exposure, the Agency assumed an 8-hour work day, 248-260 days per year, and 35 years of exposure out of a 70-year lifetime. A body weight of 60 kg was assumed since large numbers of women work in greenhouses.

Table 26. Estimated Post-Application Exposure and Risk for Workers Re-entering Greenhouses Treated With Chlorothalonil at 2.4 lb ai/A

Hours after application	DFR (µg/cm^2)	Daily exposure (mg/kg/day)	Short- and intermediate-term MOE	LADD* (mg/kg/day)	Cancer risk (based on Q_1*)	Cancer risk (MOE approach)
35	2.5	1.9	310	9.9E-4	7.6E-6	16

* Lifetime average daily dose

Table 27 presents daily and lifetime average daily exposures and risk for greenhouse workers following application of chlorothalonil at a lower application rate (1.83 lb ai/acre). This assessment is based on a study by Brouwer *et al.* in California, in which 1.83 lb ai/100 gallons of water per acre were applied to poinsettias. Brouwer *et al.* reported that the chlorothalonil residues did not dissipate during the interval. The Agency used a transfer factor 5,800 cm^2/hr (double- sided) which is based on the transfer factor generated by the Brouwer study. Hand-labor tasks were cutting, bundling, transplanting, and pruning. The Agency assumed an 8-hour work day, 248-260 days per year, and 35 years of exposure out of a 70-year lifetime. A body weight of 60 kg was assumed since large numbers of women work in greenhouses.

Table 27. Estimated Post-Application Exposure and Risk for Workers Re-entering Greenhouses Treated With Chlorothalonil at 1.83 lb ai/A

Hours after application	DFR (µg/cm^2)	Daily exposure (mg/kg/day)	Short- and intermediate-term MOE	LADD* (mg/kg/day)	Cancer risk (based on Q_1*)	Cancer risk (MOE approach)
3	0.54	0.42	>1000	2.1E-4	1.6E-6	75
4	0.74	0.57		2.9E-4	2.3E-6	52
6	0.70	0.54		2.8E-4	2.1E-6	58
12	0.62	0.48		2.4E-4	1.9E-6	65
24	0.55	0.43		2.2E-4	1.7 -6	71
36	0.60	0.46		2.4E-4	1.8E-6	65

* Lifetime average daily dose

During the course of this study, chlorothalonil residues remained at a fairly constant level, resulting in risk estimates which do not change appreciably with time since application.

There are several incidents associated with greenhouse/floriculture use patterns. In 1982, a probable incident occurred when a worker was cutting lilies still wet with chlorothalonil spray. Liquid from a stem splashed into the worker's eye; symptoms were not reported. In 1991, a possible incident occurred when a worker developed symptoms (not specified) while handling plants treated with chlorothalonil and vinclozolin. Also in 1991, a possible incident was reported when a flower cutter developed a rash after working with irises. The iris field had been treated either 6 or 14 days prior with an adjuvant, chlorothalonil, and iprodione.

Table 28 presents daily and lifetime average daily exposures and risk estimates for workers reentering treated sod farm fields to mow and maintain sod or to cut, roll, and harvest sod. The Agency assumed an application rate of 6.0 lb ai/acre as a reasonable average of existing label rates, which range from 2.08 -12.51 lb ai/acre. The Agency assumed a body weight of 70 kg, and a dislodgeable foliar residue of 13.5 $\mu g/cm^2$ based on 20% of the application rate available as dislodgeable residue on day zero, with no dissipation over the next seven days, as was observed in the Brouwer *et al.* study. For workers mowing and maintaining sodgrass, the Agency assumed a transfer factor of 1000 cm^2/hr, and for workers hand-cutting, -rolling, and -harvesting sodgrass, the Agency assumed a transfer factor of 10,000 cm^2/hr. These transfer factors are EPA estimates (Policy Memo #003, Science Advisory Council for Exposure, May 7, 1998). For the cancer estimates, the Agency assumed an 8-hour work day, 30 exposure days per year, and 35 years of work out of a lifetime of 70 years.

Table 28. Estimated Post-Application Exposure and Risk for Workers Re-entering Treated Sod

Activity	Daily Dose (mg/kg/day)	Short- and intermediate-term MOE	LADD* (mg/kg/day)	Cancer risk (based on Q_1*)
mowing, maintaining	1.5	390	9.5E-5	7.3E-7
cutting, rolling, harvesting	15	39	1.6E-3	1.2E-5

*Lifetime average daily dose

There are no reported incidents associated with this use pattern.

Table 29 presents daily and lifetime average daily exposure and risk estimates from applications to golf courses. For golfers, the Agency assumed 30 days of golf per year and 50 years of golfing; for mowers, the Agency assumed 60 days of mowing per year and 35 years of mowing. Greens mowers were assumed to mow 2 acres/day and fairways mowers were assumed to mow 20 acres/day. Daily doses are derived from MRID#s 424338-10 and -11.

Table 29. Estimated Post-Application Exposure and Risk for Golfers and Golf Course Mowers Re-entering Treated Golf Courses

Activity	Daily dose (mg/kg/day)	Short- and intermediate-term MOE	LADD* (mg/kg/day)	Cancer risk (based on Q_1*)
Golfer - walking	0.001	600,000	1.3E-9	9.7E-12
Greens mower	0.006	100,000	1.1E-8	8.1E-11
Fairways mower	0.002	300,000	3.5E-9	2.7E-11

* Lifetime average daily dose

Risks for other golfing scenarios such as using a golf cart are assumed to be much lower and were not quantified.

Tables 30 and 31 present daily and lifetime daily average exposure and risk estimates for people who are exposed after application to chlorothalonil used on residential lawns and ornamental plants. The contact rate for activities with ornamentals (5,800 cm^2/hr) is from the study by Brouwer. Rates for dermal contact with treated turf by adults (1,000 cm^2/hr) and toddlers (8,700 cm^2/hr) are based on EPA estimates for low exposure activities. Contact rates for hand-to-mouth transfer by toddlers (1.56 events/hour), ingestion of treated grass by toddlers (25 cm^2/day), and ingestion of soil from treated areas by children (100 mg/day) are default values which originate with high-end exposure scenarios. For the cancer risk estimates, the Agency assumed that activities with ornamentals occur 4 days per year for 50 years, and that an application is made once a year; for adults in dermal contact with treated turf, that contact occurred 40 days per year for 50 years, and that three applications were made each year. The Agency also assumed that reentry occurred on the day of treatment.

Table 30. Estimated Residential Post-Application Exposures and Short- and Intermediate-Term Risks

Exposure Activity	Application rate (lb ai/acre)	Hours exposed per day	DFR ($\mu g/cm^2$)	Daily dose (mg/kg/day)	MOE
Adult/ornamentals: transplanting, pruning, bundling flowers	0.183	0.67	0.41	0.023	26,000
	8.7		20	1.1	550
	15.7		35	2.0	310
Adult harvesting vegetables	0.183	0.67	0.41	0.039	15,000
	0.74		1.7	0.16	3,800
	8.7		20	1.9	320
Adult/turf: dermal contact	8.7	1	20	0.28	2,200
	11.8		26	0.38	1,600
	15.7		35	0.50	1,200
Toddler (3-year old)/turf: dermal contact	8.7	2	20	23	26
	11.8		26	30	20
	15.7		35	41	14
Toddler (3-5 year old)/ lawn: incidental, nondietary ingestion of residue, hand to mouth	8.7	2	20	1.4	420
	11.8		26	1.9	310
	15.7		35	2.6	230
Toddler (3 year old)/turf: ingestion of treated grass	8.7	NA	20	0.033	18,000
	11.8		26	0.044	14,000
	15.7		35	0.059	10,000
Children (1-6 year old) (Incidental ingestion of soil from treated areas)	8.7	NA	65 soil residue ($\mu g/cm^2$)	4.4E-4	1.4E6
	11.8		89 soil residue ($\mu g/cm^2$)	5.9E-4	1.0E6

Exposure Activity	Application rate (lb ai/acre)	Hours exposed per day	DFR ($\mu g/cm^2$)	Daily dose (mg/kg/day)	MOE
	15.7		120 soil residue ($\mu g/cm^2$)	7.9E-4	760,000
Infants (0.5 - 1.5 years) Ingestion of Paint Chips (stain/wood preservative)	0.007 lb ai/gallon	NA	NA	0.0056	110,000

There are no reported incidents associated with these use patterns.

Table 31. Surrogate Residential Post-application Scenarios and Cancer Risks from Chlorothalonil

Exposure Activity/Crop or Target	Application Rate (lb ai/acre)	DFR ($\mu g/cm^2$)	LADD* (mg/kg/day)	Cancer Risk (based on Q_1*)
Ornamentals (Transplanting/Pruning/ Bundling Flowers)	0.183	0.41	2.6E-7	2.0E-9
	8.7	20	1.3E-5	9.6E-8
	15.7	35	2.3E-5	1.8E-7
Vegetables (Harvesting)	0.183	0.41	4.6E-7	3.5E-9
	0.74	1.7	1.9E-6	1.4E-8
	8.7	20	2.2E-5	1.7E-7
Adult Dermal Contact with Turf	8.7	20	3.3E-5	2.5E-7
	11.8	26	4.4E-5	3.4E-7
	15.7	35	5.5E-5	4.2E-7

* Lifetime average daily dose

Cancer risk is calculated for adult exposures only.

Reentry Incident Information for Chlorothalonil: Each post-application risk table is followed by incident information from associated with use patterns. California is the only state that requires physicians to report the treatment of illnesses related to pesticide exposure. Between 1982 and 1992, 13 reentry worker incidents were reported as "possible" or "probable" consisting of skin sensitization and eye irritation. These incidents are linked to specific use patterns in the discussion of post-application risk above. In addition, dermatitis has been reported resulting from contact with treated wood (Johnson *et al*., 1983; and Bach and Pedersen, 1983). Symptoms of facial erythema and tightness in the chest were reported involving a female nursery worker (Maibach, 1990). The incident was reportedly investigated by Dannaker *et al*. (1995) and which a test confirmed that a dilute concentration of 0.01 percent caused an anaphylactoid reaction in the worker. It has been suggested (Maibach *et al*., 1993) that chlorothalonil be listed as a cause of contact urticaria syndrome. It should be noted however, that a dermal sensitization study conducted using guinea pigs (MRID 40546001) was negative.

Post-Application Risk Summary: Among the scenarios that the Agency assessed for post-application short- and intermediate-term risk, several resulted in risks that exceed levels which are typically considered by the Agency to be of concern:

For workers reentering treated sodfarm areas to cut, roll, and harvest sod

For toddlers in dermal contact with turf that has been treated with chlorothalonil

Among the scenarios the Agency assessed for post-application cancer risk estimates, none raised risk concerns under the Q* approach. In one scenario, cancer risk, as estimated under the MOE approach, will likely exceed standards established by the Agency for acceptable cancer MOEs:

Workers reentering treated greenhouses and fields where cut flowers and potted ornamentals are grown for cutting, bundling, transplanting, and pruning

Although the Agency has not identified an “acceptable” level of risk for cancer under the MOE paradigm, past discussions have focused on MOEs of 100 or greater. An MOE of less than 100, as has been calculated for these scenarios, is likely to be of concern.

Post-application risks from HCB: Cancer risk from HCB was not calculated; post-application exposure to HCB from chlorothalonil is not expected to be a concern based on the low level of HCB in chlorothalonil and estimates for applicator exposure. Risk from HCB is approximated by assuming that HCB is available for post-application exposures at a level proportional to the level that HCB is present in chlorothalonil formulations. The maximum allowable level of 0.05% would result in dislodgeable residues of HCB at 0.0005X the level of chlorothalonil residues. Risk would be proportionately lower.

Aggregate Risk

In examining aggregate risk, FQPA directs EPA to take into account available information concerning exposures from the pesticide residue in food and all other exposures for which there is reliable information. These other sources of exposure can include pesticide residues in drinking water, exposure from pesticides uses in and around the home, and exposure in non-residential settings, such as parks, schools, etc. Chlorothalonil has food uses as a broad spectrum fungicide applied to many crops, and is available for use by homeowners, groundskeepers, and golf course employees. Chlorothalonil is available in a variety of formulations and is applied in ways that present potential for exposure.

Short-term aggregate exposure considers high-end spikes in exposure that could occur during a short time period (typically 1-7 days) for a variety of reasons; e.g., a lawn/indoor pesticide application is made on a particular day on which a person would also consume residues of this same pesticide in the diet (food and water). To estimate risk, this short-term exposure spike is compared to pesticide levels at which toxic effects were seen in short-term toxicity studies.

Similarly, long-term aggregate exposure considers average exposure to a population over a lifetime. This average exposure is then compared to pesticide levels at which toxic effects were seen in long-term (usually chronic) toxicity studies to estimate risk. Aggregate risks from food and water are calculated as shown below:

$$\text{Aggregate Acute Risk} = \frac{\text{Acute Dietary LOEL (175 mg/kg/day)}}{\text{Acute Water Exposure + Acute Dietary Exposure}}$$

$$\text{Aggregate Chronic Risk} = \frac{\text{Reference Dose for Chlorothalonil (0.02 mg/kg/day)}}{\text{Chronic Water Exposure + Chronic Dietary Exposure}}$$

In Table 32, aggregate risk is calculated for drinking water, and food sources, and non-occupational exposures.

Table 32. Food Quality Protection Act Considerations/Risk

RISK TYPE	POPULATION GROUP	ESTIMATED RISK	
		Chlorothalonil	**HCB**
DIETARY RISK from food			
Acute Dietary Risk (for chlorothalonil, risk is estimated for residues of chlorothalonil and SDS-3701 combined)	Infants < 1 year old	MOE = 875	N/A
	Children (1-6)		
	US Population	MOE = 1166	
Chronic Non-Cancer Dietary Risk (for chlorothalonil, risk is estimated for residues of chlorothalonil and SDS-3701 combined)	Non-nursing Infants < 1 year old	60% RfD	not calculated
	Children (Ages 1-6)	approx. 60% RfD	0.05% RfD
	US Population	32% RfD	0.029% RfD
Dietary Cancer Risk (for chlorothalonil parent only)	US Population	Q_1* approach 1.2×10^{-6}	2.4×10^{-7}
		MOE = 9500	
DRINKING WATER RISK: Groundwater			
Acute Risk	Children	MOE = 110,000	N/A
	Adults	MOE = 380,000	
Chronic Non-cancer Risk	Children	8% RfD	< 1 % RfD
	Adults	2% RfD	< 1 % RfD
DRINKING WATER RISK: Surface Water			
Acute Risk	Children	MOE = 5×10^7	N/A
	Adults	MOE = 1.75×10^8	
Chronic Non-cancer Risk	Children	< 1 % RfD	< 1 % RfD
	Adults	< 1 % RfD	< 1 % RfD
Cancer Risk	US Population	Q_1* approach 8×10^{-9}	5×10^{-9}
		MOE > 1.5×10^6	

RISK TYPE	POPULATION GROUP		ESTIMATED RISK	
			Chlorothalonil	**HCB**
RESIDENTIAL RISK (high-end exposures)				
Short- and Intermediate-Term Risk, Handlers	Applying granules to turf		MOE_D = 88-49	not calculated*
	Using low-pressure hand wand on turf		MOE_D = 39-21; MOE_I = 29-16	
Short-/Intermediate-Term Risk, Residential Post-Application	Toddler in dermal contact with turf		MOE_D = 41-23	
	Adult gardening with ornamentals		MOE_D = 26,000 - 310	
Cancer risk, residential handlers	Using low-pressure hand wand on turf		Q_1* approach 8.8×10^{-6}	
Cancer risk, post-application	Adult in dermal contact with turf		Q_1* approach 4.2×10^{-7}	
AGGREGATE RISK**	Acute Risk	Children	MOE = 875	N/A
		Adult	MOE = 310+	
	Chronic Non-Cancer Risk	Children	68 % RfD	< 1% RfD
		Adult	34 % RfD	
	Cancer Risk (adults)		Q_1* approach approx. 1.2×10^{-6}	2.4×10^{-7}
			MOE = 9500	

* Residential risk to HCB was not quantified due to the expected low level of potential HCB exposure.
** Based on voluntary cancellation of home lawn use

Cumulative Effects

Chlorothalonil is a member of the polychlorinated fungicide class of pesticides. Other members of this class include hexachlorobenzene, pentachlorophenol, pentachloronitrobenzene.

Section 408(b)(2)(D)(v) of the Food Quality Protection Act requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity". The Agency believes that "available information" in this context might include not only toxicity, chemistry, and exposure data, but also

scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, including chlorothalonil, the Agency does not presently have the data or methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's generic understanding of the common mechanism of toxicity so that decisions about individual cases can be made. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on particular classes of chemicals will be heavily dependent on chemical-specific data, much of which may not be presently available.

There are pesticides for which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed). The Agency does not have, at this time, data to determine whether chlorothalonil falls into one of these categories, but for the purposes of this document, the Agency has not assumed that chlorothalonil has a common mechanism of toxicity with other substances.

C. Environmental Assessment

1. Ecological Toxicity Data

The Agency has adequate data to provide a qualitative assessment of the ecological toxicity of chlorothalonil to nontarget organisms. The following additional data would allow a more complete assessment of the ecological risk of chlorothalonil to nontarget organisms: Fish early life stage (72-4(a)), Acute marine/estuarine fish, mollusk, and shrimp (72-3 (d-f)) testing with formulated product, Aquatic plant growth (123-2) in *Lemna gibba*, and residues of SDS-3701 on foliage (70-1-SS).

Toxicity to Terrestrial Animals

Birds, Acute and Subacute Toxicity of Chlorothalonil: In order to establish the toxicity of chlorothalonil to birds, the following tests were required using the technical grade material: one avian single-dose oral (LD_{50}) study on one species (preferably mallard or bobwhite quail); two subacute dietary studies (LC_{50}) on one species of waterfowl (preferably the mallard duck) and one species of upland game bird (preferably bobwhite quail). Tables 33 and 34 summarize the avian acute oral and the avian subacute dietary toxicity findings.

Table 33. Avian Acute Oral Toxicity Findings

Test Species	% a.i.	LD_{50} mg/kg	Citation (MRID #)	Toxicity Category	Fulfills Guideline?
Mallard	96%	> 4640	00068753	Practically non-toxic	Yes
Japanese quail	98.6%	> 2000	40964105	Practically non-toxic	Partially

Table 34. Avian Subacute Dietary Toxicity Findings

	% a.i.	LC_{50} ppm	Citation (MRID #)	Toxicity Category	Fulfills Guideline?
Northern Bobwhite	96%	> 10,000	00030388	Practically non-toxic	Yes
Mallard	93.6%*	> 21,500	00039146	Practically non-toxic	Yes
Mallard	96%	> 10,000	00030389	Practically non-toxic	Yes

* The test substance was reported to be a mixture of 93.6% chlorothalonil, 3.0% SDS-2020, 1.1% SDS-3200, and 2.3% SDS-3297.

These results indicate that chlorothalonil is "practically non-toxic" to avian species on an acute oral and subacute dietary basis. The avian acute and subacute guideline requirements for parent chlorothalonil are fulfilled.

Birds, Acute and Subacute toxicity of SDS-3701: Additional studies on a degradate, SDS-3701, have been submitted. These studies are summarized in Table 35.

Table 35. Avian Acute Oral and Subacute Dietary Toxicity Findings

Test Species	% SDS-3701	Results	Citation (MRID #)	Toxicity Category	Fulfills Guideline?
Mallard	99%	LD_{50} = 158 mg/kg	00030395	Moderately toxic	Yes
Northern Bobwhite	99%	LC_{50} = 1746 ppm	00115109	Slightly toxic	Yes
Mallard	99%	LC_{50} = 2000 ppm	00115108	Slightly toxic	Yes

These studies show that SDS-3701 is "moderately toxic" on an acute oral basis and "slightly toxic" on a dietary basis to the test birds, based on a mortality response. SDS-3701 is more toxic to birds than the parent.

Birds, Chronic Toxicity of Chlorothalonil: Avian reproduction studies have been required in the past for pesticides when birds may be exposed repeatedly or continuously through persistence, bioaccumulation, or multiple applications, or if mammalian reproduction tests indicate reproductive hazard. Present product labeling of chlorothalonil in many cases allows repeat applications of the end-use product during a single growing season. In addition, approved changes to 40CFR Part 158 will generally require avian reproduction studies for all outdoor uses, regardless of repeat applications. Table 36 summarizes the avian reproduction findings.

Table 36. Avian Reproduction Findings for Chlorothalonil

Test Species	% a.i.	NOEL PPM	LOEL PPM	Endpoints affected	Citation (MRID #)	Fulfills Guideline?
Mallard	98.3	>10,000 (reprod.)	>10,000 (reprod.)	No reproductive effects cited at any test level (1000, 5000, 10,000 ppm)	40964102	Yes
Bobwhite	98.3	1000 (reprod.)	5000 (reprod.)	Overt signs of toxicity and reduced reproduction cited at 5000 ppm; overt signs of toxicity, mortalities, and profound effects upon several reproductive parameters related to egg production, hatching success, and survival of hatchlings cited at 10,000 ppm.	40964104	Yes
Mallard	99.6		Not established. Highest level of 50 ppm did not cause impairment.	NA.	00041441	Partially
Bobwhite	99.6		Not established. Highest level of 50 ppm did not cause impairment.	NA	00041440	Partially

The avian reproduction studies indicate that parent chlorothalonil does not affect avian reproduction at 1000 ppm and below; effects were seen at 5000 ppm and above (based on the bobwhite study). The guideline requirements for testing with parent chlorothalonil are fulfilled.

Birds, Chronic Toxicity of SDS-3701: Because of the high persistence of the SDS-3701 degradate, avian reproduction studies have also been required for this material. These studies are summarized in Table 37.

Table 37. Avian Reproduction Findings for SDS-3701

Test Species	% SDS-3701	NOEL PPM	LOEL PPM	Endpoints affected	Citation (MRID #)	Fulfills Guideline?
Mallard	99.6	50	100	Reduction in eggshell thickness seen at 100 ppm; at 250 ppm adult body weight, food consumption, and gonad development affected, as well as effects on numbers of eggs laid, embryonic development, eggshell thickness, hatchability, and hatching survival.	40729402	Yes
Bobwhite	99.6	100	250	Reduction in numbers of eggs laid (but not statistically significant)	40729404	Yes

Avian reproduction in birds could be affected at levels of SDS-3701 above 50 ppm.

Mammals, Acute and Chronic Toxicity of Chlorothalonil: Wild mammal testing is required on a case-by-case basis, depending on the results of the lower tier studies such as acute and subacute testing, intended use pattern, and pertinent environmental fate characteristics. In most cases, however, data from the Agency's Health Effects Division (HED) are used to determine toxicity to mammals. These data are reported in Table 38.

Table 38. Mammalian Toxicity Findings for Chlorothalonil

Test Species	LD_{50} mg/kg	NOEL PPM	LOEL PPM	Citation (MRID #)	Toxicity Category
Rat (small mammal surrogate)	>10,000			00094940	practically non-toxic
Rabbit (developmental)		330	660 (decrease in maternal body weight gain; no developmental toxicity was seen at any dose level)	41250503	N/A
Rat (developmental)		2,000	8,000 (increased resorptions of fetuses)	00130733	N/A
Rat (2 generation reproduction)		1500	3,000 (decrease in pup body weight gain; no developmental toxicity was seen at any dose level)	41706201	N/A

The available mammalian data indicate that chlorothalonil is "practically non-toxic" to small mammals on an acute oral basis, based on the rat LD_{50}. However, a number of non-lethal effects were reported, including diarrhea, lacrimation, reduced muscle tone and erythema. The only definitive NOEL for a developmental parameter was 2,000 ppm based on resorption of fetus at 8,000 ppm. A decrease in body weight gain is not considered to be a significant parameter for assessing ecological risk to reproduction.

Mammals, Acute and Chronic Toxicity of SDS-3701: Data on the toxicity of the SDS-3701 degradate to mammals is found in Table 39.

Table 39. Mammalian Toxicity Findings for SDS-3701

Test Species	LD_{50} mg/kg	NOEL PPM	LOEL PPM	Citation (MRID #)	Toxicity Category
Rat (small mammal surrogate)	242 (females)			001098	moderately toxic
Rabbit (developmental)		33	82.5 (maternal death, abortion)	00047944	NA
Rat (3-generation reproduction)		10	60 (reduced pup body weight gain)	00127844	NA
Rat (1-generation reproduction)		30	60 (reduced pup body weight gain)	00127845	NA

SDS-3701 is moderately toxic to small mammals on an acute oral basis. In a 3-generation rat reproductive study, a modest reduction in the rate of body weight gain for pups was observed at 60 ppm. However this measurement endpoint is not considered a significant parameter for assessing ecological risk to reproduction. SDS-3701 demonstrated an impact on pregnant rabbits at concentrations between 33 and 82.5 ppm.

Insects, Toxicity of Chlorothalonil

A honey bee acute contact LD_{50} study was required because chlorothalonil use could result in exposure to honey bees. The available insect acute contact toxicity findings for chlorothalonil are summarized in Table 40.

Table 40. Nontarget Insect Acute Contact Toxicity Findings

Test Species	% a.i.	Results	Citation (MRID #)	Toxicity Category	Fulfills Guideline?
Honey bee	Tech.	14% mortality at 181 µg/bee	00036935	Relatively non-toxic	Yes

Test Species	% a.i.	Results	Citation (MRID #)	Toxicity Category	Fulfills Guideline?
Honey bee	Tech.	non-toxic at 181 µg/bee	00077759	non-toxic at 181 µg/bee	Yes

There is sufficient information to characterize chlorothalonil as "relatively non-toxic" to honey bees. The guideline requirement is fulfilled.

Toxicity to Aquatic Animals

Acute Toxicity of Technical Chlorothalonil to Freshwater Fish: In order to establish the toxicity of a pesticide to freshwater fish, the minimum data required on the technical grade of the active ingredient are two freshwater fish toxicity studies. One study should use a coldwater species (preferably the rainbow trout), and the other should use a warmwater species (preferably the bluegill sunfish). The freshwater fish acute toxicity findings for the technical grade of the active ingredient are summarized in Table 41.

Table 41. Freshwater Fish Acute Toxicity Findings for Chlorothalonil

Test Species	% a.i.	LC_{50} ppb a.i.	Citation (MRID #)	Toxicity Category	Fulfills Guideline?
Rainbow trout	96	42.3	00056486	very highly toxic	Partially
Bluegill	96	59.5	00041439	very highly toxic	Yes
Bluegill	99	84	00029410	very highly toxic	Yes
Bluegill	98	51	00127862	very highly toxic	Yes
Channel catfish	96	48	00030390	very highly toxic	Yes
Fathead minnow	96	23	00030391	very highly toxic	Yes

The results of the 96-hour acute toxicity studies indicate that chlorothalonil is "very highly toxic" to fish. The guideline requirements are fulfilled.

Acute Toxicity of Formulated Product to Freshwater Fish: Formulated product testing is specified for products with direct application to aquatic habitats and for typical end-use products where the EEC for the active ingredient is $\geq LC_{50}$. Further testing of a 54% ai flowable concentrate was required to support a cranberry use. The freshwater fish acute toxicity findings for the 54%, 75%, and Bravo W-75 formulations are summarized in Table 42.

Table 42. Freshwater Fish Acute Toxicity Findings for Chlorothalonil Products

Test Species	% a.i.	LC_{50} ppb formulation (96h test)	Citation (MRID #)	Toxicity Category (FP)	Fulfills Guideline? (for Formulated Product tested)
Rainbow trout	54 (Bravo 720)	61 (33)[1]	43302101	very highly toxic	Yes
Bluegill	54 (Bravo 720)	49 (26)	42433804	very highly toxic	Yes
Rainbow trout	75 (Bravo W-75)	152[2]	00087304	highly toxic	Partially
Rainbow trout	75 (Bravo W-75)	103 (77)	00087303	highly toxic	Yes
Bluegill	75 (Bravo W-75)	167 (125)	00087258	highly toxic	Partially

[1] Value in parentheses is LC_{50} as extrapolated for technical grade chlorothalonil
[2] Value cited is for 48h test

These studies show that Bravo 720 is "very highly toxic" to both rainbow trout and bluegill. The 75% ai formulation tested is "highly toxic" to these species. Other constituents of the Bravo 720 formulation may enhance the toxic effects of the active ingredient, whereas the other constituents of Bravo W-75 appear to decrease the toxic effects of the active ingredient.

Acute Toxicity of SDS-3701 to Freshwater Fish: Testing using the degradate SDS-3701 was required due to its persistence in water. Freshwater fish acute toxicity findings for SDS-3701 are summarized in Table 43.

Table 43. Freshwater Fish Acute Toxicity Findings for SDS-3701

Test Species	% SDS-3701	LC_{50} (ppm)	Citation (MRID #)	Toxicity Category	Fulfills Guideline?
Bluegill	not avail.	45	00029415	slightly toxic	Yes (for SDS-3701)
Bluegill	99	15	00030393	slightly toxic	Yes (for SDS-3701)

These studies show that SDS-3701 is "slightly toxic" to the bluegill and is significantly less toxic than parent chlorothalonil.

Toxicity of Chlorothalonil to Early Life-Stage, Freshwater Fish: Data from fish early life-stage testing is required for chlorothalonil since it can be expected to be transported to water from the intended use site, acute LC_{50} values are less than 1 mg/L, and aquatic EECs are $\geq$ 0.01 of LC_{50}s. Previous reviews have determined that the fish full life cycle study fulfills the requirement. Fish full life cycle test findings are summarized in Table 44.

Table 44. Fish Full Life Cycle Toxicity Findings for Chlorothalonil

Test Species	% a.i.	NOEL (ppb)	LOEL (ppb)	MATC (ppb)	Citation (MRID #)	Endpoints Affected	Fulfills Guideline?
Fathead minnow	96	3	6.5	>3, <6.5; geom. mean = 4.4	00030391	hatching success and survivability	Yes

The results indicate that fathead minnow hatching success and survival are affected at between 3 and 6.5 ppb. The guideline requirement is fulfilled.

Aquatic Field Testing, Effects on Freshwater Fish for Chlorothalonil: An aquatic field study was previously submitted and reviewed (MRID # 00127862). It included some limited information regarding exposure for one soybean site. The highest reported water and sediment concentrations in two adjacent ponds were 0.6 ppb and 1.1 ppb for water and 31 ppb and 51 ppb for sediment, respectively. No mortality was observed in the study. However, the submission is considered supplemental, in part because there was only one site studied and conditions did not represent a reasonable high runoff scenario.

Acute Toxicity of Chlorothalonil for Freshwater Invertebrates: The minimum testing required to assess the hazard of a pesticide to freshwater invertebrates is a freshwater aquatic invertebrate toxicity test, preferably using first instar *Daphnia magna* or early instar amphipods, stoneflies, mayflies, or midges. The freshwater invertebrate toxicity findings for the technical are summarized in Table 45.

Table 45. Freshwater Invertebrate Toxicity Findings for Chlorothalonil

Test Species	% a.i.	LC_{50} (ppb)	Citation (MRID #)	Toxicity Category	Fulfills Guideline?
Daphnia magna	Tech.	68	00068754	very highly toxic	Yes

There is sufficient information to characterize chlorothalonil as "very highly toxic" to aquatic invertebrates. The guideline requirement is fulfilled.

Acute Toxicity of Formulated Product to Freshwater Invertebrates: Formulated product testing is specified for products with direct application to aquatic habitats and for typical end-use products where the EEC for the active ingredient is $\geq LC_{50}$. The freshwater invertebrate toxicity findings for formulated product testing are summarized in Table 46.

Table 46. Freshwater Invertebrate Toxicity of a Formulated Product

Test Species	% a.i.	LC_{50} (ppb) formulation	Citation (MRID #)	Toxicity Category (FP)	Fulfills Guideline? (for FP tested)
Daphnia magna	54 (Bravo 720)	180 (97)*	42433806	highly toxic	Yes

* Value in parentheses is LC_{50} as extrapolated for technical grade chlorothalonil

There is sufficient information to characterize Bravo 720 as "highly toxic" to aquatic invertebrates. There is no suggestion that this formulation is more toxic than the active ingredient or that the formulation makes the ai more toxic.

Acute Toxicity of SDS-3701 to Freshwater Invertebrates: Because of the aquatic persistence of the degradate SDS-3701, acute testing of this material was required. The freshwater invertebrate toxicity findings for the degradate, SDS-3701, are summarized in Table 47.

Table 47. Freshwater Invertebrate Toxicity of SDS-3701

Test Species	% SDS-3701	LC_{50} (ppm)	Citation (MRID #)	Toxicity Category	Fulfills Guideline?
Daphnia magna	99	26	00030394	slightly toxic	Yes (for SDS-3701)

The above data indicate that SDS-3701 is "slightly toxic" to *D. magna* and is significantly less toxic than parent chlorothalonil.

Chronic Toxicity of Chlorothalonil to Freshwater Invertebrates. Because chlorothalonil is expected to be transported to water from the intended use site, acute LC_{50} values are less than 1 mg/L, and aquatic EECs are $\geq$ 0.01 of LC_{50}s, chronic aquatic testing is specified. The aquatic invertebrate life-cycle toxicity findings are summarized in the Table 48.

Table 48. Aquatic Invertebrate Life-Cycle Toxicity of Technical Chlorothalonil

Test Species	% a.i.	NOEL (ppb)	LOEL (ppb)	MATC (ppb)	Citation (MRID #)	Endpoints Affected	Fulfills Guideline?
Daphnia magna	99.8	39	79	>39, <79; geom. mean = 55.5	00115107	survival, cumulative numbers of offspring/ female	Yes

The results indicate that chlorothalonil can affect aquatic invertebrate reproduction between 39 and 79 ppb. The guideline requirement is fulfilled.

Acute Toxicity of Chlorothalonil to Estuarine and Marine Animals: Acute toxicity testing with estuarine and marine organisms is required when an end-use product is intended for direct application to the marine/estuarine environment or is expected to reach this environment in significant concentrations. Peanuts and turf are some of the registered use sites for Chlorothalonil that the Agency considers to be associated with estuarine/marine habitat.

The requirements under this category include a 96-hour LC_{50} for an estuarine fish, a 96-hour LC_{50} for shrimp, and either a 48-hour embryo-larvae study or a 96-hour shell deposition study with oysters. The estuarine/marine acute toxicity findings are summarized in Table 49.

Table 49. Estuarine/Marine Acute Toxicity Findings for Technical Chlorothalonil

Test Species	LC_{50}/EC_{50} (ppb)	Citation (MRID #)	Toxicity Category	Fulfills Guideline?
Sheepshead minnow	32	00127863	very highly toxic	Yes
Pink Shrimp	154	00127864	highly toxic	Yes
Eastern Oyster (shell deposition)	3.6	00138143	very highly toxic	Yes

There is sufficient information to characterize chlorothalonil as "very highly toxic" to the sheepshead minnow and Eastern oyster, and "highly toxic" to the pink shrimp. The guideline requirement is fulfilled.

Acute Toxicity of Formulated Product to Estuarine/Marine Animals: Acute testing with marine/estuarine organisms, using formulated product, may be required to evaluate those use patterns with marine/estuarine exposure where the EEC $\geq LC_{50}$ for the active ingredient (chlorothalonil). End-use formulations do not demonstrate significantly greater acute toxicity to freshwater organisms than technical chlorothalonil within what may be considered expected statistical differences between tests or laboratories. Although testing on estuarine fish with Bravo 720 in one case resulted in a slightly lower LC_{50} than testing with the technical material, testing estuarine/marine fish with the formulated products would not likely result in an EC_{50} of less than 3.6 ppb, the acute oyster technical EC_{50}. Risk to estuarine organisms would still be based on technical chlorothalonil's impact to oysters, and so the Agency determined formulation testing to be unnecessary.

Except for oysters, invertebrates appear to be less sensitive to chlorothalonil and SDS-3701 than fish. Nevertheless, several factors support testing oysters with Bravo 720: 1) it may be used in coastal areas, 2) oysters are more sensitive than other invertebrates by factors of 20 - 50X, 3) oysters cannot move out of contaminated areas, and 4) oysters bioconcentrate chlorothalonil degradation products at greater than 2000X. On the other hand, even if the toxicity was twice that of parental chlorothalonil, the EC_{50} would be 1.8 ppb. This two-fold difference is not considered to be significant relative to the EECs, which are 10-fold higher than the EC_{50} of 3.6

ppb. Additionally, drift at the time of application is the only means by which oysters are exposed to the entire formulation. The frequency of such an occurrence could be low, as would the resulting water concentration. The Agency has determined that the value of such a study is low to medium.

Chronic Toxicity of Chlorothalonil to Estuarine/Marine Animals: Marine/estuarine chronic testing was required due to potential exposure from such sites as turf and peanuts. The marine/estuarine chronic (invertebrate life-cycle toxicity findings) data are found in Table 50.

Table 50. Invertebrate Life-cycle Toxicity of Technical Chlorothalonil

Test Species	% a.i.	NOEL (ppb)	LOEL (ppb)	MATC (ppb)	Citation (MRID #)	Endpoints Affected	Fulfills Guideline?
Mysid shrimp	100	0.83	1.2	>0.83, <1.2 (geom. mean = 1.0)	42433807	reproduction	Yes

The above results indicate that mysid shrimp reproduction will be affected at exposures between 0.83 and 1.2 ppb, and higher. The guideline requirement for this test has been fulfilled. Chronic data are also required for a marine/estuarine fish species, preferably the sheepshead minnow (fish early life-stage), but the value of such a study is considered low since a fathead minnow full life-cycle study is available, and the fathead minnow was slightly more sensitive than the sheepshead minnow in acute testing.

Toxicity to Plants

Toxicity of Chlorothalonil to Terrestrial Plants: Tier 1 toxicity data on the technical material are summarized in Table 51.

Table 51. Nontarget Terrestrial Plant Toxicity of Technical Chlorothalonil

Study	% a.i.	Results (lb ai/A)	Citation (MRID #)	Fulfills Guideline?
Seed germination/seedling emergence--Tier 1 (122-1A); 10 species	97.9	NOEL $\geq$ 16	42433808	Yes
Vegetative vigor--Tier 1 (122-1B); 10 species	97.9	NOEL $\geq$ 16	42433809	Yes

The results indicate that seed germination/seedling emergence and vegetative vigor were not affected in a statistically significant manner at test levels of 16 lb ai/A. Presently, the highest

registered application rate is 22.7 lb ai/A. At 16 lb ai/A, the most sensitive species (onions) showed an 11% negative response. Best professional judgement suggests that detrimental effects greater than 25% would not occur at 22.7 lb ai/A. Since 25% is the threshold for testing at Tier 2, testing under Guideline 123-1 (Tier 2) will not be required.

Toxicity of Chlorothalonil to Aquatic Plants: Aquatic plant testing is required for chlorothalonil because it has outdoor non-residential terrestrial uses and may move offsite of application by drift (e.g., it has aerial and air blast applications). Tier 2 toxicity data on the technical/TEP material are summarized in Table 52.

Table 52. Nontarget Aquatic Plant Toxicity Findings for Chlorothalonil

Test Species	% a.i.	Results (ppb)	Citation (MRID #)	Meets Guideline Requirements
Selenastrum capricornutum	97.9	EC_{50} = 190 NOEC = 50 LOEC = 100	42432801	Yes

The guideline requirements for a test on *Selenastrum capricornutum*, the freshwater green alga, are fulfilled. Due to the effects seen, testing may also be required for an additional four species in Tier 2. At this time the Agency requires only a Tier 2 test on *Lemna gibba*. If *Lemna* is more sensitive than *Selenastrum capricornutum* then *Skeletonema costatum*, *Anabaena flos-aquae*, and a freshwater diatom must be tested with parental chlorothalonil. Furthermore, if *Lemna gibba* is more sensitive than *Selenastrum capricornutum* then *Lemna* must be tested against the degradate SDS-3701. The value added for the Lemna study is high as it is the only representative for an aquatic vascular plant.

2. Environmental Fate Assessment

Status of Data

Based on the available data, the Agency is reasonably confident in its environmental fate assessment of chlorothalonil. A prospective small-scale groundwater monitoring study which was precipitated by the presence of chlorothalonil and/or degradates/metabolites in groundwater (see below) has recently been completed, although the final report has not yet been reviewed. The study should provide a quantitative measure of groundwater contamination potential. Spray drift and droplet size data are needed for estimates of exposure from drift; however, this requirement is being addressed by the Spray Drift Task Force, which should provide data in the near future.

The Agency's estimates of the concentrations of the SDS-3701 metabolite on/in plants are based in part on selected residue chemistry studies submitted for residues on human food items or

domesticated animal food or fodder. Such studies are generally not well-suited for environmental fate and effects purposes because the concentrations of residues in food harvested for humans and domestic animals generally differ from wildlife food sources because of the effects of weathering, handling, and processing conditions in the field. To improve estimates for concentrations of SDS-3701 on/in plants and the resultant potential exposure effects to non-target organisms, other data will be needed.

General Notes

Key factors in the environmental fate assessment are:

There is widespread use of chlorothalonil on many different crops. Chlorothalonil use represents approximately 15% of all US fungicide use by weight. Chlorothalonil is typically applied multiple times to a crop in a season, with short intervals between applications.

Chlorothalonil is a polychlorinated aromatic fungicide, but it is atypical in that it does not have the high degree of persistence associated with many other chlorinated organics. The difference is attributed to the two nitrile groups which activate the molecule. Several of chlorothalonil's primary metabolites are also polychlorinated, and they appear to be more persistent and more mobile than chlorothalonil, as evidenced by laboratory studies, field studies, a groundwater monitoring study, and their appearance in groundwater. SDS-3701, the most prevalent metabolite, is persistent and typically reaches amounts equivalent to 10 to 40% of total applied parent in soil.

Chlorothalonil and metabolites runoff with surface water. Parent and/or degradates have been detected in some groundwater.

Transformation Processes

Chlorothalonil is transformed principally by aerobic and anaerobic microbial metabolism. Simple hydrolysis or photolysis are not major degradative pathways. Mineralization (carbon dioxide production) or evolution of volatiles is not significant under any circumstances.

Rates of Degradation and Dissipation

Residence times of chlorothalonil in the environment vary considerably. Ten to 60 day half-lives (overall) for field dissipation would be a reasonable range for typical terrestrial uses. This range of half-lives is consistent with the laboratory aerobic soil metabolism test results in four different soils whose half-lives ranged from about 10 to 40 days. Initial terrestrial field dissipation half-lives from 4 to 90 days have been reported according to a recent review of the literature, with a value of 30 days considered representative (Ware, 1992). Temperature and moisture are prominent rate factors. Interpretation of preliminary data from a groundwater

monitoring study being conducted on peanuts in North Carolina indicates a field dissipation half-life as long as approximately 4 to 6 months. For modeling purposes (PRZM/EXAMS and GENEEC), the Agency used the upper 90% confidence bound on the mean of half-lives for the four aerobic soils tested in the laboratory. The calculated value is approximately 30 days, in agreement with the value selected in the literature review.

In two different soils under anaerobic aquatic laboratory conditions (reflective of hydrosoil or sediments) half-lives were in the range of 5 to 15 days. Various laboratory aerobic aquatic test results give effective metabolic half-lives ranging from around two hours up to around 6 or 8 days; these half-lives appear to be very sensitive to experimental conditions and to show some concentration dependence. The Agency has selected aerobic aquatic half-lives of 2 and 44 hours for modeling purposes (see Aerobic Aquatic Metabolism and Water Resources below) to estimate environmental concentrations (EECs) and to derive risk quotients for aquatic systems. In the modeling process, the input values for aerobic aquatic half-lives (2 hours and 44 hours) were adjusted to a lower temperature (from 25^{o}C to 20^{o}C) and, in accordance with Agency convention, the 2-hour value was multiplied by 3 to account for the uncertainty associated with a single value estimate. Modeled *instantaneous* pond water concentrations are essentially insensitive to the selected values for this short-lived compound. Both the more conservative 44-hour and the adjusted less conservative 2-hour half-lives are used for comparison in the risk assessment.

Based on all observations, degradation rates strongly depend on local physical and biochemical conditions. Metabolism is faster under wet, flooded or aquatic conditions, especially when there is aeration and mixing. Rates will vary depending on the availability of water and oxygen; the types of soils or sediments and their sorption characteristics; sediment concentrations; and the presence of microfauna, microflora (including algal forms) or even larger life forms.

Degradates

Five related degradates/metabolites (SDS-3701, SDS-19221, SDS-46851, SDS-47523/SDS-47524, and SDS-47525) have been identified as products of aerobic soil or anaerobic aquatic conditions. SDS-3701 is ubiquitous and consistently reaches the highest concentration, typically 10 to 40% of the total. No single one of the other four metabolites exceeded 10%, and their combined maximum total is always less than 20%. The availability of these five metabolites appears to reach constant levels or decrease slowly, indicating persistence. Except for the less mobile SDS-47523/SDS-47524, the *effective* persistence and mobility of these metabolic products is confirmed by their presence in groundwater and their behavior in a groundwater monitoring study (see Water Resources). These detections are as predicted based on satisfactory laboratory mobility studies and are consistent with partially satisfactory and ancillary terrestrial field studies.

The persistence of SDS-3701 is clearly evidenced in the data base, particularly in summary information from two Canadian studies evaluated by the Environmental Protection Service of Canada (and submitted by the registrant as part of both MRID 44006001 and 44013302). These studies clearly show the relative stability of this transformation product and its

potential to leach. The Agency agrees with the Canadian conclusions that SDS-3701 has the potential to leach, to carryover in significant percentages, and to accumulate annually in soil.

Another class of metabolites (glutathione conjugates) was identified in an aerobic aquatic metabolism study. However, rapid production of these substances in appreciable quantity may have been an artifact of experimental procedures. None of these substances were reported in any other soil or sediment metabolism or field studies.

Other metabolites remain unidentified. At the end of all the submitted metabolism or dissipation studies, metabolites variously representing 30 to 75% of the total fungicide applied were sequestered as unidentified, recalcitrant soil or sediment bound substances (not considered biologically available) or as small amounts of polar (water soluble) substances. The manufacturing impurities hexachlorobenzene (HCB) and pentachlorobenzonitrile (PCBN) were also isolated in very low concentrations in some field studies.

Bioconcentration

Chlorothalonil did not appreciably bioconcentrate in oysters or bluegill sunfish. Metabolites (conjugate substances) concentrated about 2600 times in oysters and up to 500 times in fish viscera. These recalcitrant residues effectively entered the biochemical (carbon) pool of the organisms and were slow to be eliminated.

Fate and Transport

Hydrolysis: The hydrolysis data requirement is fulfilled. Chlorothalonil is stable at pH 5 and 7. At pH 9, the half-life is in the range of 40-60 days and may be concentration dependent. After 89 days roughly 20% of parent chlorothalonil from an initial 0.4 ppm concentration remained; roughly 50% was the degradate SDS-19221 and roughly 20% was the degradate SDS-3701. Analogous results were obtained during a 72-day period for an initial chlorothalonil concentration of about 1 ppm. There were no losses due to volatility.

The major pH 9 degradate above, SDS-19221, was also stable to hydrolysis at pH 5 and 7. At pH 9, approximately 90% of SDS-19221 had not degraded after 30 days. The 10% which did degrade was converted to SDS-3133 (2,4,5,6-tetrachloroisophthalamide). (MRID 0004539, Accession No. 258779)

Photolysis in Water: The data requirement for photolysis in water is fulfilled. Studies indicate that aqueous photolysis is not a major degradative pathway. A 1987 study (MRID 40183418) gave an estimated half-life of about 65 days when the artificial source exposure time of 118 hours and intensity were converted to 12-hour sunlight days (study duration equivalent to about 33 12-hour days of sunlight). At study end, about 80% of chlorothalonil remained. The major photolyte SDS-3701 was steadily increasing and had reached a concentration of about 10%. Minor amounts of unidentified products were extractable with organic solvents or remained in the

water phase. No volatilization of parent or degradation products occurred. (MRIDs 40183418, 00040540, 00087281)

Photolysis on Soil: The data requirement for photolysis on soil is fulfilled. Chlorothalonil and the metabolite SDS-3701 are both stable against soil photolysis. Each was tested on the same two soils (silt loam, silty clay loam). There were no soil-bound residues. Additional information indicated that chlorothalonil did not leach from the test soils, but that SDS-3701 did. No volatilization losses occurred. (MRIDs 00040543, 00143751, and 00156470).

Aerobic Soil Metabolism: The submitted study, taken in the context of other information, fulfills the data requirement. In this study, half-lives for four different soils were 10, 10, 15, and 40 days. After 60 days the metabolite SDS-3701 was present at up to 32% of the applied; the metabolite SDS-19221 was present at up to about 7% at both days 7 and 16 of the study. Water soluble residues comprising up to approximately 15% of the total were not identified. In sterilized soils half-lives were longer, ranging from about 20 to 200 days. The proportion of unextracted (bound) residues remaining after a single extraction with 4:1 acetone/0.3M HCl for 30 minutes increased over time in all cases, accounting for 40 to 75% of the dose by the end of the 90 day study. (MRID 00087351)

Anaerobic Aquatic Metabolism: The data requirement for anaerobic aquatic metabolism is fulfilled. Anaerobic half-lives of chlorothalonil (combined water and soil) in two different flooded soils were in the range of 5 to 15 days. The major metabolite SDS-3701 appeared to reach a broad maximum after 1 to 2 months and to remain at near constant levels of around 30 to 40% of the dose until the end of a 4-month study in a silt loam soil. Likewise, a plateau at 15 to 20% of the dose appeared during a 2-month study in a sandy loam soil. Other metabolites included the isomers SDS-47524/47523 at up to 9% combined, SDS-19221 at up to 7%, SDS-47525 at up to 4%, and SDS-46851 at up to 3%. Less than 0.1% of residues volatilized. Chlorothalonil, either insoluble or sorbed, was primarily associated with the soil, while metabolites were approximately in equal percentages in the soil and water phases. Unidentified soil bound residues constituted 30 to 40% of the total dose by the end of the studies. (MRID 00147975)

Aerobic Aquatic Metabolism: The Agency requires no further data on aerobic aquatic metabolism. Chlorothalonil undergoes relatively rapid metabolism under aerobic aquatic conditions. However, aerobic aquatic lifetimes and metabolites require special interpretation if they are to be used for specialized purposes. In the aerobic aquatic metabolism lab study which the registrant submitted (MRID 42226101), rates of reaction and identity of degradation products were dramatically different when compared to other environmental fate laboratory and field studies. These studies include aerobic soil metabolism, anaerobic aquatic metabolism and aged mobility. Initial chlorothalonil concentrations were effectively and surprisingly reduced to less than half within 2 hours under enhanced conditions in both salt and fresh water sediments by a process which was not first-order. Apparent "half-lives" increased steadily with time. Parent represented less than 1% of the applied by 30 days.

The differences between the findings of the aerobic aquatic metabolism study and the other environmental fate studies appear to result from nonstandard experimental conditions in the aerobic aquatic metabolism studies. The study was conducted with vigorous and continuous agitation (platform shaker at 100 rpm) and aeration, and high concentration of suspended sediment (100,000 ppm, screened to remove particles larger than 0.6 mm in diameter).

These conditions do not reliably reflect behavior in a quiescent body of water such as a lake or a pond modeled with 30 ppm of suspended sediment. Rather, the conditions of this study are similar to those used for shake-flask inherent biodegradability testing suitable for sewage treatment purposes. Rapid churning of large quantities of suspended sediment is ideal for sewage treatment, but would in general give higher rates of reaction than would be expected under natural conditions. Agitation and aeration could result in shorter half-lives.

Under these conditions, chlorothalonil at 25C and at an initial system concentration of about 0.6 ppm was quickly removed from solution in both salt and fresh water sediments (water:sediment ratio of about 9:1). The immediate ("zero time") removal of most of the parent (about 90 percent from salt solution, 75 percent from freshwater) was most likely due to sorption. Simple sorption coefficients derived from "zero time" concentrations would be, in standard units, about 100 for the salt water system and 25 for fresh water. These coefficients are consistent with those calculated from adsorption/desorption study results. The observed rapid metabolism most likely took place at the interface between sediment and water.

The major identified transformation products (metabolites) were sequestered in the sediment as complex, organically extractable glutathione[1] conjugates (or other sulfur species). These products were organically extractable from the sediment. None of these were identified in any other metabolism or field studies. It is plausible that production of these substances in appreciable quantity may have been an artifact of experimental procedures. Certain steps in the lab procedure called for the addition of up to 10% hydrochloric acid to the samples, with further concentration of the acid in subsequent steps. This harsh treatment is known to lyse cells of organisms present in the mixture, thus causing the release of cellular substances such as glutathione. These substances in above normal concentrations are then free to conjugate or otherwise react with chlorothalonil or its derivatives at rates higher than would occur in normal internal metabolism, and to compete with other chemical reactions previously observed. Even in the absence of hydrochloric acid, vigorous, sustained agitation of the sample mixture could cause the mechanical rupture of cells and the release of cellular substances.

In this study, SDS-67042, present up to 25 or 30% and SDS-67042 sulfoxide, present at around 15% were predominant. Other metabolites of this class were SDS-66432, SDS-66382,

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[1] Glutathione is a peptide (primary link in protein synthesis) which occurs widely in plant and animal tissues and plays an important role in biological oxidation-reduction processes and the activation of some enzymes. It contains one amino acid residue each of glutamic acid, cysteine, and glycine.

and SDS-13353. The non-conjugated product SDS-3701 (which is ubiquitous as a major metabolite in all other studies) comprised only up to 5 or 10% of the dose. Some of the conjugate substances reached a fairly constant level (a combined total of 40-60% of the applied) after 30 days, and appeared eventually to become sequestered primarily as irreversibly or permanently bound residues. Another large component of the dose, unidentified sediment bound residues, remained at a fairly constant level after about 6 to 12 hours and achieved concentrations of 20-35% after 30 days. Smaller amounts (9-14%) of unidentified polar materials were also formed.

The relatively high rates of metabolism observed in this study are supported in the outside literature. Davies (Davies, 1985a,b and 1988) found a range of half-lives of from about 4 to 150 hours in extensive laboratory experiments using both water and different substrates obtained from natural streams, different degrees of aeration, and cooler temperatures (5 to 15 C). Walker, *et al.* (Walker, 1988) at EPA laboratories compared the relative rates of degradation of 14 pesticides using a shake-flask test of inherent biodegradability. Under the conditions of his experiment, Walker determined a half-life of about 44 hours in an estuarine water/sediment system and of about 200 hours in filtered estuarine water at 25 C. Chlorothalonil was among those pesticides which degraded fastest. Degradates were not identified in these studies, except for glutathione conjugates in fish tissue.

Although Walker's water/sediment samples were vigorously shaken and had coarse sand removed by settling, the suspended sediment concentration of 500 ppm used was markedly less than the 100,000 ppm in the submitted study. Additionally, Walker employed hexane as the extractant, and acid was not used in the extraction procedures. Without agitation and with less sediment, it is reasonable to assume that the rate of metabolism would be slower and the corresponding half-life even longer than the 44 hours observed by Walker. When corrected for temperature, Davies' independent results for still stream water match Walker's 44 hours for water/sediment, but are much less than the more directly comparable 200 hours for Walker's filtered estuarine water. Based on available data, and depending on ambient strata and conditions, the Agency has determined effective degradation half-lives for chlorothalonil may range from two hours to 200 hours.

Mobility: The data requirements for mobility (batch equilibrium and aged column leaching) are fulfilled. Integrated mobility results from the batch equilibrium and aged column leaching studies are summarized as follows. Five degradates were identified and tested: SDS-46851, SDS-47525, SDS-3701, SDS-47523/47524, and SDS-19221. The first three of these were mobile and leached in all soils. In sand, parent chlorothalonil and the metabolite SDS-47523/47524 were moderately mobile to mobile and were detected in the leachate. They were only slightly mobile and did not appear in the leachate from the other representative soils. SDS-19221 was mobile in all soils and leached in all soils except a clay loam.

Lab batch equilibrium studies with four soils showed chlorothalonil to be only slightly mobile in silty clay loam, silt, and sandy loam and moderately mobile in sand. Freundlich K(ads) values were 26, 29, 20, and 3, respectively, but were only determined in the very narrow range of

0.1 to 0.5 ppm, rather than spanning several orders of magnitude in concentration, as required to establish a firm relationship. Exponents (1/n values) were sequentially 0.79, 0.83, 0.94 and 0.75. From corresponding percentages of soil organic matter of 3.2, 0.7, 3.2, and 0.6 yield, the reviewer calculated Freundlich KOC values of approximately 1400, 7000, 1100, and 900, respectively (based on the standard normalization: organic matter = 1.7 x organic carbon). From these results, it is apparent that sorption is not simple and that organic carbon alone does not account for the process. Desorption was less than 10% for all soils except the sand, where it varied from about 10 to 30%. (MRID 00115105)

Aged soil column studies (7-14 day aging) with four different soils were conducted. These soils were classified as sand, sandy loam, silt loam, and clay loam. Parent chlorothalonil and SDS 47523/47524 were detected in the sand leachate; they were slightly mobile in the other soils, but were not in their leachates. SDS-19221 was in the leachate from all soils except the clay loam, where it was mobile. The remaining metabolites leached from all soils. (MRID 00153730)

Accumulation: The data requirement for bioconcentration is fulfilled. In separate studies with bluegill sunfish and oysters, parent chlorothalonil did not bioconcentrate. For fish, Bioconcentration Factors (BCFs) are substantially less than 1000X, considered to be a threshold of concern--75X edible and 264X whole for bluegill, 9.4X edible and 16X whole for catfish--indicating that the bioaccumulation potential of chlorothalonil is low. A total residue BCF (consisting primarily of unidentified metabolites or conjugate substances) was about 500X for fish and 2600X in oysters, suggesting some potential for the bioaccumulation of chlorothalonil degradates in oysters. These recalcitrant residues effectively entered the biochemical (carbon) pool and were slow to be eliminated (MRIDs 00086620, 00029411, 0086630, 43070601). In general, these substances are thought to be biologically unavailable, but their long-term effects are not known. The literature supports these results in fish, and indicates the metabolic formation of glutathione conjugates.

Terrestrial Field Dissipation: Extensive data from field dissipation studies have been submitted for chlorothalonil, but historically none of these data have been fully satisfactory. By considering the most useful ancillary data and verifying consistency with other Guideline studies and outside sources of information, the Agency is able to satisfactorily assess terrestrial fate, and requires no more field data. Conclusions from the various sources are summarized below.

Submitted data show a range of initial field half-lives of 14 to 59 days. Compilations from other sources (Ware, 1992) show a wider span of from 4 to 90 days with a "selected" value of 30 days. Four field studies evaluated by the Environmental Protection Service of Canada (and submitted by the registrant as part of both MRID 44006001 and 44013302) provided similar but more comprehensive information on dissipation in two Canadian and two US soils. Overall, 10 to 60 days could be considered a reasonable range for half-lives for most uses of chlorothalonil.

Preliminary data from a groundwater monitoring study being conducted on peanuts in North Carolina (see Water Resources below) indicate a field dissipation half-life as long as 4 to 6

months.

Metabolites identified are SDS-3701, SDS-47523/47524 (isomers combined), SDS-19221, SDS-47525, and SDS-46851. Sampling methodology was generally insufficient to define the depth of leaching, but chlorothalonil residues were detected at least to 45 cm and SDS-3701 down to 135 cm in some studies. Manufacturing impurities hexachlorobenzene (HCB) and pentachlorobenzonitrile (PCBN) were also isolated in some studies.

Spray Drift: Drift data have not yet been submitted. The Agency believes that Droplet Size Spectrum (201-1) and Drift Field Evaluation (202-1) data are necessary to address ecotoxicological issues. GB Biosciences is a member of the Spray Drift Task Force and has the option to satisfy these requirements through the Spray Drift Task Force according to PR Notice 90-3.

Water Resources

Groundwater: The available information is inadequate to assess exposure to chlorothalonil and chlorothalonil degradates from ground water on a national level. However, sufficient information is available on local detections of chlorothalonil residues (mostly degradates) in groundwater to extrapolate some conclusions and generalizations. The data clearly show that at least under hydrogeologically vulnerable conditions, groundwater contamination by chlorothalonil degradates, most notably degradate SDS-46851, is likely to occur. (SDS-46851 has been determined to be non-toxic.) Limited occurrences of chlorothalonil parent at low concentrations ($\leq$1.1 µg/L) in groundwater have also been noted. Several of the parent chlorothalonil detections may have been due to contamination or faulty well construction. Detections of chlorothalonil degradates in groundwater were associated with potato and peanut use.

A number of chlorothalonil degradates have been identified in groundwater. Four of these degradates, although not chlorothalonil itself, were found in groundwater in Long Island, New York, and were attributed to potato use. The reported ground water metabolites are SDS-46851, SDS-47525, SDS-3701, and SDS-19221. They were measured at the highest combined concentration of approximately 16 ppb (µg/L) in New York. Parent chlorothalonil has been detected in Massachusetts, Florida, Maine, and California at levels typically below 1.0 µg/L. Several of these detections may be due to faulty well construction or contamination during well installation. Chlorothalonil parent (trace to 0.3 µg/L) and the degradates SDS-46851 (trace to 10.1 µg/L) and SDS-47525 (0.2 µg/L) have recently been detected by the registrant in a ground-water monitoring study currently being conducted in North Carolina, on peanuts. The results of the North Carolina prospective monitoring study are summarized separately at the end of this section; the other groundwater monitoring studies are described below and are summarized in Table 53.

Table 53. Summary of Wells Sampled, Wells with Detections, and Concentration Ranges of Chlorothalonil and Degradates from completed Groundwater Monitoring Studies

Source	MDL[1] (µg/L)	Parent			Degradates		
		# Wells Sampled	# Wells Detects	Range (µg/L)	Sampled	Detects	Range (µg/L)
CA	0.10	614	1	0.8-1.1	NA[2]	NA	-
FL		25	1	0.14	NA	NA	-
MA	0.015	19	2	0.22-0.38	NA	NA	-
ME			1	trace	NA	NA	-
NY	2.0	24	0	ND[3]	24	8	1.1-12.6
NPS[4]	0.060	1347	0	ND	NA	NA	-

[1] Method Detection Limit
[2] Not Analyzed for
[3] Not Detected
[4] National Survey of Pesticides in Drinking Water Wells

Chlorothalonil residues were detected (0.22 µg/L, 0.38 µg/L) in two shallow ground-water wells by the Cape Cod Golf Course Monitoring Project (Eichner and Carbonell, 1990). The detection limit was reported as 0.015 µg/L. The authors postulate that the detections may be due to contamination resulting from well installation.

Metabolites (SDS-3701, SDS-19221, SDS-46851, and SDS-47525) of chlorothalonil (SDS-2787) were detected in 16.4 percent (11 of 67 samples) of samples in Suffolk County, New York (Harris and Andreoli, 1988). The concentration of degradates in the New York study ranged from 1.1 to 12.6 µg/L for individual breakdown products. The highest combined concentration of chlorothalonil and degradation products was 16.3 µg/L. Contaminants were primarily found in shallow private wells, but also were detected in a 97-foot deep public water supply well. The detection limit was not reported. Wells sampled, when the depth was known, ranged in depth from 5 to 100 feet. The source of the chlorothalonil was agricultural use on potatoes. The wells sampled were located <10 to 2500 ft from the potato fields.

An earlier, EPA review (USEPA, 1984) appears to contain a more complete assessment of the data later summarized and reported by Harris and Andreoli (1988), and described above. This review indicates that 24 wells were sampled in Suffolk County, Long Island, New York from September 14, 1981 to October 22, 1981 (R.R. Griffiths. Report Doc. # 561-3AS-82-0065-001 DS2787. Acc. # 253315). From 23 of the 24 wells, five separate analyses were conducted for the analytes SDS-3701, SDS-19221, SDS-46851, SDS-47524, and SDS-47525. The parent chlorothalonil was also analyzed for in all 24 wells. The parent and degradate SDS-47524 were not detected in any of the samples. Degradates were identified in 8 of the 24 wells, and in 11 of 139 samples. The detections were as follows: SDS-3701 (3.6 µg/L), SDS-19221 (2.8 µg/L), SDS-46851 (5.9, 2.0, 7.9, 12.6, 2.0, 3.9, and 8.5 µg/L), and SDS-47525 (2.0, 2.0, and 5.0 µg/L).

The reported quantification limit was 2.0 µg/L.

The Pesticide in Ground Water Database (USEPA, 1991; 1992) also reported detections of chlorothalonil residues in ground water in 1 of 25 wells in Florida (0.14 µg/L), Maine (trace) and 1 of 614 wells in Humbolt County, California (0.8 to 1.1 µg/L) with a detection limit of 0.1 µg/L. The chlorothalonil detections in California were attributed to faulty well construction.

The National Survey of Pesticides in Drinking Water Wells (NPS) conducted by the USEPA (1990) collected 1347 well water samples from community and rural domestic drinking water wells. The survey was designed to obtain results that would be statistically representative of 10.5 million rural domestic wells and more than 94,600 wells in 38,300 community water systems. The NPS (USEPA, 1990) did not detect parent chlorothalonil in any well water samples with a minimum reporting limit for parent chlorothalonil of 0.060 µg/L. The lack of detections for chlorothalonil in this study is not entirely unexpected because chlorothalonil parent is not very persistent and has limited mobility. The inclusion of chlorothalonil degradates (especially SDS-46851) would have increased the probability of detections. The likelihood of any of the limited number of wells sampled in the NPS being located in an area where chlorothalonil was used was not considered (may not be known).

Prospective Groundwater Monitoring Study (166-1): GB Biosciences began a small-scale prospective groundwater monitoring study in North Carolina on peanuts in 1994. The study, which was conducted according to an Agency-approved protocol, has been completed, although the final report has not yet been reviewed. The field portion of the study was terminated in the summer of 1997. The registrant submitted several interim reports (MRID 43642101, D125423; MRID 43959401, D224906; and MRID 44291101, D237337). Preliminary review indicates that the North Carolina site is not as vulnerable as the Long Island, New York site, but still hydrologically vulnerable. Water table depths over time ranged between ~23 to ~28 feet. Bromide tracer movement shows that recharge has occurred at the site. An April 1997 Interim Report indicated frequent detections of the degradate SDS-46851 in 8 of 9 monitoring wells during a 24-month period, and a very limited number of detections of chlorothalonil parent and degradate SDS-47525. Reported concentrations of SDS-46851 ranged from <0.1 µg/L to 10.1 µg/L and SDS-47525 from <0.2 µg/L to 0.20 µg/L. Chlorothalonil ranged from trace levels to 0.3 µg/L and occurred only during three sampling intervals (a two-month period prior to the 7th and 8th applications through sampling one month after the final application.) These chlorothalonil detections may be due to movement around well casing or other preferential flow pathways, as these detections sometimes occurred before the arrival of the bromicide tracer. The maximum SDS-46851 concentration (10.1 µg/L) for the NC study is of the same order of magnitude as the New York data (12.6 µg/L). The New York sampling is the only other groundwater sampling analyzed for this metabolite.

Although conclusions concerning the prospective groundwater monitoring study are not yet final, several conclusions concerning the potential of chlorothalonil and its degradates to contaminate ground water can be made. It appears that parent chlorothalonil has limited potential

to reach groundwater, even under hydrologically vulnerable conditions. Where there have been detections of chlorothalonil, concentrations have been low (generally < 1.0 µg/L) and often attributed to atypical sources. This also appears to be generally true for degradates SDS-3701 and SDS-47525. The degradate SDS-46851, which is nontoxic, however, appears likely to contaminate ground water at concentrations that have been as high as 10.1 µg/L in NC and 12.6 µg/L under vulnerable conditions. Since the degradates have only been included for analysis under conditions in vulnerable areas (NC, NY), concentrations at less vulnerable areas are not known, however, concentrations are generally lower at less vulnerable sites.

Surface Water: Chlorothalonil can contaminate surface water at application via spray drift or after application through runoff and erosion. Substantial fractions of applied chlorothalonil could be available for runoff for several weeks to months post-application (See Aerobic Soil Metabolism, Terrestrial Field Dissipation above). The intermediate soil/water partitioning of chlorothalonil indicates that chlorothalonil runoff will probably be via both dissolution in runoff water and adsorption to eroding soil in typical cases where runoff volume greatly exceeds sediment yield (see Mobility above).

The resistance of chlorothalonil to hydrolysis, direct aqueous photolysis, and volatilization (Henry's Law constant = 2.6 X 10^{-7} atm*m^3/mol), coupled with only an intermediate susceptibility to degradation in soil under aerobic conditions indicate that chlorothalonil may be somewhat persistent in the water columns of some aqueous systems that have low microbiological activities and relatively long hydrological residence times. Aerobic aquatic metabolism half-lives from around two hours to 6-8 days have been reported under various conditions. The two hour half-life is associated with experimental conditions which correspond more closely to aerated and agitated sewage treatment (shake-flask test for inherent biodegradability) than to natural systems. However, the Agency has included the 2-hour half-life at the low end of aerobic aquatic half-lives for modeling purposes. Based on anaerobic aquatic metabolism half-lives of 5-15 days, chlorothalonil would also be susceptible to degradation in anaerobic sediments.

The intermediate soil/water partitioning of chlorothalonil indicates that its concentration in suspended and bottom sediment will be substantially greater than its concentration in water. However, in typical cases where water volume greatly exceeds suspended and available bottom sediment, a substantial percentage of chlorothalonil within an aquatic system will also be dissolved in the water column in addition to being adsorbed to suspended and bottom sediment. Bioconcentration Factors (BCFs) substantially less than 1000X (75X edible and 264X whole for bluegill; 9.4X edible and 16X whole for catfish) indicate that the bioaccumulation potential of chlorothalonil is low. A total residue (consisting primarily of degradates) BCF of 2600X in oysters suggests some potential for the bioaccumulation of chlorothalonil degradates in oysters.

The major degradate of chlorothalonil in the soil under aerobic conditions is SDS-3701. SDS-3701 may be more persistent and mobile than chlorothalonil. Consequently, substantial amounts of SDS-3701 may be available for runoff for longer periods than chlorothalonil, and SDS-3701 may be more persistent in water/sediment systems than chlorothalonil. The greater

mobility of SDS-3701 suggests that it exhibits lower soil/water partitioning than chlorothalonil--that is, that SDS-3701 would be associated more with water than soil relative to the parent. Therefore, the ratio of SDS-3701 runoff loss via dissolution in runoff to runoff loss via adsorption to eroding soil for SDS-3701 may be substantially greater than for chlorothalonil. In addition, the ratios of concentrations dissolved in the water column to concentrations adsorbed to suspended and bottom sediment may be substantially higher for SDS-3701 than for chlorothalonil. SDS-19221, SDS-46851 and SDS-47525 have also been detected in groundwater and have comparable or greater persistence and mobility than parent chlorothalonil.

An ancillary 1982 aquatic field surface water study reviewed by the Agency for a second time in 1994 (MRIDs 00137146, 00127862) did not represent a reasonable high runoff scenario and suffered several other major deficiencies. However, in concert with established lab soil mobility studies, it does indicate that potential exists for runoff of parent and metabolites in varying proportions in the water and soil phases when favorable runoff conditions arise shortly after application.

The screening model GENEEC was used to generate Tier 1 EECs for chlorothalonil (using a generic high runoff site over 56 days) in a 1ha surface area, 2m deep pond draining 10ha turf plots. The Agency estimated maximum peak, 4-day average, 21-day and 56-day average concentrations. The GENEEC EECs for turf, the assumed application rates/intervals, and assumed environmental fate input are listed in Table 63. The EECs were generated for a range of assumed aerobic aquatic half-lives (2 hours and 44 hours). The half-lives were adjusted, for modeling, to a lower temperature (25^{o}C to 20^{o}C) and the 2-hour value was also multiplied by 3, in accordance with Agency convention, to account for the uncertainty associated with a single value estimate. The Agency no longer generates Tier 2 EECs for turf because of the difficulties and uncertainties associated with modeling turf.

PRZM 2.3/EXAMS 2.94 was used to generate Tier 2 (single site over multiple years) EECs for chlorothalonil in a 1 ha surface area, 2 m deep pond draining 10 ha cucurbit, peanut, potato, and tomato fields. Each site was simulated over 36 years. One-in-10 year maximum peak, 4-day average, 21-day average, 60-day average and 90-day average concentrations were estimated. The PRZM/EXAMS EECs are listed in Table 63 along with the assumed application rates/intervals, and assumed environmental fate inputs. As was the case for the GENEEC EECs, the PRZM/EXAMS EECs were generated for a range of assumed aerobic aquatic half-lives (2 hours and 44 hours). As previously stated, real-life localized, ambient conditions and substrates could extend the range of actual half-lives.

The GENEEC and PRZM/EXAMS EECs are generated for high exposure agricultural scenarios and represent one in ten year EECs in a stagnant pond with no outlet that receives pesticide loading from an adjacent 100% cropped, 100% treated field. As such, the computer generated EECs represent conservative screening levels for ponds, lakes, and flowing water.

The South Florida Water Management District (SFWMD; Miles and Pfeuffer 1994)

summarized chlorothalonil detections in samples collected every two to three months from 27 surface water sites from November 1988 through November 1993. Approximately 810 samples (30 sampling intervals X 27 sites sampled/interval) were collected from the 27 sites from November 1988 through November 1993. Chlorothalonil was detected in 25 samples at concentrations ranging from 0.003 to 0.035 μg/L. Detection limits ranged from 0.001 to 0.006 μg/L, with a quantification limit of approximately 0.2 μg/L. Six of the samples had concentrations $\geq$ 0.010 μg/L. There was no testing for degradates, which, based on groundwater and environmental fate data, could be prevalent at considerably higher concentrations than parent.

As part of the National Water Quality Assessment (NAWQA) program, the USGS collected ground and surface water samples from 20 study units during 1993-1995 and analyzed them for pesticides including chlorothalonil. Samples were collected at fixed intervals once every week or every two weeks during use seasons and less frequently (generally monthly) at other times. Additional samples were also collected during high flow. Although no detailed results are currently available to the Agency, the USGS did provide a summary for all 20 study units combined (David J. Wangsness of USGS - personal communication). For surface water, chlorothalonil was detected in only 6 of 1850 samples above a detection limit of 0.035 µg/L ranging to a maximum concentration of 0.68 µg/L.

Of the 20 study units sampled, 17 overlapped areas of chlorothalonil use. These include the Appalachicola - Chattahoochee River Basin which overlaps heavy chlorothalonil use on peanuts along the southern Georgia/Alabama border. These data represent flowing water and dilution effects in actual watersheds. Again, there was no testing for degradates.

The NAWQA data demonstrate the large effects of dilution from untreated portions of the watersheds. Since the concentrations were measured in samples collected from study units that generally overlapped areas of chlorothalonil use, including intensive use on peanuts in the southeast, they can probably be used for estimating actual typical risks in the flowing water portions of chlorothalonil treated watersheds. However, since the NAWQA study is not a chlorothalonil specific study, sampling sites do not necessarily represent reasonable worst case scenarios immediately downstream of heavily treated areas, especially for flowing waters.

3. Exposure and Risk Assessment

Risk characterization integrates the results of the exposure and ecotoxicity data to evaluate the likelihood of adverse ecological effects. The means of this integration is called the quotient method. Risk quotients (RQs) are calculated by dividing exposure estimates by acute and chronic ecotoxicity values.

RQ = EXPOSURE/TOXICITY

RQs are then compared to OPP's levels of concern (LOCs). These LOCs are used to analyze potential risk to nontarget organisms and the need to consider regulatory action. RQs

which exceed LOCs indicate that a pesticide used as directed has the potential to cause unacceptable risk to nontarget organisms. LOCs currently address the following risk presumption categories:

- Acute high -- potential for acute risk is high; regulatory action may be warranted in addition to restricted use classification

- Acute restricted use -- the potential for acute risk is high, but may be mitigated through restricted use classification

- Acute endangered species - endangered species may be adversely affected

- Chronic risk - the potential for chronic risk is high; regulatory action may be warranted.

Currently, the Agency does not perform assessments for chronic risk to plants, acute or chronic risks to nontarget insects, or chronic risk from granular/bait formulations to birds or mammals.

The ecotoxicity test values (i.e., measurement endpoints) used in the acute and chronic risk quotients are derived from required studies. Examples of ecotoxicity values derived from short-term laboratory studies that assess acute effects are: LC_{50}s (for fish and birds), LD_{50}s (for birds and mammals), EC_{50}s (for aquatic plants and aquatic invertebrates), and EC_{25}s (for terrestrial plants). Examples of toxicity test effect levels derived from the results of long-term laboratory studies that assess chronic effects are LOECs (for birds, fish, and aquatic invertebrates), NOECs (for birds, fish and aquatic invertebrates), and MATCs (for fish and aquatic invertebrates). For birds and mammals, the NOEC generally is used as the ecotoxicity test value in assessing chronic effects, although other values may be used when justified. Generally, the MATC (defined as the geometric mean of the NOEC and LOEC) is used as the ecotoxicity test value in assessing chronic effects to fish and aquatic invertebrates. However, the NOEC is used if the measurement endpoint is production of offspring or survival.

Risk presumptions and the corresponding RQs and LOCs are found in Tables 54-56.

Table 54. Risk Presumptions for Terrestrial Animals (Birds and Wild Mammals)

Risk Presumption	RQ	LOC
Acute High Risk	EEC[1]/LC_{50} or EEC[2]/LD_{50}[3]	0.5
Acute Restricted Use	EEC/LC_{50} or EEC/LD_{50}	0.2
Acute Endangered Species	EEC/LC_{50} or EEC/LD_{50}	0.1
Chronic Risk	EEC/NOEC	1

[1] Estimated Environmental Concentration (in ppm) on avian/mammalian food items
[2] mg ai/ft^2
[3] mg ai consumed/day

Table 55. Risk Presumptions for Aquatic Animals (Fish and Invertebrates)

Risk Presumption	RQ	LOC
Acute High Risk	EEC[1]/LC_{50} or EC_{50}	0.5
Acute Restricted Use	EEC/LC_{50} or EC_{50}	0.1
Acute Endangered Species	EEC/LC_{50} or EC_{50}	0.05
Chronic Risk	EEC/MATC or NOEC	1

[1] EEC = ppm or ppb in water

Table 56. Risk Presumptions for Plants (Terrestrial and Aquatic)

Risk Presumption	RQ	LOC
Terrestrial Plants		
Acute High Risk	EEC[1]/EC_{25}	1
Acute Endangered Species	EEC/EC_{05} or NOEC	1
Aquatic Plants		
Acute High Risk	EEC[2]/EC_{50}	1
Acute Endangered Species	EEC/EC_{05} or NOEC	1

[1] EEC = lbs ai/A
[2] EEC = ppm or ppb in water

Exposure and Risk to Nontarget Terrestrial Animals from Chlorothalonil

Residues found on dietary food items following chlorothalonil application may be compared to LC_{50} and NOEL values to predict acute and chronic risk, respectively. The maximum concentrations of residues of chlorothalonil which may be expected to occur on selected avian or mammalian dietary food items following a single 1.0 lb foliar application rate are provided in the table below. Residues per lb ai applied for four food types are developed from Hoerger and Kenaga (1972) and Kenaga (1973), with modifications suggested by Fletcher, *et al.* (1994); the "broadleaf plants" category includes forage and is considered applicable to small insects while the "fruits" category includes seeds and is considered applicable to large insects.

Table 57. Estimated Environmental Concentrations on Avian and Mammalian Food Items (ppm) Following a Single Application at 1 lb ai/A)

Food Items	EEC (ppm)--Predicted Maximum Residue[1]	EEC (ppm)--Predicted Mean Residue[1]
Short grass	240	85
Tall grass	110	36
Broadleaf/forage plants & small insects	135	45
Fruits, pods, seeds, & large insects	15	7

[1] Predicted maximum and mean residues are for a 1 lb ai/a application rate and are based on Hoerger and Kenaga (1972) as modified by Fletcher *et al.* (1994).

Fletcher residue values adjusted for the application rate are used to estimate the amount of residue added to various environmental media (e.g., short grass, insects) at each application. The FATE model is then used to estimate degradation between applications and both maximum and time-averaged residue concentrations over the multiple applications. Since foliar half-life data are not available for chlorothalonil, a terrestrial field dissipation half-life in soil was used. A half-life of 30 days was selected by the Agency, based on terrestrial field studies cited in Ware 1992. In some instances, because of the range of studies available, a lower-end value of 7 days was also utilized. These half-lives are in contrast to those used to estimate human health risk from post-application exposure. In general, those estimates rely on shorter half-lives which were derived from dislodgeable foliar residues. In addition to dislodgeable residues, residues which are available to wildlife in feed items may include those that are bound to the surface (not dislodgeable) or those that are found within the feed items. It is logical that such residues may be more persistent than those that are more readily dislodged from plant surfaces, and the experimental half-life data support this logic. Both maximum and time-averaged EEC's were based on maximum Fletcher residue values.

The Fletcher values and the following two assumptions form the basis for estimating residues to which terrestrial organisms may be exposed:

Use sites, excluding turf and orchards, are assumed not to contain significant amounts of short grass or long grass in the field. For these sites, the only avian food items likely to receive a *direct* application are insects, the broadleaf vegetation of the treated crop and any fruit of the crop. However, estimates of chlorothalonil residues on short grass in agricultural fields will be included in the risk tables to account for the potential additional impact from other routes of exposure--inhalation, dermal and drinking water--which are not quantified in this analysis.

To be consistent with the assumption in aquatic exposure models for aerial application, only 5% of the application rate is assumed to drift to the edge of the field where it would contaminate vegetation (broadleaf vegetation and long grass). Ground application (not mist blowers) is assumed to result in 1% or less drift outside the field or the immediate border area. Therefore, the risk to birds or mammals feeding beyond the field border would be 5% or 1% of what would be the risk if feeding in the field. Although the border area immediately adjacent to the treated field may contain higher residues than the area beyond the field border they would not be higher than within the field.

Acute Risks to Birds from Chlorothalonil: No mortality of birds occurred in any of the acute and subacute tests with chlorothalonil. There was no mortality at 10,000 ppm for bobwhite quail (MRID 00030388) and mallards (MRID 00030389). Another study showed no mortality at 21,500 ppm for mallards (MRID 00039146). These data by themselves suggest minimal potential for acute risk to birds, but chlorothalonil is used at relatively high rates and is often applied several times per season. For example, on cucurbits, single applications of chlorothalonil are applied at up to 6.25 lbs ai/acre. When multiple applications are made, we have assumed that chlorothalonil will degrade between treatments with a foliar half-life of 30 days. On cucurbits and tomatoes, chlorothalonil is applied up to eight times at 2.25 lb ai/acre, and on turf, it is applied two or three times at up to 16.5 lb ai/acre or up to 10 times at 8.25 lb ai/acre. If these rates were applied to short grass, the EEC would be 1,500 ppm for cucurbits, 2,627 ppm for tomatoes, and 10,631 ppm and 6,883 ppm for turf. Most of these levels do not exceed the concentrations at which no mortality occurred. The highest EEC, for turf (10,630 ppm), barely exceeds the bobwhite quail 10,000 ppm no mortality level and is well below the mallard no mortality level of 21,500 ppm. Based on this analysis, it is likely that all uses of chlorothalonil represent minimal acute risk to birds, including endangered species.

Chronic Risk to Birds from Chlorothalonil: If the maximum exposure short grass levels presented above are used with the avian reproductive NOEL of 1,000 ppm to calculate chronic risk quotients, the LOC would be exceeded for most use sites. However, except for turf, most use sites would not have an abundance of short grass in the treatment area, although there may be a greater abundance immediately adjacent to the treated field.

The following table provides some specific EEC's and chronic risk quotients for food items likely to be found in sites where a majority (>80%) of chlorothalonil is used. The table shows chronic risk quotients calculated based on the average residues on food items. Average residues result from the pesticide being applied repeatedly, degrading over the course of time from the first application to one "between-treatment" interval beyond the last application. Note that for turf, exposure values were calculated using both 7 and 30 day half-life values in order to consider the effect mowing may have on residue accumulation in grass. The 7-day half-life parameter was also used to demonstrate whether the risk from high rates would be drastically altered when using a shorter half-life. A range of residue and risk values are calculated for turf and cherries (stone fruits) using insects and the 7-day half-life, and short grass with the 30-day half-life as the lower and upper bounds, respectively. Furthermore, the inclusion of short grass exposure and risk values for the non-turf sites serves to offset potential additional chronic risks from multiple routes of exposure not directly accounted for in our analysis (e.g., dermal, inhalation, drinking water).

Table 58. Avian Chronic Risk Quotients for Multiple Applications of Chlorothalonil Products (Broadcast), Based on a Bobwhite NOEC of 1,000 ppm and Average Residues

Site (Pest or Region)	Application Rate, lbs ai/A (# Applicat'ns; Interval, days)	Food Items[1]	Average EEC[2] (ppm)	Chronic RQ (EEC/NOEC)
Cucurbits (bellyrot)	6.25 (1;-)[3]	Insects	718	0.72
		Short grass	1,276	1.27
Cucurbits (regular)	2.25 (8;7)[3]	Insects	925	0.93
		Short grass	1,644	1.64
	1.75 (4;7)[4]	Insects	480	0.48
		Short grass	853	0.85
Stone Fruits (Cherries)	4.1 (4;10)[3]	Insects	497 (7 day)	0.50
		Short grass	1,820	1.82
Peanuts (SE US)	1.125 (9;10)[3]	Insects	418	0.42
		Short grass	743	0.74
Potatoes	1.125 (10;7)[3]	Insects	659	0.66
		Short grass	1,172	1.17
Tomatoes (Delmarva)	2.25 (8;7)[3]	Insects	925	0.93
		Short grass	1,644	1.64
Turf (Brown patch)	16.5 (3;5)[3]	Insects	2,816 (7d)	2.82
		Short grass	7,183	7.18
	8.25 (10;14)[4]	Insects	812 (7 day)	0.81
		Short grass	4,637	4.63
Turf (Dollar spot)	8.25 (3;7)[3]	Short grass	3,390	3.39
	4.0 (10;10)[4]	Insects	536 (7 day)	0.54
		Short grass	2752	2.75
Turf (Snow mold)	22.7 (1;-)[4]	Insects	986 (7 day)	0.99
		Short grass	3,883	3.88
	11.7 (3;30)	Insects	516 (7 day)	0.52
		Short grass	2,812	2.81
	22.7 (2;30)[3]	Insects	993 (7 day)	0.99
		Short grass	4,881	4.88

1. Insects are estimated to have the same residue concentration as broadleaves.
2. Assumes degradation using FATE program and 30-day aerobic soil half-life, unless specified as 7-day. Average residues calculated during time from first application to one interval period beyond last application.
3. Maximum proposed by GB Biosciences at time of analysis.
4. Typical application rate.

Acute Risks to Mammals: Chlorothalonil is considered to be "practically non-toxic" for acute effects to mammals, based on an available rat LD_{50} of >10,000 mg/kg (MRID 00094940). An LD_{50} may be used to estimate 1-day LC_{50}s for mammals based on the amount of food a mammal eats relative to its body weight.

$$\text{1-day } LC_{50} \text{ (ppm)} = \frac{LD_{50} \text{ (mg/kg) X body weight (g)}}{\text{food consumption (g)}}$$

Some small mammals consume almost 95% of their body weight per day. For them, an LD_{50} of 10,000 mg/kg may approach a 1-day LC_{50} of 10,000 ppm. For mammals that consume a lower proportion of their body weight per day, the calculated 1-day LC_{50} would be even higher. Note that since the LD_{50} is >10,000 mg/kg and no mortality occurred at this level, the calculated LC_{50} value would also be >10,000 ppm and it is assumed that no mortality would occur at that level. As was previously discussed, the highest estimated residues (10,631 ppm) for all sites would occur on turf grass following 3 applications at 16.5 lbs ai/A. Since this concentration is only slightly higher than what is probably a no mortality level, chlorothalonil appears to be of minimal risk to endangered and non endangered small mammals on an acute basis for all uses (turf, orchard, and other crops).

Chronic Risks to Mammals: The chlorothalonil chronic NOEL for mammals is 2,000 ppm, based on a rat developmental study (Accession# 00130733). This level is compared in the table below with average residues calculated on the food items of mammals within and immediately around treatment areas.

Table 59. Mammalian Chronic Risk Quotients for Multiple Applications of Chlorothalonil Products (Broadcast) Based on a rat NOEL of 2,000 ppm in a Developmental Study.

Site (Pest or Region)	Application Rate, lbs ai/A (# Applicat'ns; Interval, days)	Food Items[1]	Average EEC[2] (ppm)	Chronic RQ (EEC/NOEC)
Cucurbits (bellyrot)	6.25 (1;-)[3]	Insects	718	0.36
		Short grass	1,276	0.64
Cucurbits (regular)	2.25 (8;7)[3]	Insects	925	0.46
		Short grass	1,644	0.82
	1.75 (4;7)[4]	Insects	480	0.24
		Short grass	853	0.48
Stone Fruits (Cherries)	4.1 (4;10)[3]	Insects	497 (7 day)	0.24
		Short grass	1,820	0.91
Peanuts (SE US)	1.125 (9;10)[3]	Insects	418	0.21
		Short grass	743	0.37
Potatoes	1.125 (10;7)[3]	Insects	659	0.33
		Short grass	1,172	0.59
Tomatoes (Delmarva)	2.25 (8;7)[3]	Insects	925	0.47
		Short grass	1,644	0.82
Turf (Brown patch)	16.5 (3;5)[3]	Insects	2,816 (7 day)	1.41
		Short grass	7,183	3.59
	8.25 (10;14)[4]	Insects	812 (7 day)	0.41
		Short grass	4,637	2.32
Turf (Dollar spot)	8.25 (3;7)[3]	Short grass	3,390	1.69
	4.0 (10;10)[4]	Insects	536 (7 day)	0.22
		Short grass	2752	1.37
Turf (Snow mold)	22.7 (1;-)[4]	Insects	986 (7 day)	0.49
		Short grass	3,883	1.94
	11.7 (3;30)	Insects	516 (7 day)	0.25
		Short grass	2,812	1.40
	22.7 (2;30)[3]	Insects	993 (7 day)	0.50
		Short grass	4,881	2.44

1. Insects are estimated to have the same residue concentration as broadleaves.
2. Assumes degradation using FATE program and 30-day aerobic soil half-life, unless specified as 7-day. Average residues calculated during time from first application to one interval period beyond last application.
3. Maximum proposed by GB Biosciences at time of analysis.
4. Typical application rate.

For multiple broadcast applications of chlorothalonil and based on average residues, the mammalian chronic level of concern of 1 is exceeded for applications to turf and orchards (short grass food source). Depending upon the half-life (7 vs 30 day) the chronic risk quotient ranges from approximately 0.2 (insects) to 2.3 (short grass) for applications from 4 to 8.25 lb ai/A. Chronic risk from higher rates, especially those on turf, exceed the LOC regardless of the half-life utilized.

Exposure and Risk to Terrestrial Animals--SDS-3701

A primary degradate of chlorothalonil, SDS-3701, is more toxic to mammals and birds than parent chlorothalonil.

Table 60. SDS-3701 Toxicological /Summary for Terrestrial Animals

Chemical	Acute Toxicity			Chronic NOELs	
	Avian LD_{50} (mg/kg)	Avian LC_{50} (ppm)	Mammalian LD50 (mg/kg)	Birds (ppm)	Mammals (ppm)
Chlorothalonil	>4640	>10,000	>10,000	1,000	2,000
SDS-3701	158	1,746	242	50	33

Because SDS-3701 is more toxic than parent chlorothalonil, it is important to discuss its risk potential.

There are insufficient data to characterize with certainty how much SDS-3701 will form on avian and mammalian food items. Most of the available residue studies were designed to measure the amount of SDS-3701 that is taken up by crops and how much accumulates in vegetable items associated with human consumption such as beans and fruits. These studies typically show very small amounts of SDS-3701 occurring in crops; much less than 1 ppm. Residues of less than 1 ppm would be of minimal concern for acute or chronic effects to birds or mammals. Unfortunately, most of these studies do not provide a dependable basis for estimating how much SDS-3701 will form on avian and mammalian food items in the days immediately following treatment with chlorothalonil.

Several studies provide some indication as to how much SDS-3701 will be present on/in avian and mammalian food items (short grass, leaves, seeds and insects). These studies are on peanut hay, turf, and grass grown for seed.

Peanut Hay Study: Peanut hay can serve as a surrogate for foliage that small herbivores might consume. The residue study on peanut hay (MRID 43843601) suggests an inverse correlation between the residue levels of parent chlorothalonil and the percent of SDS-3701 that forms. The residues of SDS-3701 that formed ranged from 2.6% to 24% of parent chlorothalonil. When the actual residue level of parent chlorothalonil was about 45 ppm, SDS-3701 residues were about 1

ppm, or about 2.6% of the parent. When the actual chlorothalonil residues were about 1.7 ppm, SDS-3701 residues were 0.4 ppm or about 24%.

The peanut hay was sampled at six different sites at various times ranging from 2 to 6 weeks after the last application. In the process of making hay, the peanut plants (vines) were dried for several days to a week, then raked and baled. In this process, much of the foliage was lost, so that most of the mass of the bale is vine stem. Therefore, because of the time delay (with associated dissipation) and loss of exposed plant mass, it cannot be concluded that SDS-3701 would not occur at greater than 1 ppm on other treated vegetation.

Turf (Golf Green) Studies: At two study sites, residues of SDS-3701 were measured in turf clippings each day for 14 days while chlorothalonil was being applied at approximately 7-day intervals (MRIDs 422220-01, -02, and -03). Application rates were 5.6 to 10.6 lbs ai/acre. Residues of SDS-3701 never exceeded 1 ppm in the turf clippings treated at 5.6 lbs ai/acre and never exceeded 7 ppm in turf clippings that had been treated at 10.6 lbs ai/acre.

The grass was treated, mowed, and sampled daily, so that a fraction of the parent and degradates that were on the grass was discarded each day as the grass was cut and removed. Subsequent samples in the form of clippings would include fresh growth that diluted the concentration of both parent and degradates. This would tend to reduce the residues more than if the grass was allowed to grow, and all the parent and degradates allowed to remain for sampling. However, these studies do suggest that at least on turf that is mowed frequently, the residues of SDS-3701 do not accumulate above 7 ppm.

Because the application rates were high, and the vegetation treated and sampled was short grass on a putting green, this study represents a "high exposure" scenario relative to other chlorothalonil uses. High exposure is also evidenced by the residues of chlorothalonil during the study, which were in the thousands of ppm. Even under these high use conditions, the actual residues of SDS-3701 did not exceed 7 ppm.

Grass grown for seed: Another study (MRID 42875926) measured the residues of chlorothalonil and SDS-3701 in grass seed, seed screenings and straw. Samples were collected 37 days after the last aerial application at 1.5 lb ai/acre. While parent residues on seed and straw ranged from 30 ppm to 54 ppm, residues of SDS-3701 never exceeded 1 ppm. The difficulty in interpreting this study stems from the fact that samples were collected more than a month after the last application. It is not known what the levels of parent and degradate would have been in the interim.

Based on residues alone: While SDS-3701 is more toxic to birds and mammals than parent chlorothalonil on both an acute and chronic basis, residues less than 33 ppm SDS-3701 would not present either an acute or chronic risk. On the basis of measured residues alone, which never exceeded 7 ppm, it could be concluded that exposure from SDS-3701 represents little or no acute or chronic risk to birds or mammals. Since SDS-3701 reached a maximum of 24% of the total

measured residues in peanut hay, it is conceivable that under different conditions, residues of SDS-3701 could reach higher levels. Because of the uncertainty about what those levels may be, the degree of risk is unknown.

Based on percentage SDS-3701 formed: As indicated in the discussion above, there is no firm basis for estimating the residues of SDS-3701 on wildlife food sources. Estimated ranges for residues of SDS-3701 on turf, orchards, and nonorchard crops, using 10% as a relatively conservative upper limit of how much SDS-3701 forms relative to parent chlorothalonil, are found in Table 61.

Table 61. Estimates of SDS-3701 Residues on Terrestrial Food Items (ppm)

	Turf/Orchard		Non-orchard	
	Insects	Short Grass	Insects/ Broadleaf	Short Grass
Maximum (ppm)	86-572*	152-1016	24-148	43-262
Average (ppm)	53-426	95-757	14-92	25-164

* Lower numbers represent lowest application rate and shorter half-life (7 days); higher numbers represent highest application rate and longer half-life (30 days).

Estimations of acute and chronic risk can be made by comparing maximum EECs to acute toxicity values and average EECs to chronic values. Birds would be considered at high acute risk (LC_{50} 1,746 ppm) when exposed to short grass on turf and orchards and at chronic risk (NOEL 50 ppm) on all sites. Mammals would be at high acute (estimated LC_{50} 242 ppm) and chronic risk (NOEL 33 ppm) for all sites. Given the uncertainty of the data used to characterize the formation and fate of SDS-3701, to calculate such RQs would imply a confidence in the 10% factor that is greater than is warranted. Therefore RQs will not be calculated for birds and mammals.

Exposure and Risk to Nontarget Aquatic Animals

Expected Aquatic Concentrations, Chlorothalonil: Technical chlorothalonil displays very high toxicity to all fish species tested. It is considerably more toxic to the aquatic organisms tested than the SDS-3701 degradate. As discussed previously, the Agency used an aquatic exposure screening model (GENEEC) to develop generic EEC levels based on runoff from a 10-hectare field to a 1-hectare x 2-meter deep water body. These generic EECs take into account degradation in the field prior to a rain event. GENEEC was used to calculate the EEC for the turf use because the Agency does not have a refined aquatic exposure model for turf. GENEEC was also run for cherries and papaya (at current label rates and intervals) to compare with a reduced rate on turf proposed by GB Biosciences (4 lbs ai/A; 10 apps; at 10 day intervals). This rate falls within the 3.0 - 4.1 lbs ai/A) range for orchard crops.

Refined EECs were calculated using the Pesticide Root Zone Model (PRZM2.3) to simulate pesticides in field runoff and the Exposure Analysis Modeling System (EXAMS2.94) to simulate fate and transport in an aquatic environment. Refined EECs were calculated for tomatoes, cucurbits, potatoes, and peanuts. These crops were used as surrogates for other non-orchard sites (e.g., broccoli, carrots, lettuce, onion), and presently applied at rates ranging from 1.1-2.3 lbs ai/A. Tier I EECs (from GENEEC) and refined EECs (from PRZM/EXAMS) for chlorothalonil are presented in Tables 63 and 64. Default values were: KOC=1380; aerobic soil half-life=30 days; anaerobic soil half-life=15 days; solubility=0.8 ppm; aerobic aquatic half-life=2 hr (~8 hrs adjusted) and 44 hr (~59 hrs adjusted); 5% spray drift; 75% application efficiency.

Table 62. Estimated Environmental Concentrations for Chlorothalonil using PRZM2-EXAMS

Crop	Aerobic Aquatic Half-life, in hours	Application Rate, lbs ai/A (# applications; interval, in days)	Peak EEC, in ppb	4-Day EEC, in ppb	21-Day EEC, in ppb	60-Day EEC, in ppb	90-Day EEC, in ppb
Cucurbits	2	1.75 (4;7)*	17.6	2.6	0.81	0.81	0.56
	44	1.75 (4;7)	18.5	8.8	3.6	2.4	1.7
	2	2.25 (8;7)	32.4	5.2	1.4	1.8	1.3
	44	2.25 (8;7)	33.1	16.9	6.0	4.9	3.6
	2	6.25 (1;-)	17.6	3.5	1.1	0.81	0.55
	44	6.25 (1;-)	20.1	11.9	4.5	2.3	1.6
Peanuts	2	1.125 (6;14)*	17.5	3.3	0.91	0.88	0.69
	44	1.125 (6;14)	20.3	9.9	3.4	2.4	1.8
	2	1.125 (9;10)	24.2	4.1	1.1	1.3	1.0
	44	1.125 (9;10)	25.8	13.6	4.3	3.4	2.8
Potatoes	2	1.125 (6;10)*	5.5	1.3	0.51	0.56	0.37
	44	1.125 (6;10)	7.7	4.3	2.2	1.5	1.0
	2	1.125 (10;7)	6.8	1.6	0.54	0.77	0.58
	44	1.125 (10;7)	9.4	5.1	2.3	2.0	1.5
Tomatoes	2	1.75 (5;7)*	26.1	4.2	1.1	1.0	0.69
	44	1.75 (5;7)	26.8	14.0	4.6	2.8	1.9
	2	2.25 (8;7)	42.3	6.8	1.7	1.9	1.3
	44	2.25 (8;7)	43.8	22.6	7.2	5.0	3.5

* "Typical" application rate

Table 63. Estimated Environmental Concentrations for Chlorothalonil using GENEEC

Crop (disease)	Aerobic Aquatic Half-life, in hours	Application Rate, in lbs. ai/A (# applications; intervals in days)	Peak EEC, in ppb	Average 4-Day EEC, in ppb	Average 21-Day EEC, in ppb	Average 56-Day EEC, in ppb
Turf (Snowmold)	2	22.7 (2;30)	324	94	18	6.7
	44	"	363	250	68	26
Turf (MidWest, NE)	2	22.7 (1;-)	202	57	11	4
	44	"	227	156	42	16
Turf (NW)	2	11.4 (3;30)	190	55	10	3.9
	44	"	210	144	39	15
Turf (Brown Patch)	2	8.25 (10;14)[1]	273	78	15	5.6
	44	"	288	195	53	20
	2	16.5 (3;5)	423	122	23	8.7
	44	"	462	316	86	32
Turf (Dollar Spot)	2	4.0 (10;10)[1]	166	48	9.1	3.4
	44	"	173	118	32	12
	2	8.25 (3;7)	203	59	11	4.2
	44	"	220	150	41	15
Cherries	2	4.1 (4;10)[1]	114	33	6.2	2.3
	44	"	122	83	23	8.4
	2	3.6 (6;14)	106	31	5.8	4.6
	44	"	113	77	21	7.8
Papaya	2	3.0 (5;14)	83	24	4.5	1.7
	44	"	88	60	16	6.2
Cranberries[2]	2	5.3 (3;10)	82	21	3.9	1.4
	44		82	51	12	4.6

1. "Typical" application rate.
2. Concentration in discharge from bog. This concentration would decrease by dilution when added to receiving water.

Risk to Freshwater Fish: Acute and chronic risk quotients for freshwater fish based on modeled EECs utilizing the 2-hour adjusted aerobic aquatic half-life are captured in Table 64. The risk quotients are based on the LC_{50} for fathead minnow (most sensitive species, 23 ppb), acute RQ = peak EEC/96hr LC_{50}, and chronic RQ = 90-day EEC/fish full life-cycle NOEL (3 ppb).

Table 64. Risk Quotients for Freshwater Fish

Crop (Pest and/or Region)	Application rate in lb ai/A (# applications; interval in days)	Acute RQ	Chronic RQ
Turf (Snow mold)	22.7 (2;30)	14.5	2.2
Turf (Midwest, NE)	22.7 (1;-)	8.7	1.4
Turf (NW)	11.4 (3:30)[2]	8.2	1.3
Turf (Brown patch)	16.5 (3;5)	18.4	2.9
	8.25 (10;14)[3]	11.9	1.9
Turf (Dollar spot)	8.25 (3;7)	8.8	1.4
	4.0 (10;10)[3]	7.2	1.1
Cherries	4.1 (4:10)[3]	4.9	0.76
	3.6 (6;14)	4.6	0.73
Papaya	3.0 (5;14)	3.6	0.56
Cucurbits	6.25 (1;-)	0.77	0.18
	2.25 (8;7)	1.4	0.43
	1.75 (4;7)[3]	0.77	0.19
Tomatoes	2.25 (8;7)	1.8	0.43
	1.75 (5;7)[3]	1.1	0.23
Potatoes	1.125 (10;7)	0.30	0.19
	1.125 (6;10)[3]	0.24	0.12
Peanuts	1.125 (9;10)	1.1	0.33
	1.125 (6;14)[3]	0.76	0.23

1. Based on a 56-day average EEC for turf and orchards (GENEEC model) value and a 90-day average EEC for other crops
2. GB Biosciences suggested modeling
3. Typical application rate

Acute Risk: GENEEC-based acute risk quotients for turf and orchards and PRZM/EXAMS-based acute risk quotients at all modeled sites, except potatoes, exceed the acute high risk LOCs. The acute risk quotients for all uses including potatoes exceed the restricted use and endangered species LOCs. The non-orchard sites that were not modeled are assumed to have exposure concentrations similar to the modeled crops, so acute risk is assumed to be similar. Since the peak exposure concentrations are nearly identical for both the 2 and 44-hour aquatic aerobic half-life based modeling runs the RQ values are virtually the same.

Chronic Risk: When using the 2-hour aquatic half life, none of the chronic risk quotients (based on PRZM/EXAMS) for non-orchard crops exceed the chronic LOC for fish. The chronic risk quotients for turf (based on GENEEC 56-day average EECs) exceed the chronic risk LOC for all current application rates. Based on GENEEC 56-day average EEC's for the two modeled orchard crops, only cherries at the highest rate (6.25 lb ai/A) nearly equals (2.9) the chronic NOEL of 3 ppb. All other orchard crops will have 56-day average exposures less than 3 ppb (tomatoes and cucurbits are slightly above, and peanuts and potatoes are slightly below). If the orchard uses were examined using PRZM/EXAMS, the 90-day average EEC most likely would fall below the chronic NOEL, and so the Agency assumes minimal chronic risk to fish from chlorothalonil's use in orchards.

The findings for chronic risk are different when the 44-hour aerobic aquatic half-life-derived EECs are utilized. Turf, which exceeds chronic LOCs when evaluated with the 2-hour half-life, yields exposure concentrations approximately 4 times higher when the 44-hour half-life is used. The two surrogate orchard uses showed higher EECs ranging from 4.86 ppb for papayas to around 12 ppb for cherries, consequently, the fish chronic LOC is exceeded for orchard uses. Non-orchard uses all have 90-day average EECs around 3 ppb (tomatoes and cucurbits are slightly above), peanuts and potatoes are slightly below. Although the chronic risk ratios for tomatoes and cucurbits are higher than those for peanuts and potatoes, the latter two crops may pose a greater risk because more acreage is treated.

As discussed previously, GENEEC is a screening model designed to estimate concentrations greater than any that would be expected in the aquatic environment. PRZM/EXAMS-estimated EECs may be somewhat comparable to concentrations in an edge of the field pond receiving all of the drainage and spray drift from a 100% treated field.

The estimated one-in-ten-year EECs, whether from GENEEC or PRZM/EXAMS, are probably substantially greater than actual concentrations in most natural waters. This includes not only flowing water receiving drainage from a partially treated watershed but also lakes and ponds within treated areas, most of which do not receive all of the drainage and spray drift from an adjacent 100% treated field.

Incidents: Several fish kill incidents associated with chlorothalonil have been reported.

In 1976, after improper rinsing of equipment into a small lake in Texas, 200-300 fish were reportedly killed. Chlorothalonil residues of 0.275 ppm in water and 0.250 (presumably ppm) in a fish sample were cited.

In 1994, at the ME/New Brunswick border, 10,000 brook trout which had recently been released from a hatchery were found dead in Ouelette pond, Grand Falls, New Brunswick. Potatoes are grown in the area and it had recently rained. Maneb, esfenvalerate, and chlorothalonil were found in fish tissues but not in three water samples or one brook bank soil sample. The cause was considered "undeterminable" but "not likely due solely to pesticide runoff." (OPP IDS #I002200, reported by Lebelle Hicks, Maine Dept. Agriculture, Food, and Rural Resources)

In 1984, fish were killed in Viburnum, MO, following golf course application of several chemicals, including chlorothalonil. The specific agent of cause was undetermined, but was thought to be fungicides and herbicides sprayed on golf greens. (OPP IDS I000636-14, reported by Robert White, Conservation Agent, Missouri Dept. of Conservation)

In 1996, a fish kill was reported to the Agency by the Environmental Protection Service of Canada (Brian H. Belliveau--personal telephone communication) and the Prince Edward Island, Canada, Department of Fisheries and Environment (James P. Mutch--personal e:Mail and telephone communication). On Prince Edward Island, Canada, 40,000 salmon (parr stage) and a large (unspecified) number of trout in and upstream of Profit's Pond on Prince Edward Island were killed. Dead trout were found at least 800 meters above the pond. Dead slugs were observed up to 400 meters above the pond. Live invertebrates were observed on rocks throughout. The kill was noticed around midday on July 20, 1996. Approximately 1.25 inches of rain which had fallen in a downpour in the area of Profit's Pond on the night of July 19-20 caused considerable erosion and runoff. Similar erosive rainfall events occur in the area, but usually without noticeable effects on fish. Water and sediment analysis for 10 pesticides used in this major potato growing area detected only chlorothalonil as discussed below. However, it is possible that other pesticides were present at concentrations which would cause toxic effects, but which were below the detection limit, or which may have had additive or synergistic effects. Fish tissues were not analyzed for chlorothalonil, and there was no testing for its degradates. Conditions for late potato blight were bad at the time, and farmers were typically moving towards increased use of chlorothalonil (Bravo). The closest field was about 500 meters (0.3 mile) away, while the farthest was about 2500 meters (1.6 miles) away. A water sample taken from the pond in the afternoon of July 20 contained 4 ppb of chlorothalonil. Sediment samples taken from the pond and surrounding sites had chlorothalonil concentrations ranging from approximately 10 to 60 ppb.

An autopsy on trout indicated that they were otherwise healthy and their condition was consistent with a toxic chemical effect. Although for technical reasons Canadian authorities did

not establish a definitive, formal attribution for the cause of the kill, the event does clearly show that chlorothalonil is susceptible to runoff and may cause adverse effects.

Risk to Freshwater Invertebrates: The acute and chronic risk quotients for freshwater invertebrates based on modeled EECs utilizing the 2-hour adjusted aerobic half-life are found in Table 65. The risk quotients are based on: the lowest LC_{50} for D. magna (68 ppb), acute RQ = peak EEC/LC_{50}, and the chronic RQ = 21-day EEC/freshwater invertebrate life-cycle NOEL (39 ppb).

Table 65. Risk Quotients for Freshwater Invertebrates

Crop (Pest and/or region)	Application rate in lbs ai/A (# applications; interval in days)	Acute RQ	Chronic RQ
Turf (Snow mold)	22.7 (2;30)	4.8	0.46
Turf (Midwest, NE)	22.7 (1;-)	3.0	0.28
Turf (NW)	11.4 (3;30)	2.8	0.26
Turf (Brown patch)	16.5 (3;5)	6.2	0.60
	8.25 (10;14)*	4.0	0.38
Turf (Dollar spot)	8.25 (3;7)	3.0	0.28
	4.0 (10;10)*	2.4	0.23
Cherries	4.1 (4;10)*	1.7	0.16
	3.6 (6;14)	1.6	0.15
Papaya	3.0 (5;14)	1.2	0.12
Cucurbits	6.25 (1;-)	0.26	0.03
	2.25 (8;7)	0.48	0.04
	1.75 (4;7)*	0.26	0.02
Tomatoes	2.25 (8;7)	0.62	0.04
	1.75 (5;7)*	0.38	0.03
Potatoes	1.125 (10;7)	0.10	0.01
	1.125 (6;10)*	0.08	0.01
Peanuts	1.125 (9;10)	0.36	0.03
	1.125 (6;14)*	0.26	0.02

* "Typical" application rate

Acute risk quotients based on the GENEEC exposure model exceed the acute high risk LOC for turf and orchard uses. The highest rate for tomatoes exceeds the acute high risk LOC for the PRZM/EXAM modeled crop uses. Except for potatoes, and mint at 1.1 lb ai/A, which

exceed only the endangered species acute LOC, the acute risk quotients at all sites exceed the restricted use and endangered species LOCs for aquatic invertebrates. The chronic risk quotients for all sites are below the chronic LOC for freshwater aquatic invertebrates. When the 44-hour aerobic aquatic half-life is used to estimate exposure neither the acute nor the chronic risk are significantly changed.

Risk to Estuarine/Marine Animals: Acute and chronic risk quotients based on modeled EECs utilizing the 2-hour adjusted aerobic aquatic half-life are captured in Table 66. The risk quotients are based on: acute RQ = peak EEC/LC_{50} (sheepshead = 32 ppb, pink shrimp = 154 ppb, oyster = 3.6 ppb), chronic RQ = 21-day EEC/mysid life cycle NOEL (0.83 ppb).

Table 66. Risk Quotients for Estuarine and Marine Organisms

Crop (Pest and/or Region)	Application rate, lbs ai/A (# applications; interval in days)	Test Species	Acute RQ	Chronic RQ
Turf (Snow mold)	22.7 (2;30)	Sheepshead minnow Oyster Pink shrimp Mysid	10.1 90 2.1 ---	---- ---- ---- 21.7
Turf (Midwest, NE)	22.7 (1;-)	Sheepshead minnow Oyster Pink shrimp Mysid	6.3 56.1 1.3 ---	--- --- --- 13.3
Turf (NW)	11.4 (3;30)	Sheepshead minnow Oyster Pink shrimp Mysid	5.9 52.8 1.2 ---	--- --- --- 12.0
Turf (Brown patch)	16.3 (3;5)	Sheepshead minnow Oyster Pink Shrimp Mysid	13.2 117.5 2.7 ----	---- ---- ---- 28.0
	8.25 (10;14)*	Sheepshead minnow Oyster Pink Shrimp Mysid	8.5 75.8 1.8 ----	---- ---- ---- 18.0

Crop (Pest and/or Region)	Application rate, lbs ai/A (# applications; interval in days)	Test Species	Acute RQ	Chronic RQ
Turf (Dollar spot)	8.25 (3;7)	Sheepshead minnow Oyster Pink Shrimp Mysid	6.3 56.4 1.3 ----	---- ---- ---- 13.4
	4.0 (10;10)*	Sheepshead minnow Oyster Pink Shrimp Mysid	5.2 46.1 1.1 ----	---- ---- ---- 11.0
Cherries	4.1 (4;10)*	Sheepshead minnow Oyster Pink Shrimp Mysid	3.6 31.7 .74 ---	--- --- --- 7.5
	3.6 (6;14)	Sheepshead minnow Oyster Pink Shrimp Mysid	3.3 29.4 .69 ---	--- --- --- 7.0
Papaya	3.0 (5;14)	Sheepshead minnow Oyster Pink Shrimp Mysid	2.6 23.1 .54 ---	--- --- --- 5.4
Cucurbits	6.25 (1;-)	Sheepshead minnow Oyster Pink shrimp Mysid	0.55 4.9 0.11 ----	---- ---- ---- 1.3
	2.25 (8;7)	Sheepshead minnow Oyster Pink shrimp Mysid	1.0 9.0 0.21 ----	---- ---- ---- 1.7

Crop (Pest and/or Region)	Application rate, lbs ai/A (# applications; interval in days)	Test Species	Acute RQ	Chronic RQ
	1.75 (4;7)*	Sheepshead minnow Oyster Pink shrimp Mysid	.55 4.9 0.11 ---- 	---- ---- ---- 0.97
Tomatoes	2.25 (8;7)	Sheepshead minnow Oyster Pink shrimp Mysid	1.3 11.8 0.27 ---- 	---- ---- ---- 2.0
	1.75 (5;7)*	Sheepshead minnow Oyster Pink shrimp Mysid	0.82 7.3 0.17 ---- 	---- ---- ---- 1.3
Potatoes	1.125 (10;7)	Sheepshead minnow Oyster Pink shrimp Mysid	0.21 1.9 0.04 ---- 	---- ---- ---- 0.65
	1.125 (6;10)*	Sheepshead minnow Oyster Pink shrimp Mysid	0.17 1.5 0.04 ---- 	---- ---- ---- 0.61
Peanuts	1.125 (9;10)	Sheepshead minnow Oyster Pink shrimp Mysid	0.76 6.7 0.16 ---- 	---- ---- ---- 1.3
	1.125 (6;14)*	Sheepshead minnow Oyster Pink shrimp Mysid	0.55 4.9 0.11 ---- 	---- ---- ---- 1.1

*Typical application rate

The acute risk quotients for marine organisms exceed the acute high risk, restricted use, and endangered species LOCs for marine/estuarine fish and invertebrates for all modeled use sites

(and presumably those represented by these sites but not specifically modeled). Acute risk quotients for estuarine fish exceed the high risk LOC for all use sites except for potatoes. However, the margin of exceedance is substantially lower than for oysters. For shrimp, the acute risk quotients exceed the high risk LOC for turf and cherries, but for no other use sites. This suggests that estuarine organisms with sensitivities similar to oysters are at greater risk than fish or shrimp. The chronic risk quotients at all modeled sites, except potatoes, exceed the chronic LOCs for marine/estuarine invertebrates (using mysid as the representative species). Chronic exceedences for use sites other than turf are relatively small.

When the 44-hour aerobic aquatic half-life is used to estimate exposure, the acute risk to estuarine organisms is not significantly changed. However, the 44-hour half-life results in a 4-fold exceedance of the LOC for chronic risk to aquatic invertebrates for *all* uses–turf, orchard, and vegetable.

Exposure and Risk to Nontarget Plants

Terrestrial Plants: Non-target terrestrial plants inhabit non-aquatic areas. Non-target "semi-aquatic" plants are plants that usually inhabit low-lying wet areas that may or may not be dry in certain times of the year. These plants are not obligatory aquatic plants in that they do not live in a continuously aquatic environment. The terrestrial and "semi-aquatic" plants are exposed to pesticides from runoff, drift or volatilization.

Runoff exposure is determined from a preliminary EEC. This runoff is characterized as a one acre treated area to one acre sheet runoff (for chlorothalonil, 1% runoff, given solubility < 10 ppm) to an adjacent acreage for terrestrial plants; or channelized runoff from 10 acres (10 times the acreage for sheet runoff) to a low-lying area some distance away for semi-aquatic and terrestrial plants.

Spray drift exposure is determined by assuming 5% of the pesticide application will drift over to an adjacent acreage or to a much longer distance for aerial application, and 1% for ground application.

The EC_{25} value of the most sensitive species in the seedling emergence study is used with runoff exposure to determine the risk quotient. The value can also be used with drift exposure to emerging non-target plants. The EC_{25} value of the most sensitive species in the vegetative vigor study may also be used with the drift exposure. For evaluation of risk to endangered plant species, the NOEC (or EC_{05} value) is used from both the seedling emergence and vegetative vigor studies.

In the case of chlorothalonil, a Tier 2 study was not conducted because there was a less than 25% response at 16 lb ai/A rate. For this assessment, the Agency has assumed that the EC_{25} in Tier 1 studies for both seedling emergence and vegetative vigor studies is $\geq$ 16 lb ai/A. Although studies were not conducted at the maximum rate of 22.7 lb ai/acre, the most severe impact at 16 lb ai/A was an 11% reduction in the fresh weight of onions. (Thus, all risk quotients, whether for exposure to roots or to foliage, and whether for endangered or non-endangered species, will be based on an $EC_{25} > 16$ lb ai/A). Turf EECs and risk quotients for terrestrial and semi-aquatic plant species are summarized in Table 67. The turf application rate of 22.7 lbs ai/A used in these calculations represents the high-end of potential exposure.

Table 67. Turf EECs and Risk Quotients for Terrestrial Plants In Dry and Semi-aquatic Areas

Type of EEC	EEC (lbs a.i./A)	Risk Quotient (Non-endangered species)	Risk Quotient (Endangered species)
sheet runoff	0.22	< 0.014	$\leq$ 0.014
channel runoff	2.24	< 0.14	$\leq$ 0.14
drift + sheet runoff	1.34	< 0.08	$\leq$ 0.08
drift + channel runoff	3.36	< 0.21	$\leq$ 0.21
spray drift (aerial applic.)	1.12	< 0.07	$\leq$ 0.07
spray drift (ground applic.)	0.22	< 0.014	$\leq$ 0.014

Even at this high application rate, all risk quotients are still well below the LOC of 1. Thus, no site is considered to exceed an LOC for terrestrial or semi-aquatic plants with a single application.

While it is theoretically possible to estimate residues on off-site plants from multiple applications of chlorothalonil, given the assumed rate of degradation of chlorothalonil on foliage (half-life range of seven to 30 days based on estimated foliar dissipation and aerobic soil metabolism studies), it is unlikely chlorothalonil residues would accumulate to levels greater than 16 lb ai/acre. Multiple applications of chlorothalonil are needed because chlorothalonil is non-systemic and fresh applications are needed to protect newly emerged plant growth, or because chlorothalonil degrades or dissipates between treatments. The Agency assumes there is little or no risk to either endangered or non-endangered terrestrial plants from two applications at the 22.7 lb ai/A rate (the highest rate/number of applications combination, found on turf).

Aquatic Plants: Exposure to non-target aquatic plants may occur through either runoff or drift from terrestrial sites. Aquatic EECs are the same as those used in the chlorothalonil risk assessment for fish and aquatic invertebrates, and are derived using the adjusted 2-hour aerobic aquatic half-life.

Normally, the aquatic risk assessment is based on testing for five species. For chlorothalonil, the species for which test data are missing are: *Lemna gibba, Anabaena flos-aquae, Skeletonema costatum,* and a freshwater diatom. The risk assessment is usually made for endangered and non endangered aquatic vascular plants from the surrogate duckweed *Lemna gibba*. This study is not available for chlorothalonil. Algae and diatom risk assessments are considered useful indicators of impact to food sources of aquatic organisms. The only available aquatic plant study is with the freshwater green alga *Selenastrum capricornutum.* Therefore, this species will serve as a surrogate for endangered as well as non endangered aquatic plants. The risk quotients and EEC values for aquatic plants are summarized in Table 68. The risk quotients are based on EC50 = 190 ppb, NOEC = 50 ppb, RQ = EEC/EC_{50} or NOEC.

Table 68. Risk Quotients for Aquatic Plant Species

Crop (Pest and/or Region)	Application rate in lbs ai/A (#applications; interval in days)	Risk Quotient (non-endangered species)	Risk Quotient (endangered species)
Turf (Snow mold)	22.7 (2;30)	1.7	6.5
Turf (Midwest, NE)	22.7 (1;-)	1.1	4.0
Turf (NW)	11.4 (3;30)	1.0	3.8
Turf (Brown patch)	16.5 (3;5)	2.2	8.5
	8.25 (10;14)*	1.4	5.5
Turf (Dollar spot)	8.25 (3;7)	1.1	4.1
	4.0 (10;10)*	0.8	3.3
Cherries	4.1 (4; 10)*	0.6	2.3
	3.6 (6;14)	0.6	2.1
Papaya	3.0 (5;14)	0.4	1.7
Cucurbits	6.25 (1;-)	0.09	0.35
	2.25 (8;7)	0.17	0.7
	1.75 (4;7)*	0.09	0.35
Tomatoes	2.25 (8;7)	0.22	0.9
	1.75 (5;7)*	0.14	0.5
Potatoes	1.125 (10;7)	0.04	0.14
Peanuts	1.125 (6;10)*	0.03	0.11
	1.125 (9;10)	0.13	0.5
	1.125 (6;14)[2]	0.09	0.35

* Typical application rate.

Except for turf uses, risk quotients at other sites do not exceed the LOC for aquatic plants, including endangered aquatic plants. The aquatic plant risk quotients for turf (and presumably orchards, using GENEEC modeled estimates) exceed the non-endangered and endangered LOC by small margins. This risk assessment for plants reflects toxicity for only one aquatic plant species (*Selenastrum capricornutum*).

When utilizing the 44-hour aerobic aquatic half-life, the acute risk LOC for non-endangered plants is not exceeded. Endangered plants would be at potential risk from all sites (except potatoes); where RQs range from 1.4 to 3.4.

Endangered Species

The registered uses of chlorothalonil may adversely affect endangered species of birds (chronically), mammals (chronically), freshwater fish (acutely and chronically), freshwater invertebrates (acutely) and aquatic plants.

The Endangered Species Protection Program is expected to become final at sometime in the future. Limitations in the use of chlorothalonil may be required at that time to protect endangered and threatened species, but these limitations have not been defined and may be formulation-specific. EPA anticipates that a consultation with the Fish and Wildlife Service may be conducted in accordance with the species-based priority approach described in the Program. After completion of the consultation, registrants will be informed if any required label modifications are necessary. Such modifications would most likely consist of a generic label statement referring pesticide users to use limitations contained in county bulletins.

Risk Characterization

Overview of Usage: Chlorothalonil is a broad spectrum fungicide registered for use on a variety of food and non-food use sites. The actual poundage used per year has reached over 14 million lbs. Most uses represent very small percentages of the total that is applied annually nationwide for all uses. The exceptions are potatoes (12%), peanuts (34%), paint (13%), and golf courses (10%). Chlorothalonil is also used on other turf sites. Application rates range from 0.75 lbs a.i./A (tomatoes) to over 22 lbs a.i./A (turf), with multiple applications typically at intervals of 5 to 30 days.

Impact to Water Resources: It appears that parent chlorothalonil has limited potential to reach groundwater, even under hydrologically vulnerable conditions. Where there have been detections of chlorothalonil (California, Florida, Maine, Massachusetts, and North Carolina), concentrations have been low (generally < 1.0 µg/L) and often attributed to atypical sources.

Degradates (metabolites) of chlorothalonil have been found in groundwater in New York and North Carolina. The reported metabolites in ground water are SDS-46851, SDS-47525, SDS-3701, and SDS-19221, and were measured at the highest combined concentration of

approximately 16 µg/L in New York in 1981. The degradate SDS-46851, which is nontoxic, appears likely to contaminate ground water at concentrations that have been as high as 10.1 µg/L in NC and 12.6 µg/L under vulnerable conditions.

Chlorothalonil can contaminate surface water at application via spray drift or after application through runoff and erosion. Substantial fractions of applied chlorothalonil are available for runoff for several weeks to months post-application. The intermediate soil/water partitioning of chlorothalonil (Freundlich K_ds of 3, 20, 26, 29) indicates that chlorothalonil runoff will probably be via both dissolution in runoff water and adsorption to eroding soil in typical cases where runoff volume greatly exceeds sediment yield.

The resistance of chlorothalonil to hydrolysis, direct aqueous photolysis, and volatilization, coupled with only an intermediate susceptibility to degradation in soil under aerobic conditions indicate that chlorothalonil may be somewhat persistent in the water columns of some aqueous systems that have low microbiological activities and relatively long hydrological residence times. Aerobic aquatic metabolism half-lives from around two hours to 6-8 days have been reported under various conditions. The 2-hour half-life is associated with experimental conditions which correspond more closely to aerated and agitated wastewater treatment (shake-flask test for inherent biodegradability) than to natural systems, but was used as a low-end half-life in this assessment.

Bioconcentration Factors (BCFs) are substantially less than 1000X, considered to be a threshold of concern--75X edible and 264X whole for bluegill, 9.4X edible and 16X whole for catfish-- indicating that the bioaccumulation potential of chlorothalonil is low. A total residue BCF (consisting primarily of degradates) of 2600X in oysters suggests some potential for the bioaccumulation of chlorothalonil degradates in oysters.

The major degradate of chlorothalonil in the soil under aerobic conditions is SDS-3701. SDS-3701 appears to be more persistent and mobile than chlorothalonil. Consequently, substantial amounts of SDS-3701 may be available for runoff for longer periods than chlorothalonil and SDS-3701 may be more persistent in water/sediment systems than chlorothalonil.

The GENEEC and PRZM/EXAMS EECs previously discussed are generated for high exposure agricultural scenarios and represent reasonable worst case or one in ten year EECs in a stagnant pond with no outlet, receiving pesticide loading from an adjacent 100% cropped, 100% treated field. As such, the computer generated EECs represent conservative screening levels for ponds, lakes, and flowing water.

As indicated previously, under the NAWQA program, the USGS collected ground and surface water samples from 20 study units during 1993-1995 and analyzed them for pesticides including chlorothalonil. The USGS provided OPP with a summary for all 20 study units combined. Seventeen of 20 study units sampled overlapped areas of chlorothalonil use. For

surface water, chlorothalonil was detected in only 6 of 1850 samples (6/1850 = 0.32%) above a detection limit of 0.035 µg/L ranging to a maximum concentration of 0.68 µg/L.

The NAWQA data are measured chlorothalonil concentrations in flowing water and demonstrate the large effects of dilution from untreated portions of the watersheds. Since the concentrations were measured in samples collected from study units that generally overlapped areas of chlorothalonil use, they can probably be used for estimating actual typical risks in the flowing water portions of chlorothalonil treated watersheds. However, since the NAWQA study is not a chlorothalonil-specific study, sampling sites may not represent reasonable worst case scenarios for chlorothalonil in flowing surface water.

Environmental Risk: Chlorothalonil is atypical for a fungicide of its type in that it does not show the high degree of persistence associated with many other chlorinated organics. Several of its metabolites exhibit greater persistent and mobility, and so are of potentially greater long-term environmental significance.

Based on predominance of use on different sites and potential exposures to wildlife, the use sites that have been most closely examined in this analysis are peanuts, cucurbits, tomatoes and turf.

Peanuts, potatoes, cucurbits, and tomatoes represent a significant portion of chlorothalonil usage. The risk quotients for cucurbits, peanuts, and tomato exceed high acute risk freshwater fish LOCs, acute marine/estuarine LOCs, and chronic estuarine invertebrate LOCs. Chronic risk to birds may result from multiple routes of exposure in chlorothalonil treated tomato and cucurbit fields. The highest RQs are for estuarine organisms: acute for mollusks (represented by oysters) and chronic for crustacea (represented by shrimp)–no data are available to calculate chronic RQs for estuarine/marine fish and mollusks.

Mollusks which may be at risk include freshwater mussels (a phylum that includes numerous freshwater endangered species). When chlorothalonil is used extensively near estuarine or marine habitats, the risk quotients suggest possible adverse impacts to invertebrates such as mollusks (e.g., oysters and clams) and crustacea (e.g., shrimp). However, the edge of the field pond scenario captured by the models is probably as conservative for estuaries as it is for flowing freshwater.

In Table 69, RQs which exceed high acute or chronic LOCs are in **boldface**. Peak EECs were used to calculate acute risk quotients for aquatic organisms (see discussion below on use of peak EECs versus 96-hour averages for acute risk). EECs which were averaged over time (i.e., 21 days for invertebrates and 90 days for fish) were used to calculate chronic risk quotients. Aquatic acute risk quotients are based on a 2-hour aerobic aquatic half-life, aquatic chronic risk quotients are calculated for both a 2-hour and a 44-hour aerobic aquatic half-life, and terrestrial chronic risk quotients are based on a 30-day aerobic soil half-life.

Table 69. Highest Risk Quotients for Peanut, Potato, Cucurbit and Tomato Uses

	Risk Quotients (those in **bold** exceed high acute or chronic LOCs)						
Crop, EEC	Avian Acute, Chronic	Mammal Acute, Chronic	Freshwater Fish Acute, Chronic based on 2h half-life (44h half-life)	Freshwater Invert. Acute, Chronic based on 2h half-life (44h half-life)	Aquatic Plant (Endangered)	Estuarine Acute for Fish, Oyster, Shrimp	Estuarine Chronic mysid based on 2h half-life (44h half-life)
Peanut, Max EEC	<LOC*, N/A	<LOC*, N/A	**1.1**, N/A	0.36, N/A	0.48	0.76, **6.7**, 0.16	N/A
Peanut, Avg EEC	N/A, 0.74	N/A, 0.37	N/A, 0.33 (0.9)	N/A, 0.03	N/A	N/A	1.3 (**5.2**)
Potato, Max EEC	<LOC*, N/A	<LOC*, N/A	0.3, N/A	0.1, N/A	0.14	0.21, **1.29**, 0.04	N/A
Potato, Avg. EEC	N/A, **1.17**	N/A, 0.59	N/A, 0.19 (0.6)	N/A, 0.01 (0.03)	N/A	N/A	0.65 (**1.9**)
Tomato, Max EEC	<LOC*, N/A	<LOC*, N/A	**1.8**, N/A	**0.62**, N/A	0.85	**1.3, 11.8**, 0.27	N/A
Tomato, Avg EEC	N/A, **1.64**	<LOC*, 0.82	N/A, 0.43 (**1.1**)	N/A, 0.04	N/A	N/A	**2.0** (**8.0**)
Cucurbit, Max EEC	<LOC*, N/A	<LOC*, N/A	**1.4**, N/A	0.48, N/A	0.65	**1.0, 9.0**, 0.21	NA
Cucurbit, Avg EEC	N/A, **1.64**	N/A, 0.82	N/A, 0.43 (**1.1**)	N/A, 0.04	N/A	N/A	**1.7** (**6.8**)

* A qualitative conclusion of minimal risk was made.

Turf (predominantly sod farms, lawns, and golf courses), to which about 14% of the annual poundage of chlorothalonil is applied, represents the next highest annual usage of chlorothalonil after peanuts, potatoes, cucurbits and tomatoes. In addition, the application rates for turf are higher than for other crops. Birds and mammals are at chronic risk from the parent, while acute risk is not expected to be high. Freshwater and estuarine fish and aquatic invertebrates are at high acute risk from chlorothalonil's use on turf. Based on presently available data, only freshwater fish and estuarine invertebrates are at chronic risk. Aquatic plants are at high risk from use of chlorothalonil on turf. Risk to aquatic organisms is based on exposure concentrations derived from GENEEC since refined models have not yet been developed for turf, adding some conservatism to the conclusions.

The chronic terrestrial risk quotients on turf range from about 0.5 to 7.6 (birds) and 0.2 to 3.8 (mammals). Of special concern is the fact that many golf courses are frequented by animals such as ducks, geese and rabbits that graze extensively on the short grass. Chronic risk quotients for birds and mammals from the turf use are greater than other sites because the application rates are much higher and the prevalent vegetation would be short grass, which will have higher

residues than other food items.

In Table 70, RQs which exceed high acute or chronic LOCs are in **boldface**. Peak EECs were used to calculate acute risk quotients for aquatic organisms (see discussion below on use of peak EECs versus 96-hour averages for acute risk). EECs which were averaged over time were used to calculate chronic risk quotients. Terrestrial risk was derived from EECs based on a 30-day aerobic soil half-life. Acute aquatic risk quotients were derived from EECs based on 2-hr aquatic aerobic half-life. Chronic aquatic risk quotients were based on a 56-day average for fish and a 21-day average for invertebrates.

Table 70. Highest Risk Quotients for Chlorothalonil Turf Use

Risk Quotients (those in **bold** exceed high acute or chronic LOCs)							
Type of EEC	Avian Acute, Chronic	Mammalian Acute, Chronic	Fish Acute, Chronic	Aquatic Invertebrate Acute, Chronic	Aquatic Plants	Estuarine Acute Fish, Oyster, Shrimp	Estuarine Chronic Mysid
Maximum	<LOC*, N/A	<LOC*, N/A	**18.5**, N/A	**6.3**, N/A	**2.2**	**13, 118**, **2.8**	N/A
Average	N/A, **7.6**	N/A, **2.41**	N/A, **2.9**	N/A, 0.6	N/A	N/A	**28**

* A qualitative conclusion of minimal risk was made.

Orchard crops present a slightly lower, but similar risk to birds, mammals, fish, and freshwater aquatic invertebrates as the 4 lb ai/A use on turf, based on similarities between application parameters for cherries and turf (cherries at 4.1 lb ai/A, 4 applications at 10-day intervals; turf at 4.0 lb ai/A, 10 applications at 10-day intervals). Aquatic EECs for the two scenarios are very close: peak, cherries 114 ppb, turf 166 ppb; average 21-day, cherries 6.2 ppb, turf 9.1 ppb; average short grass, cherries 1820 ppm, turf 2752 ppm. The magnitude of risk to estuarine organisms is probably mitigated somewhat because orchards are not typically associated with coastal locations, and so risk to estuarine organisms is considered low. Risk to aquatic plants from orchard use of chlorothalonil is similar to the risk posed by turf. Use on other non-orchard crops (e.g., mint, onions) appears to pose risks similar to those posed by the three non-orchard crops (peanuts, tomatoes and cucurbits) which were examined in detail.

Uncertainties and Points of Clarification

Use of Models: GENEEC is a screening model for determining which uses and/or chemicals may pose risks to aquatic organisms and may need to be analyzed further. Normally further analysis would involve refined modeling of EECs. Since a refined model has not been developed for turf, GENEEC values are all that can be used for risk quotient calculation. GENEEC may overestimate exposure values. The PRZM/EXAMS model used for the other crops, although refined, is also a screening model that uses the same pond scenario; however, because it takes into

account more fate factors, PRZM/EXAMS, a Tier 2 screening model, usually generates lower EECs than the GENEEC or Tier 1 screening estimates.

GENEEC and PRZM2.3/EXAMS2.94 are both based on a scenario where 10 hectares of treated land drain into a 1 hectare pond 2 meters deep. This scenario does not reflect estuarine or marine habitat situations. Thus, any risk quotients calculated for estuarine or marine organisms are probably more valuable as comparative risk numbers (between species and between uses) as opposed to representing absolute risk. It is not possible to state with certainty that exposure concentrations in estuaries would be less or greater than the modeled EEC.

Acute Risk to Fish: Based on GENEEC values for turf, orchards and cranberries, fish are considered to be at risk of acute impact, although these conclusions are qualified by limitations of the modeling system.

Other data have been useful in helping us determine the likelihood that chlorothalonil will kill fish. In addition to the incident data cited previously, a study by W. Ernst, *et al.*, was intended to determine the residues in a pond treated with chlorothalonil, and determine, among other things, any acute impacts to fish. Residue levels in the pond immediately after direct spraying of the water surface ranged from 171 to 883 ppb. Rainbow trout were exposed by placing them in cages suspended in the treated pond (10 fish per cage; five cages). No mortalities of caged rainbow trout were observed. This study represents a situation where aqueous concentrations apparently exceed the fish LC50, but no fish died. It represents only one pond, and we do not know if these results would be duplicated in other situations where fish were exposed. The sizes of the trout in the study are not provided, although they are described as 1-year old hatchery grown fish. At this age, they could be as large as five or six inches. This is much larger than the specimens used in laboratory tests, which are usually between one and two inches long. It is likely that smaller fish would be more sensitive than the fish used in this study, but the results of this study should not be dismissed.

Of the four fish kill incidents described previously, one incident was attributed to improper rinsing into a lake and resulted in chlorothalonil concentrations of 275 ppb in lake water. The other fish kill incidents may have been caused, at least in part, by normal use of chlorothalonil; but a definitive, formal attribution of cause could not be made.

SDS-3701: A primary degradate of chlorothalonil, SDS-3701, is substantially more toxic to birds and mammals, but is less toxic to fish and aquatic invertebrates than parent chlorothalonil. The Agency spent considerable time investigating the possibility that SDS-3701 may represent an ecological risk. It is concluded, with some certainty, that SDS-3701 does not represent a significant risk to aquatic organisms. Available residue studies suggest it is not present in/on avian or mammalian food items at concentrations likely to be an acute or chronic risk to these organisms, but when the degradate is assumed to form on terrestrial food items at 10% of the

applied parent concentration, both acute and chronic risk are predicted for birds and mammals. Birds would be considered at high acute risk in orchards and turf and at chronic risk on all sites. Mammals would be at high acute and chronic risk for all sites. Given the uncertainty of the data used to characterize the formation and fate of SDS-3701 additional residue data on foliage are being required to describe the magnitude of the residue exposure.

Persistence of Chlorothalonil: Chlorothalonil's potential chronic impact to aquatic organisms, principally to fish, should be considered in light of the relative persistence of chlorothalonil in aquatic environments. Half-lives range from a low of around 2 hours to around two weeks. Although EECs indicating chronic NOELs are exceeded are from a (non-flowing) farm pond scenario, the shorter half-life (2 hours) that was used in the models was generated under conditions that maximized the degradation rate such as would occur in flowing water with substantial suspended sediment. Longer half-lives may occur in sluggish or standing water with little suspended sediment.

A shorter half-life may reduce the total impact of chlorothalonil to aquatic organisms. It would be a factor in some situations such as in flowing water where movement of the pesticide downstream would continually expose new organisms. The more rapid the degradation, the shorter the distance downstream where hazardous residue levels would occur. In summary, whereas aquatic organisms in non-flowing aquatic habitat appear to be at high acute and chronic risk, those residing in flowing water may be at lesser risk.

Extent of Usage: Relative to many fungicides, the poundage of chlorothalonil used annually is high, suggesting that the national impact of chlorothalonil use could be high. In addition, chlorothalonil is applied repeatedly at very high rates on some use sites, especially turf, so that "hot spots" may occur with adverse effects to localized ecosystems. Potential regional concern for impacts to estuaries arises from chlorothalonil's use on peanuts. Peanuts are grown throughout the southeast, but they are concentrated in an area extending from southeastern Alabama to southwestern Georgia, probably not in close proximity to estuarine habitats. Chlorothalonil used on peanuts grown along the Texas Gulf, coastal Virginia and North Carolina could adversely affect the oyster beds in those regions. Chlorothalonil was reported as having the highest volume of three fungicides discussed in NOAA's publication, "Agricultural Pesticide Use in Coastal Areas: A National Summary" (NOAA, 1992).

Mollusks, A Special Risk Concern

Oysters and presumably other mollusks are particularly sensitive to chlorothalonil. They appear to be at higher risk than other aquatic or marine species on all modeled use sites. With an EC_{50} of 3.6 ppb based on shell deposition, oysters are about 10 times and 40 times more sensitive than sheepshead minnow and shrimp, respectively. Oysters exhibit a potential to bioconcentrate combined parent chlorothalonil and metabolites, with a BCF of 2600X (relative to a threshold of concern of 1000X), and are important ecologically, as filter feeders, and economically. Freshwater mussels are also represented in this risk assessment by the oyster data. The mitigating factor for both freshwater and estuarine mollusks is water movement, e.g., flowing streams and rivers for mussels and tidal flushing for oysters.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data for an active ingredient, whether products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of generic (i.e., active ingredient-specific) data required to support reregistration of products containing chlorothalonil as an active ingredient. The Agency has completed its review of these generic data, and has determined the data are sufficient to support reregistration of all products containing chlorothalonil under the conditions specified in the RED. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of chlorothalonil, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B were sufficient for the Agency to assess the registered uses of chlorothalonil and to conclude that chlorothalonil, labeled and used as specified in this document, will not cause unreasonable risks to humans or the environment. Therefore, these uses are eligible for reregistration, with appropriate risk reduction measures and conditions (as described in the document).

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data, published scientific literature, and the data identified in Appendix B. Although the Agency has found that the uses of chlorothalonil are eligible for reregistration under the conditions defined in this RED, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing chlorothalonil if new information comes to the Agency's attention, if the data requirements for registration (or the guidelines for generating such data) change, or as evolving risk assessment and management policy make it necessary or prudent.

B. Eligibility Decision

The Agency has determined that chlorothalonil products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment. Under the mandate of the Food Quality Protection Act of 1996, the Agency has determined that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to chlorothalonil. Therefore, the Agency concludes that products containing chlorothalonil are eligible for reregistration contingent upon the implementation of the mitigation measures set forth in this document.

C. Regulatory Position

1. Acute Dietary Risk from Food

MOEs for chlorothalonil and SDS-3701 combined range from 875 (infants and children) to 1750 (ages 13 and over). As discussed previously, and MOE of 300 has been determined to be adequately protective, and the Agency does not have acute dietary risk concerns for chlorothalonil. HCB does not have an acute dietary endpoint, and the Agency does not have acute dietary risk concerns for HCB.

2. Chronic Non-Cancer Dietary Risk from Food

Chlorothalonil and SDS-3701 combined occupy 60% of the RfD for the most highly exposed segment of the population (non-nursing infants less than 1 year old), and 32% of the RfD for the general population. The Agency does not have chronic non-cancer risk concerns for chlorothalonil. HCB occupies 0.05% of the RfD for the most highly exposed segment of the population (children between the ages of 1 and 6), and 0.03% of the RfD for the general population. The Agency does not have chronic non-cancer risk concerns for HCB in chlorothalonil.

3. Dietary Cancer Risk from Food

As explained previously, the Agency has estimated dietary cancer risk for chlorothalonil using both the Q* and MOE approaches, but uncertainties about the non-linear mechanism and the appropriate level at which to regulate cancer risk under the MOE approach lead the Agency to base its regulatory decision on the Q_1*. Under the Q* approach, cancer risk is estimated at 1.2×10^{-6}, at the lower limit of the level at which the Agency typically takes regulatory action. Under the MOE approach, cancer risk is estimated at MOE = 9500. The Agency has determined that the cancer risk estimates for chlorothalonil do not exceed the level for regulatory action.

Dietary cancer risk for HCB in chlorothalonil (using the Q* approach) is estimated at 2.4×10^{-7}, and the Agency does not have dietary cancer risk concerns for HCB in chlorothalonil alone. Dietary cancer risk for HCB and the related contaminant pentachlorobenzene in chlorothalonil and other pesticides has been estimated at 1.8×10^{-6}. As explained previously, this aggregate risk assessment is subject to considerable uncertainty and the estimate exceeds the level at which the Agency typically has concerns. In addition, the Agency was aware that reducing concentrations of HCB was technologically feasible and prudent.

To address this risk, the registrants of chlorothalonil have agreed that the level of HCB in chlorothalonil technical and manufacturing-use products must be no greater 0.004% (40 ppm) by January 1, 2003. This is the lowest level that has been shown to be technologically feasible for chlorothalonil. The registrants have agreed to certify this final level and interim levels according to the schedule shown below. The subject registrations are conditional on achieving these milestones, and failure to achieve any milestone will result in a suspension of manufacture or import of the subject products until such time as the target concentration is achieved. The registrants have also agreed to maintain approximately historic levels of production and import of

chlorothalonil manufacturing-use product during this period of HCB reduction to assure that chlorothalonil with higher concentrations of HCB will not be stockpiled and formulated. The subject products follow separate timelines according to the type of product into which they may be formulated because it may take longer to achieve interim reductions in the paint additive parent products while the registrant attempts to overcome some pigmentation problems which may be associated with purification.

Date	Product to be added to paint	Other
July 1, 1999	---	150 ppm
January 1, 2000	250 ppm	150 ppm
January 1, 2001	150 ppm	100 ppm
January 1, 2003	40 ppm	40 ppm

If any one of these milestones is not achieved by January 1, 2008, the affected registrants have committed to the immediate cancellation of subject registrations without opportunity for appeal.

4. Acute Dietary Risk from Water

MOEs for drinking water risk for chlorothalonil are in excess of 110,000 for children, the most highly exposed population subgroup, and in excess of 380,000 for adults. Since an MOE of 300 is thought to be protective, the Agency does not have acute dietary (drinking water) risk concerns for chlorothalonil.

5. Chronic Non-Cancer Dietary Risks from Water

Chlorothalonil in drinking water occupies 8% of the RfD for children, the most highly exposed subgroup, and 2% of the RfD for adults. The Agency does not have chronic non-cancer dietary (drinking water) risk concerns for chlorothalonil.

HCB originating from chlorothalonil occupies < 1% of the RfD for children, the most highly exposed subgroup. The Agency does not have chronic non-cancer dietary (drinking water) risk concerns for HCB originating in chlorothalonil.

6. Dietary Cancer Risks from Water

Dietary cancer risk from chlorothalonil in water was estimated at 8×10^{-9} under the Q* approach and MOE >1.5 million under the MOE approach. The Agency does not have dietary cancer (drinking water) risk concerns for chlorothalonil.

Dietary cancer drinking water risk from HCB in chlorothalonil was estimated at 5×10^{-9}. The Agency does not have drinking water cancer risk concerns for HCB in chlorothalonil. Dietary cancer drinking water risk for HCB and the related contaminant pentachlorobenzene in chlorothalonil and other pesticides was not quantified because data are lacking, but potential exposures are very low, and the Agency does not have dietary cancer risk concerns from HCB in water.

7. Handler Risk

Occupational and residential handler short- and intermediate term risk estimates were below an MOE of 100 for:

--mixer/loaders handling wettable powder formulations in all scenarios at baseline attire, i.e., long-sleeve shirt, long pants, shoes, and socks plus chemical-resistant gloves, no respirator (inhalation exposure)

--applicators using specialty air-assisted equipment on golf courses in all scenarios at baseline attire, i.e., long-sleeve shirt, long pants, shoes, and socks plus chemical-resistant gloves, no respirator (dermal exposure),

--mixer/loaders and applicators using tractor-drawn spreaders to apply granular products to turf (inhalation exposure),

--residential applicators using granular formulations and low pressure hand wands on turf (primarily dermal exposures and some inhalation exposure), and

--professional painters applying chlorothalonil-containing paint with airless sprayers (inhalation exposures).

Risk estimates for these handlers exceed the Agency's levels of concern. Additionally, the inhalation MOE was below 100 (82) for mixer/loaders using closed systems for pressure-treatment of wood with products containing chlorothalonil. This assessment was based on assumptions and data derived from similar use scenarios. The magnitude of the inhalation risk estimate associated with a closed system is counterintuitive. The Agency concluded that a more refined risk assessment was needed, and is requiring data to refine it as described in Chapter V.

Occupational and residential cancer risk estimates (using the Q_1*) exceeded levels which typically are of concern for:

--mixer/loaders handling wettable powder formulations to support aerial and chemigation applications wearing baseline attire and chemical-resistant gloves, and

--residential handlers using granular formulations and low pressure hand wands on turf.

8. Post-application risk

Post-application short- and intermediate-term risk estimates for workers reentering sodfarm areas to cut, roll, and harvest treated turf exceed the Agency's level of concern. For workers re-entering treated sod farm areas for these hand-labor tasks, the short- and intermediate MOE = 39.

Post-application occupational cancer risk estimates (using the MOE approach) for workers re-entering treated areas to cut and maintain flowering plants and cut flowers were MOE

= 16. The Agency has not yet determined whether the MOE approach is valid for chlorothalonil cancer risk assessment or an appropriate MOE at which to regulate cancer risk, but discussions on that regulatory level have centered on MOEs of 100 or above. It seems likely that if the MOE approach is adopted, risks of this magnitude would be of concern. In the interim, the Agency seeks information on use patterns in the flowering plant and cut flower industry in order to determine whether post-application exposures meet criteria for assessment under the MOE approach.

For residential post-application exposures related to the use of chlorothalonil on turf and ornamentals, short- and intermediate-term MOEs ranged from 14 to 26,000. MOEs for toddlers exposed to treated turf were below the level which the Agency believes is protective of human health. Residential cancer risks for post-application exposure (Q*, adults only) to treated ornamentals and turf were below the level the Agency typically considers to be of concern.

All other assessed occupational and residential risk estimates for chlorothalonil and HCB were below the levels the Agency typically considers to be of concern.

Mitigation of occupational and residential risks: To protect occupational handlers of pesticides containing chlorothalonil, the registrants have agreed that:

--wettable powder formulations must be packaged in water soluble bags or labeled for use only in closed mixing/loading systems,

--mixer/loaders and applicators using tractor drawn spreaders to apply granular formulations to turf must wear dust masks,

--applicators using specialty air-assisted application equipment on turf must wear chemical- resistant gloves in addition to baseline attire,

--painters using airless sprayers should wear respirators,

-workers who reenter treated areas after the restricted-entry interval but within 7 days of treatment must receive special notification about eye irritation hazards and have access to on-site eye-flushing equipment, and

--for some scenarios assessed in this document, handler risk was determined to be acceptable when the assessment was based on handlers wearing chemical-resistant gloves (for dermal risk) or respirators (for inhalation risk). For the associated use patterns, handlers must wear chemical-resistant gloves as worn in exposure scenarios resulting in acceptable dermal risk in this risk, and handlers must wear respirators as worn in exposure scenarios resulting in acceptable inhalation risk. The correct type of respirator must be designated on product labels in accordance with Pesticide Registration Notice 98-9. These use patterns are:

--for mixing/loading wettable powder formulations (chemical-resistant gloves)

--for mixing/loading liquid flowable formulations (chemical-resistant gloves)

--for mixing/loading dry flowable formulations (gloves)

--for applications using handheld equipment (chemical-resistant gloves)

--for applications in enclosed areas (respirator)

-- for applying paint using sprayers (respirator)

No data are available to assess exposures to handlers applying chlorothalonil with an ignitable fogger (smoke generator) product or to workers who may be exposed to residues post-application, so the Agency relied on experience with other chlorothalonil products and other smoke generators and fumigants to devise an appropriate risk control strategy. The Agency's determination of appropriate control measures was based on the logic described below.

Even though dermal exposure to handlers was not assessed in this document, the Agency has concluded that some dermal exposure -- particularly to the hands and forearms -- is possible, since there are opportunities for dermal contact with the chlorothalonil during the lighting of the canisters (e.g., opening the canisters, lighting the content, spilling contents) and during removal of the canisters following application (e.g., residue on canister, spilling contents of unlit canister). Therefore, chemical-resistant gloves should be worn by handlers in addition to the baseline attire of long-sleeve shirt, long pants, socks, and shoes.

Inhalation exposure and risk was not assessed in this document. However, based on the use pattern, there is concern for inhalation of the smoke generated by the product in addition to concern about inhalation of chlorothalonil in the smoke. Therefore, EPA has determined that a respirator is warranted during application and during any entry, including entry to operate ventilation equipment, that occurs before full ventilation (see below) has taken place. Possible inhalation exposures to handlers (e.g., applicators and persons entering the treated greenhouse to monitor air levels or operate ventilation equipment) would be predicated on the length of time the handler is exposed. A full-face organic-vapor-removing respirator with a dust/mist prefilter should adequately mitigate risks for brief exposure periods, such as routine application or entry to operate ventilation equipment. However, for longer exposure periods, such as in very large greenhouses or other situations where handler activities exceed approximately 10 minutes of exposure, EPA has concluded that an air-supplied respirator is the prudent choice. The specific conditions for which different types of respirators are required are detailed in Chapter V.

Since no exposure or risk assessment is possible due to lack of data, the Agency is requiring additional risk mitigation measures for handlers consistent with the WPS. These measures are detailed in Chapter V.

No post-application inhalation exposure or risk assessment was performed for entry following smoke generator applications. However, based on the low vapor pressure of chlorothalonil, EPA concludes that ventilation of sufficient duration could adequately mitigate reentering workers' inhalation exposures and risks following smoke generator applications. Once appropriate ventilation has occurred, EPA has no reason to conclude that inhalation exposures to reentering workers would exceed those following other greenhouse applications, such as

backpack applications. The WPS establishes generic entry restrictions when applied pesticides are applied as a smoke in a greenhouse. the special labeling instructions for smoke generator products in PR Notice 93-7 further describes these restrictions. These restrictions are detailed in Chapter V.

No post-application dermal exposure or risk assessment was performed for entry following smoke generator applications. However, EPA believes that postapplication dermal exposures following other greenhouse applications, such as backpack applications, would be a reasonable surrogate for dermal exposures following smoke generator applications. Therefore, EPA will establish the same restricted-entry interval for smoke generator applications as for other applications in greenhouses.

In the absence of data, as a prudent safety measure, and because of the level of detail involved with complying with the restrictions cited above, EPA is requiring the following additional restrictions for smoke generator products containing chlorothalonil.

Ignitable foggers (smoke generator) products containing chlorothalonil must be designated at Restricted Use Products. EPA is prohibiting their use in residential and other noncommercial greenhouses. EPA is prohibiting applications to greenhouses that are attached to structures where persons must be present during the application *unless* the greenhouse is entirely sealed off from the attached structure, and someone must maintain constant visual or voice contact with any handler who is applying or otherwise handling the smoke generator product in a greenhouse.

To protect residential handlers of pesticides containing chlorothalonil and children who are exposed to chlorothalonil after application of chlorothalonil to home lawns, the registrants have agreed that products containing chlorothalonil are prohibited for use on home lawns.

To protect reentry workers who cut, roll, and harvest sod treated with chlorothalonil, the registrants have agreed that sod treated with chlorothalonil must be harvested, rolled, and palletized mechanically.

Other residential risks could not be quantified, but risk concerns and uncertainties about exposure resulted in the following agreements with registrants:

To mitigate concerns about the packaging and concentration of chlorothalonil additives for paint, the registrants have agreed that chlorothalonil mildewicidal additives must be labeled to prohibit sale over-the-counter in retail outlets. The registrants have committed to working with the Agency to develop measures for the protection of employees of paint sales outlets who mix mildewicidal additives into paint for sale.

To mitigate concerns about the in-container preservative use of chlorothalonil, particularly because the chlorothalonil content of products in which the preservative is used may not be known to the purchaser, and because such preservatives may be used in paints intended for use by children, the registrants have agreed that the in-container preservative use of chlorothalonil is prohibited.

9. Ecological Risk

Levels of concern were exceeded for a number of crops, including peanuts and potatoes. In addition, many chlorothalonil labels do not provide specific application rate maximums. To protect wildlife, the registrants have agreed to some application rate reductions and to specify total seasonal maximum application rates on all labels. The new application regimens are detailed in Table 71 below.

Table 71. Maximum allowable application rates for chlorothalonil products

Site	Maximum individual application rate in lbs ai/A (minimum retreatment interval in days) = maximum seasonal total in lbs ai/A/season
Bean (snap)	2.25(7) = 9
Bean (dry)	1.5 (7) = 6
Blueberry	3.0 (10) = 9
Carrot	1.5 (7) = 15
Celery	2.25 (7) = 18
Cole crops	1.5 (7) = 12
Conifers	4.1 (28 or 7 for seed beds only) = 16.5
Corn (sweet & grown for seed)	1.5 (7) = 9
Cranberry	5.0 (10) = 15
Cucurbit	2.25 (7) = 15.75
Filberts	3 (14) = 9
Golf course:	
greens	11.3 (14) + 7.3 (7) = 73
tees	11.3 (14) + 7.3 (7) = 52
fairways	11.3 (1 application) + 7.3 (7) = 26
Grass grown for seed	1.5 (14) = 4.5
Mint	1.0 (7) = 3
Ornamentals	1.55 (7) = 36.4 (seasonal maximum applies to field-grown only)
roses	1.1 (7) = 36.4 (seasonal maximum applies to field-grown only)
pachysandra	3.1 (7) = 36.4 (seasonal maximum applies to field-grown only)
Onion (dry bulb) and garlic	2.25 (7) = 15
Onion, green; leek, shallot, onion grown for seed	2.25 (7) = 6.7
Papaya	2.25 (14) = 6.75
Parsnip	1.5 (7) = 6
Passion fruit	1.5 (14) = 7.5

Site	Maximum individual application rate in lbs ai/A (minimum retreatment interval in days) = maximum seasonal total in lbs ai/A/season
Peanut	1.125 (14) = 9
Potato	1.125 (5) = 11.25
Sod farm	11.3 (one application) + 7.3 (7) = 26
Soybean	1.8 (14) = 4.5
Stone fruits including cherries	3.1 (10) = 15.5
Tomato	2.16 (7) = 15.1
Turf (general)	11.3 (one application) + 8.2 (7) = 26

The registrants have agreed that buffers are required between estuarine/marine water bodies and agricultural crops treated with chlorothalonil--at least 150 feet for aerial and air-blast applications and 25 feet for ground applications.

10. Water resources

To protect water resources, the registrants have agreed that:

--manufacturing-use product labels must contain required Environmental Hazard Statements,

--end-use product labels must prohibit application to surface waters and contamination of water with equipment washwater, and

--surface water and groundwater label advisories are required on end-use product labels.

11. Food Quality Protection Act Findings

Determination of Safety for US Population

EPA has determined that the established tolerances for chlorothalonil, with the amendments and changes specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, that there is a reasonable certainty of no harm for the general population. In reaching this determination, EPA has considered the available information on the aggregate exposures (both acute and chronic) from non-occupational sources, food and drinking water, as well as the possibility of cumulative effects from chlorothalonil and other compounds that may have a similar mechanism of toxicity.

The Agency has determined that some application methods for residential application of chlorothalonil to home lawns pose unacceptable risks. Based on the available information, post-

application exposure of toddlers through dermal contact with treated lawns also poses unacceptable risks. Consequently, the registrants have agreed that the home lawn use of chlorothalonil will be prohibited on manufacturing-use product labels, that the use will be deleted from end-use product labels, and products registered solely for home lawn use will be voluntarily canceled. The aggregate risk estimate for chlorothalonil, with the elimination of this and other uses and restrictions imposed through this RED, does not appear to exceed the Agency's level of concern. Because chlorothalonil and several other pesticides are contaminated with HCB, EPA has also considered potential for aggregate exposure and risk to HCB. The Agency has concluded that the carcinogenic risk associated with HCB may exceed acceptable levels and that it is prudent to reduce the HCB content of chlorothalonil. The registrants have agreed to lower their contribution to the total by reducing concentrations of HCB in chlorothalonil to the level that has been shown previously to be technologically feasible. The Agency is also pursuing the reduction of HCB and the related contaminant PCB in other pesticides.

Determination of Safety for Infants and Children

EPA has determined that the established tolerances for chlorothalonil, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCA, and that there is a reasonable certainty of no harm for infants and children through dietary exposure. The safety determination for infants and children considers the factors noted above for the general population, but also takes into account the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of chlorothalonil residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from chlorothalonil residues, EPA considered the completeness of the database for developmental and reproductive effects, the nature of effects observed, and other information.

Based on current data requirements, chlorothalonil has a complete data base for developmental and reproductive toxicity. Reliable studies cited earlier in this document indicate no special sensitivity of young organisms to chlorothalonil. No evidence of an increased sensitivity to young rat or rabbits was seen following *in utero* and post-natal exposures to chlorothalonil. In the developmental toxicity study with rats, developmental toxicity occurred at a dose which also produced maternal toxicity. In the developmental toxicity with rabbits, no maternal or developmental toxicity was observed at the highest dose tested. In the rat two-generation study, parental toxicity was observed at the lowest dose tested while no toxicity to the offsprings was seen even at the highest dose tested. Additionally, there is no indication of increased susceptibility in the prenatal developmental toxicity studies in rabbits or the two-generation reproduction study in rats following exposure to the metabolite SDS-3701. The contaminant HCB was not considered in this evaluation.

The Agency concludes that the 10x Safety Factor for enhanced sensitivity to infants and children (as required by FQPA) for chlorothalonil should be removed.

In deciding to continue to make reregistration determinations during the early stages of FQPA implementation, EPA recognizes that it will be necessary to make decisions relating to FQPA before the implementation process is complete. In making these early, case-by-case decisions, EPA does not intend to set broad precedents for the application of FQPA to its regulatory determinations. Rather, these early decisions will be made on a case-by-case basis and will not bind EPA as it proceeds with further policy development and rulemaking that may be required.

If EPA determines, as a result of this later implementation process, that any of the determinations described in this RED are no longer appropriate, the Agency will consider itself free to pursue whatever action may be appropriate, including but not limited to, reconsideration of any portion of this RED.

Endocrine Disrupter Effects

EPA is required to develop a screening program to determine whether certain substances (including pesticides and inerts) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other endocrine effect..." The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed three years from the passage of FQPA (August 3, 1996) to implement this program. At that time, EPA may require further testing of this active ingredient and end-use products for endocrine disrupter effects.

12. Tolerance Reassessment

Tolerance Reassessment Summary

The tolerances listed in 40 CFR §180.275(a) are for the combined residues of chlorothalonil and SDS-3701. Sufficient data are available to ascertain the adequacy of the established tolerances for: apricots; asparagus; bananas; beans, dry; beans, succulent; blueberries; broccoli; Brussels sprouts; cabbage; carrots; cauliflower; celery; cherries; cocoa beans; coffee beans; corn, sweet (K + CWHR); cranberries; cucumbers; melons; mushrooms; nectarines; onions, dry bulb; papaya; parsnips, roots; passion fruit; peaches; peanuts; plums; potatoes; prunes; pumpkins; soybeans; squash, summer; squash, winter; and tomatoes.

The available field trial data indicate that the established tolerance for green onions is too low. A higher tolerance is necessary.

Tolerances must be proposed for the combined residues of chlorothalonil and its 4-hydroxy metabolite in/on sweet corn forage. Available field trial residue data indicate that a level of 65 ppm would be appropriate.

New tolerances for the combined residues of chlorothalonil and SDS-3701 have recently been established for asparagus (0.1 ppm, PP#2E04042; proposed rule, PR Notice dated 6/19/96, pp 31073-31075), blueberries (1 ppm, PP#0E3899; FR dated 3/13/96, pp.10280-10282), filberts

(0.1 ppm, PP#2E04113; FR dated 3/13/96, pp. 10280-10282), and mushrooms (1 ppm, PP#6E03410;FR dated 3/13/96, pp. 10280-10282). Tolerances for the combined residues of chlorothalonil and SDS-3701 have been proposed for almonds (0.05 ppm, PP#3F02875), almond hulls (0.2 ppm, PP#3F02875), mangoes (1 ppm, PP#2E04018), and pecans (0.02 ppm, PP#7F03471). In addition, the registrant has proposed a new tolerance for peaches (3 ppm, PP#3F2815), and new tolerances for cherries (PP#5F03183) at 0.5 ppm for sweet cherries (the current tolerance) and 3 ppm for sour cherries to support a proposed amended use which would allow applications after shuck split.

Efforts are being made to obtain a tolerance for residues of chlorothalonil in/on snowpeas since chlorothalonil is used on snowpeas grown in Guatemala. FDA monitoring data from 93 samples of snowpeas imported from Guatemala during 1992 showed detectable residues in/on 48 samples with an average residue of 0.036 ppm and a high residue of 0.9 ppm (CBTS No. 11929, DP Barcode D191687, 8/16/93, M. Flood).

Tolerances have been proposed (PP#6F4611) for residues of SDS-3701 in milk (0.1 ppm), fat (0.1 ppm), kidney (0.5 ppm), meat byproducts except kidney (0.05 ppm) and meat (0.03 ppm) for cattle, goats, sheep, hogs, and horses.

The tolerances with regional registrations listed in 40 CFR §180.275(b) are for the combined residues of chlorothalonil and SDS-3701. Sufficient data are available to ascertain the adequacy of the established tolerances for mint hay and filberts.

No food/feed additive tolerances are required for the combined residues of chlorothalonil and SDS-3701.

Table 72 summarizes the tolerance reassessment for chlorothalonil.

Table 72. Tolerance Reassessment Summary for Chlorothalonil

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Tolerances listed under 40 CFR 180.275(a):			
Apricots	0.5	0.5	
Asparagus	0.1	0.1	
Bananas (NMT 0.05 ppm in edible pulp)	0.5	0.5 0.05	*Bananas* *Bananas, pulp*
Beans (dry)	0.1	0.1	*Beans, dry*
Beans, snap	5	5	*Beans, succulent*
Blueberries	1	1	
Broccoli	5	5	
Brussels sprouts	5	5	
Cabbage	5	5	
Carrots	1	1	
Cauliflower	5	5	
Celery	15	15	
Cherries (sweet and sour)	0.5	0.5	
Cocoa beans	0.05	0.05	
Coffee beans	0.20	0.20	*Coffee beans, green*
Corn, sweet (K - CWHR)	1	65	*Corn, sweet (K + CWHR)*
Cranberries	5	5	
Cucumbers	5	5	
Melons	5	5	
Mushrooms	1	1	
Nectarines	0.5	0.5	
Onions, dry bulb	0.5	0.5	
Onions, green	5	to be determined	Either a higher tolerance is necessary or the PHI must be increased.
Papayas	15	15	
Parsnips (root)	1	1	*Parsnips, roots*
Passion fruit	3	3	
Peaches	0.5	0.5	
Peanuts	0.3	0.3	

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Plums	0.2	0.2	
Potatoes	0.1	0.1	
Prunes	0.2	0.2	*Prunes, fresh*
Pumpkins	5	5	
Soybeans	0.2	0.2	
Squash, summer	5	5	
Squash, winter	5	5	
Tomatoes	5	5	
Tolerances listed under 40 CFR 180.275(b):			
Filberts	0.1	0.1	
Mint hay	2	2	
Tolerances to be established under 40 CFR 180.275(a):			
Corn, field, grain		0.05	
Corn, field, fodder		50	
Corn, sweet, forage		65	
Corn, sweet, fodder		50	
Peanut hay		20	
Tolerances to be established under 40 CFR 180.275(c):			
Milk		0.1	Tolerances for residues of SDS-3701 only
Fat		0.1	
Kidney		0.5	
Meat Byproducts except kidney		0.05	
Meat		0.03	

13. CODEX Harmonization

Numerous maximum residue limits (MRLs) for chlorothalonil residues in plant commodities have been established by Codex. Codex currently sets MRLs based on residues of chlorothalonil *per se* in plant commodities; the US tolerance expression is for combined residues of chlorothalonil and SDS-3701. Because the tolerance expressions for Codex MRLs and US tolerances are different, harmonization of Codex MRLs and US tolerances is not currently possible. The Codex MRLs and the applicable US tolerances are presented in Table 73. All chlorothalonil MRLs in Table 73 are final unless otherwise indicated in parentheses.

Table 73. Codex MRLs and Applicable US Tolerances

Commodity	MRL (mg/kg)	US Tolerance (ppm)
Banana	0.2 (Step 8)	0.5
Blackberries	10	--
Broccoli	5	5
Brussels sprouts	5	5
Cabbages, head	5	5
Carrot	1	1
Cauliflower	5	5
Celery	15	15
Cereal grains	0.2 (Step 8)	(0.05; field corn grain)*
Cherries	10	0.5
Citrus fruits	5	--
Common bean (pods and/or immature seeds)	5	5
Cranberry	5	5
Cucumber	5	5
Currants, black, red, white	25	--
Endive	10	--
Grapes	10 (Step 7B)	--
Kale	10	--
Lettuce, head	10	--

Commodity	MRL (mg/kg)	US Tolerance (ppm)
Lima bean (dry)	0.5	0.1
Melons, except watermelon	5	5
Onion, bulb	5	0.5
Peach	25	0.5
Peanut	0.1	0.3
Peanut, whole	0.5	0.3
Peppers	10	--
Potato	0.1	0.1
Pumpkins	5	5
Raspberries, red, black	10	--
Squash, summer	5	5
Sugar beet	1	--
Sweet corn (corn-on-the-cob)	1	1
Tomato	5	5
Winter squash	5	5
Witloof chicory (sprouts)	10	--

* A tolerance of 0.05 ppm has been proposed on corn grain.

14. Summary of Risk Management Decisions

Dietary Risk

The Agency does not have acute or chronic non-cancer dietary risk concerns for chlorothalonil or HCB in chlorothalonil. No risk mitigation is necessary to address acute or chronic non-cancer dietary risk.

The Agency has used two approaches, representing linear (Q_1* approach) and non-linear models (MOE approach), for estimating the carcinogenic risk of chlorothalonil. The Agency does not have dietary cancer risk concerns for chlorothalonil using the Q_1* approach. Issues related to the dietary cancer risk estimate under the MOE approach are not resolved.

The SAP has recommended that additional work is necessary before a definitive conclusion can be reached about the validity of the non-linear model for chlorothalonil.

Therefore, the Agency's conclusions on chlorothalonil's mechanism of carcinogenicity are not yet resolved. In addition, the non-linear model yields a measure of risk outside of our usual regulatory experience, i.e., an MOE for cancer risk. The Agency has not determined the appropriate MOE at which to regulate cancer risk.

Traditionally, most carcinogenic pesticides were believed to have a linear mechanism thought not to result in a threshold of carcinogenicity, so that risk at low levels of exposure could be readily extrapolated from the relatively high doses examined in animal carcinogenicity testing. Risk at these low levels was expressed as a probability, and the point at which the Agency became concerned about dietary risk was above 1×10^{-6} or one in a million. The Agency has estimated a carcinogenic risk of 1.2×10^{-6} for chlorothalonil.

For other, non-cancer endpoints thought to have a threshold below which adverse effects do not result, the Agency has traditionally taken the margin of exposure approach to quantifying risk. In instances where the toxicological database is complete, an effect observed in animal testing is presumed to have an adequate margin of safety in humans if the MOE is 100 or greater--a safety factor of 10 to account for intraspecies variability multiplied by another factor of 10 to account for interspecies variability. For an effect observed in humans, an MOE of 10 to account for intraspecies variability only is adequate. As discussed previously, FQPA dictates that in both cases, another safety factor of 10 can be included to account for uncertainties in the data base or increased susceptibility of children. It can be removed or reduced depending on the strength of the data base and its findings. The Agency must determine whether these same factors are adequate to protect from the dietary cancer risk associated with chlorothalonil, which has been calculated to have a dietary cancer MOE of 9500.

The Agency is concerned about dietary cancer risk associated with HCB in chlorothalonil, and more broadly, in other pesticides. These concerns are based on the carcinogenic hazard as well as uncertainties about exposure. For chlorothalonil, the Agency is requiring that HCB concentrations in all products be reduced to concentrations of 0.004% or less. This level has been identified as a level which is realistically achievable, and the Agency believes at this time that such a reduction, across the board for chlorothalonil registrations, is prudent given the uncertainty about levels of HCB exposure in the human diet.

Occupational Risk

Handlers participating in the exposure studies upon which chlorothalonil occupational risks were calculated by OPP wore chemical-resistant gloves in some scenarios and respirators in some scenarios. Occupational risks in some of the scenarios were found to be acceptable, but current labels for corresponding products in some cases do not require personal protective equipment as protective as that used in the risk assessment. Labels must be revised so that glove and respirator requirements reflect assessment parameters which were the basis of acceptable risk estimates.

The Agency has risk concerns for short- and intermediate-term occupational exposures in the following scenarios:

- for mixer/loaders, wettable powder, open bag, for aerial and chemigation applications, inhalation exposure;
- for mixer/loaders, wettable powder, open bag, for ground applications, inhalation exposure;
- for mixer/loaders and applicators using tractor-drawn spreaders to apply granular formulations to turf, inhalation exposure
- for mixer/loader/applicators (occupational use), indoor painting using an airless sprayer with interior latex paint inhalation exposure;
- for mixer/loader/applicators (occupational use), outdoor painting using an airless sprayer with exterior alkyd paint, inhalation exposure; and
- for applicators, specialty air-assisted equipment on golf courses (open cab), at higher application rates, dermal exposure.
- for mixer/loader/applicators using handheld (e.g., backpack) equipment, dermal exposure; and
- for mixers/loaders/applicators using handheld (e.g., backpack) equipment in enclosed areas, inhalation exposure.

To address the mixer/loader risk from wettable powder formulations, the Agency is requiring that all wettable powder formulations for occupational use be packaged in water soluble bags or be labeled for use in closed systems only. To address the risks associated with the use of granules applied to turf with tractor-drawn spreaders, the mixer/loaders and applicators involved in such operations are required to wear dust masks. The Agency believes that respirator requirements imposed by OSHA and captured in Material Data Safety Sheets help address the risks from the use of airless sprayers for applying chlorothalonil-containing paint, but in addition, chlorothalonil paint additives will now bear labeling on the use of respirators during painting. To address applicator risk for specialty air-assisted equipment on golf courses, the Agency is requiring that workers wear chemical-resistant gloves.

As discussed previously, this document presents, when applicable, carcinogenic risk estimates using two approaches. Carcinogenic risk estimates can be calculated using the Q* approach for any term of exposure, but for estimates using the MOE approach, exposures must be of sufficient duration to be considered chronic. The Agency believes that handlers of chlorothalonil products are not likely to be subject to chronic exposure; therefore, cancer risk

assessments were not conducted for handlers under this approach. Cancer risk can be estimated for handlers of chlorothalonil products using the Q_1* approach. The following scenario results in cancer risks of concern for occupational and residential handlers under the Q_1* approach:

For mixer/loaders, wettable powder-open bag, for aerial and chemigation applications to tomatoes and celery.

To address the mixer/loader risk from wettable powder formulations, the registrants have agreed that all wettable powder formulations for occupational use must be packaged in water soluble bags or be labeled for use in closed mixing/loading systems only.

Short- and intermediate-term occupational post-application risk estimates were calculated for a number of chlorothalonil use scenarios. The Agency has risk concerns for short- and intermediate-term occupational post-application exposures in the following scenario:

For workers reentering treated sodfarm areas to cut, roll, and harvest sod

To address these risks, the registrants have agreed that product labeling will require that sod treated with chlorothalonil be mechanically cut, rolled, and palletized.

Although the Agency believes that handlers of chlorothalonil pesticides are not likely to be chronically exposed to chlorothalonil, some workers who reenter treated areas after application may be. Occupational post-application cancer risk from chlorothalonil was calculated using both the Q* and MOE approaches for these workers. The following scenarios result in post-application cancer risks under the MOE approach:

For workers reentering treated greenhouses where cut flowers and potted ornamentals are grown for cutting, bundling, transplanting, and pruning

Although the Agency has not identified an “acceptable” level of risk for cancer under the MOE paradigm, past discussions have focused on MOEs of 100 or greater. An MOE of less than 100, as has been calculated for these scenarios, is likely to be of concern. However, the Agency lacks information to determine definitively whether post-application exposure in the cut flower scenario is sufficient to warrant a cancer risk assessment using the MOE approach. To ascertain whether cut flower worker exposure should be considered chronic exposure under the MOE paradigm, data are required on use patterns of chlorothalonil on cut flower crops, particularly in greenhouses, such as the frequency and duration of chlorothalonil applications and the variety of post-application work tasks associated with the cut flower industry and other significant greenhouse uses of chlorothalonil. These data may be supplied in part in the form of records from commercial flower production greenhouses and facilities.

The Agency has risk concerns about eye irritation for reentry workers. A 48-hour restricted-entry interval was previously established for chlorothalonil for uses covered by the

Worker Protection Standard, based on the eye irritation data for the active ingredient. In developing the reregistration risk assessment, we concluded that chlorothalonil residues do not necessarily dissipate sufficiently during this interval to eliminate our concerns. In fact, we were unable to identify a reasonable interval after which eye irritation would not be a concern. The restricted-entry interval will be modified to 12 hours and alternate means have been adopted for mitigating eye irritation risks during reentry because of the economic necessity for hand-labor tasks to be performed in relatively short intervals after treatment with chlorothalonil. Eye-irritation risks from reentry are now addressed through special notification of workers about the eye irritation hazard and a requirement for on-site eye-flushing equipment for seven days after application of chlorothalonil.

Residential/miscellaneous exposures

As noted previously, the Agency believes that handlers of chlorothalonil products are not likely to be subject to chronic exposure; therefore, cancer risk assessments were not conducted for handlers using the MOE approach. Using the Q* approach, the following scenarios result in cancer risk estimates for residential handlers that exceed levels typically considered to be of concern:

For residents applying granulars to turf with a belly-grinder.

For residents applying wettable powders to turf with low pressure hand wand.

The following scenario results in residential post-application short- and intermediate-term risk estimates that exceed levels which are typically considered by the Agency to be of concern:

For toddlers in dermal contact with turf that has been treated with chlorothalonil

The Agency is concerned about handler and post-application exposures to chlorothalonil from use on home lawns. To mitigate risks to homeowner handlers and children exposed after application, the registrants of chlorothalonil have agreed to delete the home lawn use from their manufacturing-use and end-use product labels and have requested voluntary cancellation of their end-use product registered solely for this use. Eliminating the home lawn use of chlorothalonil will also reduce overall use on turf, thereby addressing, in part, the Agency's concerns about ecological risks associated with chlorothalonil (see below).

The Agency is concerned about the use of paint additives containing chlorothalonil. These concerns are based on the packaging and concentration of chlorothalonil additives for paint, which present opportunities for significant accidental exposures. The registrants have agreed that chlorothalonil mildewicidal additives must be labeled to prohibit sale over-the-counter in retail outlets. In addition, the registrants have committed to working with the Agency to develop measures for the protection of employees of paint sales outlets who mix such additives into paint for sale.

The Agency is also concerned about in-container preservatives containing chlorothalonil, particularly because the chlorothalonil content of products in which the preservative is used may not be known to the purchaser, and because such preservatives may be used in paints intended for use by children. To mitigate concerns about the in-container preservative use of chlorothalonil, the registrants have agreed that the in-container preservative use of chlorothalonil will be explicitly prohibited on manufacturing-use product labels.

The Agency also has risk concerns related to the use of ignitable fogger (smoke generator) products containing chlorothalonil, but no data are available to quantify the risk. Based on general knowledge about chlorothalonil and other ignitable fogger products, the Agency is prescribing a detailed program of risk reduction measures for ignitable foggers containing chlorothalonil. These measures include the designation of the product as Restricted Use Pesticides, and requirements for respirators and ventilation of treated areas.

Ecological Risk Mitigation

Some chlorothalonil labels do not capture allowable maximum application rates and numbers of applications or minimum retreatment intervals, parameters which determine total seasonal application rates. The registrants have agreed that their product labels will be revised to reflect agreed-upon individual maximum application rates, minimum intervals between treatments, and maximum seasonal application rates. These commitments are detailed in Table 71 above.

The use of chlorothalonil results in risk quotients which exceed LOCs for both terrestrial and aquatic species.

Estuarine molluscs, as represented by oysters, are especially at risk. Coastal production of peanuts has a particular potential to impact these organisms. The registrants have agreed to amend product labels to require untreated buffers between treated agricultural fields and marine/estuarine water bodies--150' for aerial and air-blast applications and 25' for ground applications.

Water Resources

Chlorothalonil and its degradates have the potential to contaminate both groundwater and surface water under vulnerable circumstances. The Agency is requiring label statements on manufacturing use products citing National Pollutant Discharge Elimination System requirements. Standard requirements for end-use product labeling will prohibit application to surface waters and contamination of water with equipment washwater. Surface water and groundwater label advisories are also required.

Occupational and Residential Labeling Rationale/Risk Mitigation

The Worker Protection Standard (WPS): The 1992 Worker Protection Standard for

Agricultural Pesticides (WPS) established certain worker-protection requirements (personal protective equipment, restricted-entry intervals, etc.) to be specified on the label of all products that contain uses within the scope of the WPS. Uses within the scope of the WPS include all commercial (non-homeowner) and research uses on farms, forests, nurseries, and greenhouses to produce agricultural plants (including food, feed, and fiber plants, trees, turf grass, flowers, shrubs, ornamentals, and seedlings). Uses within scope include not only uses on plants, but also uses on the soil or planting medium the plants are (or will be) grown in.

At this time some of the registered uses of chlorothalonil are within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS). Uses that are outside the scope of the WPS include golf course and homeowner uses.

Personal Protective Equipment for Handlers (Mixers, Loaders, Applicators, etc.): For each end-use product, PPE requirements for pesticide handlers are set during reregistration in one of two ways:

1) If EPA determines that no regulatory action must be taken as the result of the acute effects or other adverse effects of an active ingredient, the PPE for pesticide handlers will be based on the acute toxicity of the end-use product. For occupational-use products, PPE must be established using the process described in PR Notice 93-7 or more recent EPA guidelines.

2) If EPA determines that regulatory action on an active ingredient must be taken as the result of very high acute toxicity or certain other adverse effects, such as allergic effects or systemic effects (cancer, developmental toxicity, reproductive effects, etc.):

- In the RED for that active ingredient, EPA may establish minimum or "baseline" handler PPE requirements that pertain to all or most end-use products containing that active ingredient.
- These minimum PPE requirements must be compared with the PPE that would be designated on the basis of the acute toxicity of the end-use product.
- The more stringent choice for each type of PPE (i.e., bodywear, hand protection, footwear, eyewear, etc.) must be placed on the label of the end-use product.

Personal protective equipment requirements usually are set by specifying one or more pre-established PPE units -- sets of items that are almost always required together. For example, if chemical-resistant gloves are required, then long-sleeve shirts, long pants, socks, and shoes are assumed and are also included in the required minimum attire.

Occupational-Use Products

WPS and NonWPS Uses: EPA's evaluation of the dermal and inhalation toxicity of chlorothalonil indicates that significant toxicity from either route of exposure occurs in some situations. These uses are addressed in this document with specific personal protective equipment

or engineering-control requirements. As a result of this evaluation, the Agency has determined that risks to handlers, for both WPS and non-WPS uses, do not warrant the establishment of active-ingredient-based minimum personal protective equipment or engineering-control requirements that would apply to all chlorothalonil end-use products.

Homeowner-Use Products

EPA is not establishing minimum (baseline) handler PPE for chlorothalonil end-use products that are intended primarily for homeowner use. Any PPE for homeowners will be based on the acute toxicity of the specific end use product.

Post-Application/Entry Restrictions

Restricted-Entry Interval for WPS Uses: Under the WPS, interim restricted-entry intervals (REI's) for all uses within the scope of the WPS are based on the acute toxicity of the active ingredient. The toxicity categories of the active ingredient for acute dermal toxicity, eye irritation potential, and skin irritation potential are used to determine the interim WPS REI. If one or more of the three acute toxicity effects are in toxicity category I, the interim WPS REI is established at 48 hours. If none of the acute toxicity effects are in category I, but one or more of the three is classified as category II, the interim WPS REI is established at 24 hours. If none of the three acute toxicity effects are in category I or II, the interim WPS REI is established at 12 hours. A 48-hour REI is increased to 72 hours when an organophosphate pesticide is applied outdoors in arid areas. In addition, the WPS specifically retains two types of REI's established by the Agency prior to the promulgation of the WPS: (1) product-specific REI's established on the basis of adequate data, and (2) interim REI's that are longer than those that would be established under the WPS.

During the reregistration process, EPA considers all relevant product-specific information to decide whether there is reason to shorten or lengthen the previously established REI.

During the reregistration process, EPA determined that the restricted-entry interval for all occupational-use products that contain chlorothalonil and are within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS) should be 12 hours. The basis for this decision is that chlorothalonil is a severe eye irritant and residues do not appreciably dissipate even during a 48-hour period after application. However, the Agency has determined that additional protective measures must be taken to protect reentry workers from eye irritation. These measures do not take the form of additional early-entry PPE, but rather special notification about eye irritation hazards and access to on-site eye-flushing equipment for workers entering treated areas after the restricted-entry interval but within seven days of treatment.

Early-Entry PPE: The WPS establishes very specific restrictions on entry by workers to areas that remain under a restricted-entry interval, if the entry involves contact with treated surfaces. Among those restrictions are a prohibition of routine entry to perform hand labor tasks and a

requirement that personal protective equipment be worn. Under the WPS, these personal protective equipment requirements for persons who must enter areas that remain under a restricted-entry interval are based on the acute toxicity category of the active ingredient.

During the reregistration process, EPA considers all relevant product-specific information to decide whether there is reason to set personal protective equipment requirements that differ from those set through the WPS.

The RED requirements for early-entry personal protective equipment are set in one of two ways:

1. If EPA determines that no regulatory action must be taken as the result of the acute effects or other adverse effects of an active ingredient, it establishes the early-entry PPE requirements on the basis of the acute dermal toxicity category, skin irritation potential category, and eye irritation potential category of the active ingredient.

2. If EPA determines that regulatory action on an active ingredient must be taken as the result of very high acute toxicity or to certain other adverse effects, such as allergic effects or delayed effects (cancer, developmental toxicity, reproductive effects), it may establish early-entry PPE requirements that are more stringent than would be established otherwise.

Reentry Provisions: For chlorothalonil, the Agency has determined that additional protective measures must be taken to protect reentry workers from eye irritation. These measures do not take the form of additional early-entry PPE, but rather special notification about eye irritation hazards and access to on-site eye-flushing equipment for reentry within 7 days of treatment. These measures are captured on product labeling.

WPS Double Notification Statement: "Double" notification is the statement on the labels of some pesticide products requiring employers to notify workers about pesticide-treated areas orally as well as by posting of the treated areas. The interim WPS "double" notification requirement is imposed if the active ingredient is classified as toxicity category I for acute dermal toxicity or skin irritation potential. The double notification requirement has not been adopted for chlorothalonil.

Endangered Species Statement

The Endangered Species Protection Program is expected to become final at sometime in the future. Limitations in the use of chlorothalonil may be required at that time to protect endangered and threatened species, but these limitations have not been defined and may be formulation-specific. EPA anticipates that a consultation with the Fish and Wildlife Service may be conducted in accordance with the species-based priority approach described in the Program. After completion of the consultation, registrants will be informed if any required label modifications are necessary. Such modifications would most likely consist of a generic label statement referring pesticide users to use limitations contained in county bulletins.

Spray Drift Management

The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation to develop the best spray drift management practices. The Agency is now requiring interim measures that must be placed on product labels/labeling as specified in Section V. Once the Agency completes its evaluation of the new data base submitted by the Spray Drift Task Force, whose membership consists of U.S. pesticide registrants, the Agency may impose further refinements in spray drift management practices to further reduce off-target drift and risks associated with this drift.

V. ACTIONS REQUIRED OF REGISTRANTS

This section specifies the conditions (data requirements, label changes, and other responses) necessary for the reregistration of both manufacturing-use and end-use products.

A. Additional Generic Data Requirements

The generic data base supporting reregistration of chlorothalonil for the eligible uses has been reviewed and determined to be substantially complete. In order to confirm certain assumptions upon which the eligibility decision is based, some confirmatory data are required.

Post-application/reentry exposure studies are required as confirmatory data to determine definitive REIs for all cole crops and cut flower crops. The interim REIs established in this document for these crops will be adjusted accordingly upon submission of the additional data. In addition, post-application/reentry exposure studies are required for reregistration of uses on golf courses. Requirements for such post-application exposure studies are addressed by Subdivision K of the Pesticide Assessment Guidelines. The required data include foliar residue dissipation, post-application dermal passive dosimetry exposure, and post-application inhalation passive dosimetry exposure.

Residue data have been submitted in support of establishing a tolerance on sweet corn forage and are currently under review. These data are required as a result of changes to the livestock feeds table (Table II) in Subdivision O of the Pesticide Assessment Guidelines, and therefore should not delay a reregistration eligibility decision for chlorothalonil. Additional storage stability information to support residue studies is required; however, this information is expected to be confirmatory to our conclusion that chlorothalonil residues of concern are stable under frozen storage.

Table 74. Guideline Studies Required Pursuant to this RED

Guideline #	Study Title
72-3 (d-f)	Acute marine/estuarine fish, mollusk, and shrimp; testing w/formulated product
72-4(a)	Fish early life stage

123-2	Aquatic plant growth in *Lemna gibba*
132-1(a)	Foliar residue dissipation
133-3*	Post-application dermal passive dosimetry exposure
133-4*	Post-application inhalation passive dosimetry exposure

*****Guidelines 133-3 and 133-4 are reserved at this time pending completion of the databases on agricultural and residential post-application/reentry exposure currently being developed by the Agricultural Reentry Task Force and Outdoor Residential Exposure Task Force.

B. Special Studies

There are few data addressing handler exposure when treating residential turf. The registrant is a member of the Outdoor Residential Exposure Task Force (ORETF). Data for mixer/loader/applicator treating turfgrass with chlorothalonil were required in a DCI issued in March 1995 for products registered on turfgrass (3/31/95) and are due to be submitted in October 1999. These data will be used to re-evaluate chlorothalonil handler exposure when they are submitted by the Task Force.

To address the uncertainty in the risk assessment for cut flower and ornamental plant workers reentering treated areas, particularly whether such exposure should be considered chronic exposure, data on use patterns of chlorothalonil on cut flower crops and other ornamental plants which require frequent maintenance (such as the poinsettia production facility assessed in this document), particularly those grown in greenhouses, are required. Data are needed on the frequency and duration of chlorothalonil applications and the variety, frequency, and duration of post-application work tasks associated with the cut flower industry and the production of other ornamental plants which require frequent maintenance. These data can be supplied in part in the form of records from commercial flower/ornamental production facilities and greenhouses.

Data are needed to assess risks to workers engaged in pressure treatment of wood with chlorothalonil-containing products. These data include details of the particular application system used, volume of chlorothalonil applied per treatment and per day, amount of wood treated, size of the retort, and factors in the potential exposure of workers opening and closing and removing treated wood from the retort. Chemical-specific exposure data obtained from studies, if available, will be particularly helpful.

Information is needed on potential occupational post-application exposures associated with pressure treated wood, particularly how workers who cut and build with such wood might be exposed and the amount of wood handled per day.

Information is also needed on the potential exposure to occupational and residential handlers who treat wood by dipping it into wood preservative or stain containing chlorothalonil or who apply these materials with a roller. This information must cite reasonable assumptions or

estimates of how much stain/preservative is handled per day and data on exposure levels from dipping and using a roller.

C. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The product specific data requirements are listed in Appendix E, the Product Specific Data Call-In Notice.

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria (Appendix E; Attachment E) and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

D. Labeling Requirements for Manufacturing-Use Products

Table 75. Required Labeling Changes for Manufacturing-Use Products Containing Chlorothalonil

Description	Required Labeling	Placement
Environmental Hazards Statements	"Environmental Hazards This pesticide is toxic to fish and wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	Precautionary Statements, below or after the Hazards to Humans and Domestic Animals sections

Description	Required Labeling	Placement
One of these statements may be added to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	"Only for formulation into a [fill blank with fungicide, mildewicide or other applicable term which describes the type of pesticide use(s)] for the following use(s) [fill blank only with those uses that are being supported by the MP registrant]."	Directions for Use
	"This product may be used to formulate product for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with the U.S. EPA submission requirements regarding support of such use(s)."	
	"This product may be used to formulate product for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with the U.S. EPA submission requirements regarding support of such use(s)."	
For product to be formulated into WP formulations	"This product may only be used to manufacture wettable powder formulations that 1) are packaged in water-soluble packets the outside of which contain a pictogram depicting that users should not cut, rip, or tear, or 2) bear the labeling "For use in closed mixing/loading systems only".	Directions for Use
This statement prohibits the formulation of chlorothalonil into products to be used on home lawns	"This product must not be formulated into products labeled for use on home lawns."	Directions for Use

Description	Required Labeling	Placement
This statement prohibits the formulation of chlorothalonil into mildewicidal additive products packaged for, or offered for, over-the-counter sale	"This product must not be formulated into a product intended as a mildewcidal paint additive designed for direct sale to retail customers, e.g., in a 'pillow pack' or other small volume or one-use package."	Directions for Use
This statement prohibits the use of mildewicidal additive products in paints that do not contain certain respirator labeling.	This product may only be formulated into mildewicidal paint additive products that are labeled as follows: "This product may only be added to paint products that are labeled A) with product-specific instructions for the use of a respirator during application, or B) as follows 'When applying with a sprayer, wear a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C), or a NIOSH approved respirator with any R, P, or HE filter. If oil is not present in the paint product or recommended for use as an additive in the paint product, add "N" as an additional respirator type.'"	Directions for Use
This statement prohibits the formulation of chlorothalonil into in-container preservative products.	"This product must not be used to formulate products for use as in-container preservatives."	Directions for Use

E. Labeling Requirements for End-use Products

The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR 156.10 and other applicable notices. All end-use product labels [e.g. multiple active ingredient (MAI) labels, SLN's, and products subject to generic data exemption] must be amended such that they are consistent with the basic producer labels.

Table 76. Required Labeling Changes for End-Use Products Containing Chlorothalonil

Description	Required Labeling	Placement
End-Use Products Intended for Occupational Use (WPS and Non-WPS)		
Restricted Use Statement for smoke generator products containing chlorothalonil	"Restricted Use Pesticide based on potential risks to applicators and workers exposed post-application"	At top of front panel and again at beginning of Directions for Use
Determining PPE labeling requirements for end-use products containing this active ingredient	The PPE, if any, that would be established on the basis of the acute toxicity category of each end-use product must be compared to the active-ingredient specific personal protective equipment specified below. The more protective PPE must be placed on the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7. PPE Requirements for **sole-active-ingredient** end-use products that contain chlorothalonil: The product labeling must be revised to adopt the handler personal protective equipment and/or engineering control requirements set forth in this section. Any conflicting PPE requirements on the current labeling must be removed. PPE Requirements for **multiple-active-ingredient** end-use products that contain chlorothalonil: The handler personal protective equipment and/or engineering control requirements set forth in this section must be compared to the requirements on the current labeling and the more protective must be retained. For guidance on which requirements are considered more protective, see PR Notice 93-7.	Precautionary Statements under Hazards to Humans and Domestic Animals

Description	Required Labeling	Placement
PPE requirements for wettable powder formulations	“Mixers, loaders, applicators and all other handlers must wear: --long-sleeve shirt and long pants, and --shoes plus socks. In addition, chemical-resistant gloves* must be worn by: (1) mixers/loaders, (2) other handlers exposed to the concentrate, (3) cleaners/repairers of equipment, (4) applicators using airblast equipment for golf course applications, (5) and applicators using handheld equipment. In addition, a dust/mist filtering respirator** must be worn by (1) mixers/loaders, (2) others exposed to the concentrate, and (3) applicators and other handlers in enclosed areas, such as a greenhouse. ” *For the glove statement, use the statement established for chlorothalonil through the instructions in Supplement Three of PR Notice 93-7. ** The type of respirator must be specified as: "a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C), or a NIOSH-approved respirator with any R, P, or HE filter.’ If oil is not present in the product or recommended for use as an additive/diluent to the product, add "N” as an additional respirator type.	Precautionary Statements under Hazards to Humans and Domestic Animals

Description	Required Labeling	Placement
PPE requirements for dry flowable, and liquid flowable formulations	“Mixers, loaders, applicators and all other handlers must wear: --long-sleeve shirt and long pants, and --shoes plus socks. In addition, chemical-resistant gloves* must be worn by: (1) mixers/loaders, (2) other handlers exposed to the concentrate, (3) cleaners/repairers of equipment, (4) applicators using airblast equipment for golf course applications, (5) and applicators using handheld equipment. In addition, a dust/mist filtering respirator** must be worn by applicators and other handlers in enclosed areas, such as a greenhouse. ” *For the glove statement, use the statement established for chlorothalonil through the instructions in Supplement Three of PR Notice 93-7. **The type of respirator must be specified as: a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C), or a NIOSH-approved respirator with any R, P, or HE filter.’ If oil is not present in the product or recommended for use as an additive/diluent to the product, add "N” as an additional respirator type. ”	Precautionary Statements under Hazards to Humans and Domestic Animals

Description	Required Labeling	Placement
PPE requirements for products formulated as a smoke generator	Applicators and other handlers must wear: -- long-sleeve shirt and long pants, -- shoes plus socks, -- chemical-resistant gloves,* and -- a respirator of a type as specified below. A full-face organic-vapor-removing respirator with a prefilter** is required for handlers lighting 3 canisters or less per application and for handlers who remain in the treated area before full ventilation has taken place for 10 minutes or less. A self-contained breathing apparatus is required for any handler lighting more than 3 canisters per application or any handler (i.e., persons entering to operate ventilation equipment) remaining in the treated area before full ventilation has taken place for longer than 10 minutes at a time. *For the glove statement, use the statement established for chlorothalonil through the instructions in Supplement Three of PR Notice 93-7. ** The type of respirator must be specified as: a respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefic TC-14G), or a NIOSH-approved respirator with an organic vapor cartridge or canister with any R, P, or HE filter.' If oil is not present in the product or recommended for use as an additive/diluent to the product, add "N" as an additional respirator type. "	Precautionary Statements under Hazards to Humans and Domestic Animals

Description	Required Labeling	Placement
PPE requirements for paint additive products that contain chlorothalonil as a mildewicide	"When applying paints containing this product with a sprayer, painters should wear a respirator*." *If the paint product does not already recommend/require a respirator for sprayer applications, the respirator statement on the paint product must be: 'When applying with a sprayer should wear a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C), or a NIOSH approved respirator with any R, P, or HE filter.' If oil is not present in the paint product or recommended for use as an additive in the paint product, add "N" as an additional respirator type. "	Precautionary Statements under Hazards to Humans and Domestic Animals
PPE requirements for granular products labeled for use on turf	"When mixing/loading or applying this product to turf via tractor-drawn spreader, wear a dust mask."	Precautionary Statements under Hazards to Humans and Domestic Animals
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry."	Precautionary Statements under Hazards to Humans and Domestic Animals, following PPE
User Safety Requirements for all end-use products that specify coveralls in the PPE for handlers	"Discard clothing or other materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."	Precautionary Statements under Hazards to Humans and Domestic Animals, following PPE and general User Safety Requirements

Description	Required Labeling	Placement
Engineering Controls	"Engineering Controls When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS."	Precautionary Statements under Hazards to Humans and Domestic Animals, following User Safety Requirements
Engineering Controls for all wettable powder products contained in water-soluble bags	In addition to the above Engineering Controls, wettable powder products contained in water-soluble packaging must also have the following statement: "Water-soluble bags when used correctly qualify as a closed loading system under the WPS. Handlers handling this product while it is enclosed in intact water soluble bags are permitted to wear long-sleeved shirt, long pants, shoes and socks, and chemical-resistant gloves, provided the other required PPE is immediately available in case the bag is opened."	Precautionary Statements under Hazards to Humans and Domestic Animals, following User Safety Requirements
User Safety Recommendations	"User Safety Recommendations "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing. "Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."	Precautionary Statements under Hazards to Humans and Domestic Animals, following Engineering Controls--Must be placed in a separate box

Description	Required Labeling	Placement
Environmental hazards, ground- and surface water statements	"This pesticide is toxic to aquatic invertebrates and wildlife. Do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high-water mark. Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment washwater or rinsate." "This chemical is known to leach through soil into groundwater under certain conditions as a result of label use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination." "This chemical can contaminate surface water through spray drift. Under some conditions, it may also have a high potential for runoff into surface water for several days to weeks after application. These include poorly draining or wet soils with readily visible slopes toward adjacent surface waters, frequently flooded areas, areas overlaying extremely shallow ground water, areas with in-field canals or ditches that drain to surface water, areas not separated from adjacent surface waters with vegetated filter strips, and areas over-laying tile drainage systems that drain to surface water."	Precautionary Statements under Environmental Hazards

Description	Required Labeling	Placement
Application Restrictions	"Do not apply this product in a way that will contact workers or other persons, or pets, either directly or through drift. Only protected handlers may be in the area during application"	For WPS products, place directly above the Agricultural Use Requirements Box. For non-WPS products, place in Directions for Use under General Precautions and Restrictions

Description	Required Labeling	Placement
Entry Restrictions for Smoke Generator formulations	**"Entry Restrictions:** Entry (including early entry that would otherwise be permitted under the WPS) by any person -- other than a correctly trained and equipped handler who is performing a handling task permitted by the WPS -- is PROHIBITED in the entire greenhouse (entire enclosed structure/building) from the start of application until one of the WPS ventilation criteria has been met. The WPS ventilation criteria include: (1) ten air exchanges are completed; (2) two hours of mechanical ventilation; (3) four hours of passive ventilation; (4) eleven hours with no ventilation followed by 1 hour of mechanical ventilation; (5) eleven hours with no ventilation followed by 2 hours of passive ventilation; or (6) twenty-four hours with no ventilation. After ventilation is completed, do not enter or allow worker entry into the entire enclosed area during the remainder of the 12-hour restricted-entry interval (REI), except as allowed by the WPS. The WPS ventilation criteria and REI do not begin until application is complete. Application is complete when smoke is no longer being produced. **PPE for Entry During the Restricted Entry Interval:** --PPE for entry by handlers into smoke-treated greenhouses before WPS ventilation criteria have been met is listed in the "Hazards to Humans and Domestic Animals" section of this labeling.	Directions for Use, Agricultural Use Requirements box, as specified by Supplement Three of PR Notice 93-7.

Description	Required Labeling	Placement
Entry Restrictions for Smoke Generator formulations, continued	--PPE for early entry into smoke-treated greenhouses after ventilation is complete -- that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is: -- coveralls, -- chemical-resistant gloves, -- shoes plus socks, and -- protective eyewear.”	Directions for Use, Agricultural Use Requirements box, as specified by Supplement Three of PR Notice 93-7.
Notification Requirements for smoke generator products	**Notification:** Notify workers of the application by warning them orally and by posting warning signs outside all entrances to the greenhouse.	Directions for Use, Agricultural Use Requirements box, as specified by Supplement Three of PR Notice 93-7.
Restricted Entry Interval for all formulations, except smoke generator formulations, that contain WPS uses	For single-active-ingredient end-use products that contain chlorothalonil, the entry restrictions set forth in this section must be incorporated on the product labeling. Any conflicting entry restrictions for WPS uses must be removed. For multiple-active-ingredient end-use products that contain chlorothalonil the entry restrictions set forth in this section must be compared to the entry restrictions on the current labeling and the more protective must be retained. A specific time period in hours or days is considered more protective than "sprays have dried" or "dusts have settled.” "Do not enter or allow workers to enter treated areas during the restricted-entry interval (REI) of 12 hours.”	Directions for Use, Agricultural Use Requirements box, as specified by Supplement Three of PR Notice 93-7.

Description	Required Labeling	Placement
Early Entry PPE for all formulations, except smoke generator formulations, that contain WPS uses	"PPE required for early entry to treated areas is permitted under the Worker Protection Standard and that involves contact with anything that has been treated such as plants, soil, or water is: -- coveralls, -- chemical-resistant gloves, -- shoes plus socks, and -- protective eyewear."	Directions for Use, Agricultural Use Requirements box, as specified by Supplement Three of PR Notice 93-7.
Additional requirements for reentry into treated areas-- for WPS uses only, including smoke generator formulations	Eye Irritation Warnings: The following statements must be placed on the labeling of every chlorothalonil end-use product that contains directions for WPS uses: "Special Eye Irritation Provisions: This product is a severe eye irritant. Although the restricted-entry interval expires after 12 hours, for the next 6 ½ days entry is permitted only when the following safety measures are provided: (1) At least one container designed specifically for flushing eyes must be available in operating condition at the WPS-required decontamination site intended for workers entering the treated area. (2) Workers must be informed, in a manner they can understand: -- that residues in the treated area may be highly irritating to their eyes, --that they should take precautions, such as refraining from rubbing their eyes, to keep the residues out of their eyes, -- that if they do get residues in their eyes, they should immediately flush their eyes using the eyeflush container that is located at the decontamination site or using other readily available clean water, and -- how to operate the eyeflush container."	Directions for Use, Agricultural Use Requirements box immediately following Early Entry PPE requirements

Description	Required Labeling	Placement
Entry restrictions for non-WPS products	“Do not enter or allow others to enter the treated area until sprays have dried.”	**If no WPS uses are on the label --** Place the Non WPS entry restrictions in the Directions for Use, under the heading "Entry Restrictions." **If WPS uses are also on label --** Follow the instructions in PR Notice 93-7 for establishing a Non-Agricultural Use Requirements box, and place the appropriate Non WPS entry restrictions in that box.

Description	Required Labeling	Placement
Required application procedures for smoke generator products	"Required application procedures: (1) all entries to the structure must be blocked/barricaded and posted with the required warning signs; (2) all greenhouse vents must be closed and all circulating fans must be turned off; (3) all misting systems must be turned off; (4) an applicator wearing required personal protective equipment must perform the remaining tasks; (5) the applicator must remove the tops of the canisters; (6) each canister must be placed in position in the greenhouse; (7) after all canisters are set out, the canister furthest from the exit to the greenhouse must ignited first; (8) if the canisters are placed in parallel walks, rather than one central aisle, an applicator must be assigned to light the canisters in each walk, so that application starts simultaneously and the applicators exit the greenhouse simultaneously; (9) each applicator ignites each canister using a hand-held propane torch (not matches or cigarette lighter) that remains lit for the entire application; (10) each applicator continues quickly to the next can until all cans are ignited, then exits greenhouse immediately; (11) entry into the greenhouse to relight ignitors that failed to activate the smoke generator is prohibited -- if any smoke generator is activated in the greenhouse -- unless the task is performed by an applicator wearing baseline attire, chemical-resistant gloves, and an air-supplying respirator equipped to supply air for the time necessary for the relighting process.	Directions for Use under General Precautions and Restrictions

Description	Required Labeling	Placement
Additional Application Restrictions for Smoke Generator products	"For use in commercial greenhouses only. Use in residential greenhouses or other indoor plant sites is prohibited." "Do not apply this product to a greenhouse that is attached to another structure, including another greenhouse, unless the greenhouse to be treated is entirely sealed off from the other structures."	Directions for Use under General Precautions and Restrictions
Buffers for marine/estuarine areas for all products applied to agricultural sites	“This product must not be applied within 150 feet (for aerial and air-blast applications) or 25 feet (for ground applications) of marine/estuarine water bodies unless that there is an untreated buffer area of that width between the area to be treated and the water body.”	Directions for Use under General Precautions and Restrictions

Description	Required Labeling	Placement
Spray Drift label requirements for products with aerial applications	"Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment-and-weather-related factors determine the potential for spray drift. The applicator and the grower are responsible for considering all these factors when making decisions. The following drift management requirements must be followed to avoid off-target drift movement from aerial applications to agricultural field crops. These requirements do not apply to forestry applications, public health uses or to applications using dry formulations. 1. The distance of the outer most nozzles on the boom must not exceed 3/4 the length of the wingspan or rotor. 2. Nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees. Where states have more stringent regulations, they should be observed. The applicator should be familiar with and take into account the information covered in the Aerial Drift Reduction Advisory Information. Aerial Drift Reduction Advisory Information. [This section is advisory in nature and does not supersede the mandatory label requirements.]	Directions for Use, under General Precautions and Restrictions

Description	Required Labeling	Placement
Spray Drift label requirements for product with aerial applications, continued	**INFORMATION ON DROPLET SIZE** The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. Applying larger droplets reduces drift potential but will not prevent drift if applications are made improperly, or under unfavorable conditions (see Wind, Temperature). **CONTROLLING DROPLET SIZE** **!** Volume - Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets. **!** Pressure - Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure. **!** Number of nozzles - Use the minimum number of nozzles that provide uniform coverage. **!** Nozzle Orientation - Orienting nozzles so that the spray is released parallel to the airstream produces larger droplets than other orientations and is the recommended practice. Significant deflection from horizontal will reduce droplet size and increase drift potential.	Directions for Use, under General Precautions and Restrictions

Description	Required Labeling	Placement
	CONTROLLING DROPLET SIZE, continued **!** Nozzle Type - Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles. Solid stream nozzles oriented straight back produce the largest droplets and the lowest drift potential. **BOOM LENGTH** "For some use patterns, reducing the effective boom length to less than 3/4 of the wingspan or rotor length may further reduce drift without reducing swath width. **WIND** "Drift potential is lowest between wind speeds of 2-10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application should be avoided below 2 mph due to variable wind direction and high inversion potential. NOTE: Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift. **TEMPERATURE AND HUMIDITY** When making applications in low relative humidity, set up equipment to produce larger droplets to compensate for evaporation. Droplet evaporation is most severe when conditions are both hot and dry.	Directions for Use, under General Precautions and Restrictions

Description	Required Labeling	Placement
Spray Drift label requirements for product with aerial applications, continued	**TEMPERATURE INVERSIONS** Applications should not occur during a temperature inversion because drift potential is high. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing."	Directions for Use, under General Precautions and Restrictions
For products to be used on sodfarm turf	"Sodfarm turf treated with chlorothalonil prior to harvest must be mechanically cut, rolled, and harvested."	Directions for Use, under Application Instructions
For products with directions for use on turfgrass or ornamentals	"Use of this product on home lawns is prohibited."	Directions for Use, under Application Instructions

Description	Required Labeling		Placement
Maximum Application Rates	For each site listed below, the listed maximum individual and seasonal application rates must not be exceeded and the listed minimum retreatment intervals must not be decreased		Directions for Use
	Site	Maximum individual application rate in lbs ai/A (minimum retreatment interval in days) = maximum seasonal total in lbs ai/A/season	
	Bean (snap)	2.25(7) = 9	
	Bean (dry)	1.5 (7) = 6	
	Blueberry	3.0 (10) = 9	
	Carrot	1.5 (7) = 15	
	Celery	2.25 (7) = 18	
	Cole crops	1.5 (7) = 12	
	Conifers	4.1 (21 or 7 for seed beds only) = 16.5	
	Corn (sweet & grown for seed)	1.5 (7) = 9	
	Cranberry	5.0 (10) = 15	
	Cucurbit	2.25 (7) = 15.75	
	Filberts	3 (14) = 9	
	Golf course:		

Description	Required Labeling		Placement
	greens	11.3 (14) + 7.3 (7) = 73	Directions for Use
	tees	11.3 (14) + 7.3 (7) = 52	
	fairways	11.3 (1 application) + 7.3 (7) = 26	
	Grass grown for seed	1.5 (14) = 4.5	
	Mint	1.0 (7) = 3	
	Ornamentals	1.55 (7) = 36.4 (seasonal maximum applies to field-grown only)	
	roses	1.1 (7) = 36.4 (seasonal maximum applies to field-grown only)	
	pachysandra	3.1 (7) = 36.4 (seasonal maximum applies to field-grown only)	
	Onion (dry bulb) and garlic	2.25 (7) = 15	
	Onion, green; leek, shallot, onion grown for seed	2.25 (7) = 6.7	
	Papaya	2.25 (14) = 6.75	
	Parsnip	1.5 (7) = 6	
	Passion fruit	1.5 (14) = 7.5	
	Peanut	1.125 (14) = 9	
	Potato	1.125 (5) = 11.25	

Description	Required Labeling		Placement
	Sod farm	11.3 (one application) + 7.3 (7) = 26	Directions for Use
	Soybean	1.8 (14) = 4.5	
	Stone fruits including cherries	3.1 (10) = 15.5	
	Tomato	2.16 (7) = 15.1	
	Turf (general)	11.3 (one application) + 8.2 (7) = 26	
End-Use Products intended for Residential/Homeowner/Consumer, Non-occupational Uses			
Environmental hazards, ground- and surface water statements	Use statement cited under "End-Use Products Intended for Occupational Use (WPS and Non-WPS)" at Environmental hazards, ground- and surface water statements		Precautionary Statements under Environmental Hazards
Entry restrictions of residential/consumer/ nonWPS uses	"Do not allow people or pets to enter treated areas until sprays have dried or dusts have settled."		Directions for Use under General Precautions and Restrictions
Application Restrictions	"Do not apply this product in a way that will contact other persons, or pets, either directly or through drift."		Directions for Use under General Precautions and Restrictions
For products with directions for use on ornamentals	"Use of this product on home lawns is prohibited."		Directions for Use, Application Instructions
Products which are labeled as mildewicidal additives	"This product may not be added to paint by residential users/consumers."		Directions for Use, Application Instructions

Description	Required Labeling		Placement
Maximum Application Rates	For each site listed below, the listed maximum individual and seasonal application rates must not be exceeded and the listed minimum retreatment intervals must not be decreased		Directions for Use, Application Instructions
	Site	Maximum individual application rate in lbs ai/A (minimum retreatment interval in days) = maximum seasonal total in lbs ai/A/season	
	Bean (snap)	2.25(7) = 9	
	Bean (dry)	1.5 (7) = 6	
	Blueberry	3.0 (10) = 9	
	Carrot	1.5 (7) = 15	
	Celery	2.25 (7) = 18	
	Cole crops	1.5 (7) = 12	
	Conifers	4.1 (21 or 7 for seed beds only) = 16.5	
	Corn (sweet & grown for seed)	1.5 (7) = 9	
	Cucurbit	2.25 (7) = 15.75	
	Filberts	3 (14) = 9	
	Mint	1.0 (7) = 3	
	Ornamentals	1.55 (7) = 36.4 (seasonal maximum applies to field-grown only)	

Description	Required Labeling		Placement
	roses	1.1 (7) = 36.4 (seasonal maximum applies to field-grown only)	
	pachysandra	3.1 (7) = 36.4 (seasonal maximum applies to field-grown only)	
	Onion (dry bulb) and garlic	2.25 (7) = 15	
	Onion, green; leek, shallot, onion grown for seed	2.25 (7) = 6.7	
	Papaya	2.25 (14) = 6.75	
	Parsnip	1.5 (7) = 6	
	Passion fruit	1.5 (14) = 7.5	
	Peanut	1.125 (14) = 9	
	Potato	1.125 (5) = 11.25	
	Soybean	1.8 (14) = 4.5	
	Stone fruits including cherries	3.1 (10) = 15.5	
	Tomato	2.16 (7) = 15.1	

F. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision (RED). Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy"; Federal Register, Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrants may distribute and sell chlorothalonil products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED. Registrants and persons other than registrants remain obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.

VI. APPENDICES

Appendix A is 232 pages long and is not being included in this RED. Copies of Appendix A are available upon request per the instructions in Appendix E.

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case 0097 covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to 0097 in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. the reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 605-6000.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns:

A	Terrestrial food
B	Terrestrial feed
C	Terrestrial non-food
D	Aquatic food
E	Aquatic non-food outdoor
F	Aquatic non-food industrial
G	Aquatic non-food residential
H	Greenhouse food
I	Greenhouse non-food
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

3. Bibliographic citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Chlorothalonil			
REQUIREMENT		**USE PATTERN**	**CITATION(S)**
PRODUCT CHEMISTRY			
61-1	**Chemical Identity**	ABCDEFGHIJK	00039157, 00043700, 00087289, 00087319, 00087342, 00147866, 00152528, 40461001, 41206001, 41256801, 41753301, 41756601, 41815701, 41822101, 41893101, 42454901, 42498501, 42552501, 42683301, 42789401, 42824301, 42976101, 43310001, 43594001, 43646601, 44391901
61-2A	**Start. Mat. & Mnfg. Process**	ABCDEFGHIJK	00042438, 00087297, 00143748, 00159499, 40202501, 42148502, 42148503, 42148504, 44071109, 44115001, 44391901
61-2B	**Formation of Impurities**	ABCDEFGHIJK	40202502, 40613001, 42148505, 42779301, 44391901
62-1	**Preliminary Analysis**	ABCDEFGHIJK	00143748, 40333801, 42915301
62-2	**Certification of limits**	ABCDEFGHIJK	41822102, 42148507, 44171202, 44391901
62-3	**Analytical Method**	ABCDEFGHIJK	40459602, 42354606, 42976102, 43683601
63-2	**Color**	ABCDEFGHIJK	42354607
63-3	**Physical State**		
63-4	**Odor**		
63-5	**Melting Point**	ABCDEFGHIJK	42354608
63-6	**Boiling Point**		
63-7	**Density**	ABCDEFGHIJK	40047601
63-8	**Solubility**	ABCDEFGHIJK	42354608

Data Supporting Guideline Requirements for the Reregistration of Chlorothalonil			
REQUIREMENT		**USE PATTERN**	**CITATION(S)**
63-9	**Vapor Pressure**		
63-10	**Dissociation Constant**		
63-11	**Octanol/Water Partition**		
63-12	**pH**	ABCDEFGHIJK	42433802, 42454903
63-13	**Stability**	ABCDEFGHIJK	42354608
63-14	**Oxidizing/Reducing Action**	ABCDEFGHIJK	41206007, 42148511, 42354611
63-15	**Flammability**	ABCDEFGHIJK	41206008, 42354612
63-16	**Explodability**	ABCDEFGHIJK	42148512, 354613
63-17	**Storage stability**	ABCDEFGHIJK	00143749, 00143749, 42186502
63-18	**Viscosity**	ABCDEFGHIJK	40047601
63-19	**Miscibility**	ABCDEFGHIJK	40047601, 42354615
63-20	**Corrosion characteristics**	ABCDEFGHIJK	42454903
63-21	**Dielectric breakdown volt**	ABCDEFGHIJK	42354616
ECOLOGICAL EFFECTS			
71-1A	**Acute Avian Oral - Quail/Duck**	ABCDEFJK	00030395, 00068753, 40964105
71-2A	**Avian Dietary - Quail**	ABCDEFJK	00030388, 00115109
71-2B	**Avian Dietary - Duck**	ABCDEJK	00030389, 00039146, 00115108
71-4A	**Avian Reproduction - Quail**	ABCDEJK	00041440, 40729403, 40729404, 40964103, 40964104
71-4B	**Avian Reproduction - Duck**	ABCDEJK	00041441, 40729401, 40729402, 40964101, 40964102
72-1A	**Fish Toxicity Bluegill**	ABCDEFJK	42433804

Data Supporting Guideline Requirements for the Reregistration of Chlorothalonil			
REQUIREMENT		**USE PATTERN**	**CITATION(S)**
72-1B	**Fish Toxicity Bluegill - TEP**	ABCDEFJK	00087258
72-1C	**Fish Toxicity Rainbow Trout**	ABCDEFGHIJK	00087303, 00087304
72-1D	**Fish Toxicity Rainbow Trout- TEP**	ABCDEFGHIJK	42433805, 43302101
72-2A	**Invertebrate Toxicity**	ABCDEFGHIJK	42433806
72-2B	**Invertebrate Toxicity - TEP**	ABCDEFGHIJK	00068754
72-3A	**Estuarine/Marine Toxicity - Fish**	ABCDEFJK	00127863
72-3B	**Estuarine/Marine Toxicity - Mollusk**	ABCDEFJK	00138143
72-3C	**Estuarine/Marine Toxicity - Shrimp**	ABCDEFJK	00127864
72-4A	**Early Life Stage Fish**	ABCDEFJK	00029410, 00029415, 00030390
72-4B	**Life Cycle Invertebrate**	ABCDEFJK	42433807, 42924901
72-6	**Aquatic Organism Accumulation**	ABCDEFJK	43070601
72-7B	**Actual Field - Aquatic Organisms**	ABCDEFJK	44286001
122-1A	**Seed Germination/Seedling Emergence**	ABCDEFJK	42433808
122-1B	**Vegetative Vigor**	ABCDEFJK	42433809
122-2	**Aquatic Plant Growth**	ABCDEFJK	42432801
123-2	**Aquatic Plant Growth**	ABCDEFJK	42432801
141-1	**Honey Bee Acute Contact**	ABCDEJK	00036935, 00077759
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	ABCDEFGHIJK	00011514, 00011515, 00030353, 00030357, 00038909, 00038910, 00042447, 00047937, 00047938, 00055020, 00094941, 43678401

Data Supporting Guideline Requirements for the Reregistration of Chlorothalonil			
REQUIREMENT		**USE PATTERN**	**CITATION(S)**
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	ABCDEFGHIJK	00094940
81-3	**Acute Inhalation Toxicity - Rat**	ABCDEFGHIJK	00094942, 00100787, 40640401, 40649801, 43678403
81-4	**Primary Eye Irritation - Rabbit**	ABCDEFGHIJK	00246769, 00030350
81-5	**Primary Dermal Irritation - Rabbit**	ABCDEFGHIJK	00246843
81-6	**Dermal Sensitization - Guinea Pig**	ABCDEFGHIJK	00144112
82-1A	**90-Day Feeding - Rodent**	ABCDEFGHIJK	00138148, 00258769, 00127852, 00258768, 00127850
82-1B	**90-Day Feeding - Non-rodent**	ABCDEFGHIJK	43653602
82-2	**21-Day Dermal - Rabbit/Rat**	ABCDEFGHIJK	44119101, 00158254
82-3	**90-Day Dermal - Rodent**	ABCDEFGHIJK	00112735
83-1A	**Chronic Feeding Toxicity - Rodent**	ABCDEFGHIJK	see 83-2
83-1B	**Chronic Feeding Toxicity - Non-Rodent**	ABCDEFGHIJK	00114034, 43653603
83-2A	**Oncogenicity - Rat**	ABCDEFGHIJK	00030286, 00146945, 41250502
83-2B	**Oncogenicity - Mouse**	ABCDEFGHIJK	00127858, 40243701, 00030286
83-3A	**Developmental Toxicity - Rat**	ABCDEFGHIJK	00130733
83-3B	**Developmental Toxicity - Rabbit**	ABCDEFGHIJK	41250503
83-4	**2-Generation Reproduction - Rat**	ABCDEFGHIJK	41706201
84-2A	**Gene Mutation (Ames Test)**	ABCDEFGHIJK	00030288, 00030289, 00030290, 00030291, 00147949
84-2B	**Structural Chromosomal Aberration**	ABCDEFGHIJK	40559103, 00147948, 43700602, 43700601, 00147947, 00147946, 00127853, 00127854

Data Supporting Guideline Requirements for the Reregistration of Chlorothalonil			
REQUIREMENT		**USE PATTERN**	**CITATION(S)**
85-1	**General Metabolism**	ABCDEFGHIJK	44223002, 44240901
85-2	**Dermal Penetration**	ABCDEFGHIJK	43600103
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
132-1A	**Foliar Residue Dissipation**	ABCDHIJK	00147976, 42875902, 42875903, 42875904, 43938401
132-1B	**Soil Residue Dissipation**	ABCDHIJK	00147976, 42875902, 42875903, 42875904, 43938401
133-3	**Dermal Passive Dosimetry Exposure**	ABCDHIJK	00144248, 00147976, 4035050, 42433810, 42433811, 42723501, 43600101, 43600102, 43623201, 43623202, 43842001, 44119102, 44119103
133-4	**Inhalation Passive Dosimetry Exposure**	ABCDHIJK	00144248, 00147976, 40350501, 42433810, 43600101, 43600102, 43623201, 43623202, 43842001, 44119102
231	**Estimation of Dermal Exposure at Outdoor Sites**	ABCDEFGJK	42875902, 42875903, 42875904, 470025045, 42433810, 42433811
232	**Estimation of Inhalation Exposure at Outdoor Sites**	ABCDEFGJK	42875902, 42875903, 42875904, 470025045, 42433810, 42433811
ENVIRONMENTAL FATE			
160-5	**Chemical Identity**	ABCDEFGHIJK	see 61-1
161-1	**Hydrolysis**	ABCDEFGHIJK	00040539
161-2	**Photodegradation - Water**	ABCDEFGJ	00040540, 00087281, 40183418, 41030001
161-3	**Photodegradation - Soil**	ABCJ	00040541, 00040542, 00040543, 00087348, 00087349, 00156470, 41030002

Data Supporting Guideline Requirements for the Reregistration of Chlorothalonil			
REQUIREMENT		**USE PATTERN**	**CITATION(S)**
162-1	**Aerobic Soil Metabolism**	ABCDEHIJK	00087351, 00040547, 00087285, 43879601
162-2	**Anaerobic Soil Metabolism**	ABC	00147975
162-3	**Anaerobic Aquatic Metabolism**	ABCDEFGJ	00147975
162-4	**Aerobic Aquatic Metabolism**	DEFGJ	42226101, 43890604
163-1	**Leaching/Adsorption/Desorption**	ABCDEFGHIJK	00029406, 00040546, 00115105, 00137232, 00138144, 00143752, 00153731, 44483404, 44483405
163-2	**Volatility - Lab**	ABHI	00040539
164-1	**Terrestrial Field Dissipation**	ABCDEFK	00071625, 00071627, 0008730, 00087332, 00087369, 41564828, 41564829, 41564830, 42433813, 42433814, 42875907, 44006001, 44013302
164-2	**Aquatic Field Dissipation**	DEFG	00127861
165-2	**Field Rotational Crop**	ABCD	41564831-41564846
165-4	**Bioaccumulation in Fish**	ABCDEFGJ	00086620, 00029411, 0086630, 43070601
165-5	**Bioaccumulation - Aquatic NonTarget**	ABCDEFGJ	00086620, 00029411, 0086630, 43070601, 44286001
166-1	**Ground Water - Small Prospective**	ABCJ	44006001, 44091501, 44291101, 44483401
166-2	**Ground Water - Small Retrospective**	ABCJ	43959401, 43959402, 44254801
RESIDUE CHEMISTRY			
171-4A	**Nature of Residue - Plants**	ABDHK	00029409, 00087287 00138147, 00139550, 40684801, 41630801, 42554002

Data Supporting Guideline Requirements for the Reregistration of Chlorothalonil			
REQUIREMENT		**USE PATTERN**	**CITATION(S)**
171-4B	**Nature of Residue - Livestock**	ABDHK	44071601, 44071602, 44419501, 00038919, 00087679, 00092413, 00127843, 41576001, 41576002
171-4C	**Residue Analytical Method - Plants**	ABDEHK	00038929, 00084634, 00087365, 00109661, 00112738, 00114035, 00115103, 00156523 00161154, 00161165, 00161190
171-4D	**Residue Analytical Method - Animal**	ABDEH	44419501
171-4E	**Storage Stability**	AB	43832401, 43832402
171-4H	**Magnitude of Residues - Irrigated Crop**	AB	00084828-0084832, 00097847
171-4J	**Magnitude of Residues - Meat/Milk/Poultry/Egg**	AB	00087251-00087253
171-4K	**Crop Field Trials**	AB	00029905, 00039239, 00040470, 00078929, 00084833, 00087255, 00087273, 00087275, 00087346, 00087354, 00097503, 00097505, 00097847, 00126732, 00130005, 00138146, 00141398, 00159588, 00161076, 00161190, 00164474, 40000102, 40000103-40000116, 40183401-40183417, 40684802, 41614901, 41819401, 41844101, 41988201, 42059001, 42073901, 42245502, 42272901, 42839802, 42875920, 42875922-42875927, 42944402, 43843601, 43924101, 44191001
171-4L	**Processed Food**	AB	00052999, 00138145, 41630801, 41630802, 42800501, 42944403
171-5	**Reduction of Residues**	AB	00038928

GUIDE TO APPENDIX C

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID number". This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

   b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

   c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

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MRID	CITATION

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

GENERIC DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient(s) identified in Attachment 1 of this Notice, the Data Call-In Chemical Status Sheet, to submit certain data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient(s). Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. how you will comply with the requirements set forth in this Notice and its Attachments 1 through 4; or,

2. why you believe you are exempt from the requirements listed in this Notice and in Attachment 3, Requirements Status and Registrant's Response Form, (see section III-B); or,

3. why you believe EPA should not require your submission of data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 4).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 3-31-99).

This Notice is divided into six sections and five Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

Section I	-	Why You Are Receiving This Notice
Section II	-	Data Required By This Notice
Section III	-	Compliance With Requirements Of This Notice
Section IV	-	Consequences Of Failure To Comply With This Notice
Section V	-	Registrants' Obligation To Report Possible Unreasonable Adverse Effects
Section VI	-	Inquiries And Responses To This Notice

The Attachments to this Notice are:

Attachment 1	-	Data Call-In Chemical Status Sheet
Attachment 2	-	Data Call-In Response Form (Insert A)
Attachment 3	-	Requirements Status And Registrant's Response Form (Insert B)
Attachment 4	-	List Of All Registrants Sent This Data Call-In Notice

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient(s) and reevaluated the data needed to support continued registration of the subject active ingredient(s). This reevaluation identified additional data necessary to assess the health and safety of the continued use of products containing this active ingredient(s). You have been sent this Notice because you have product(s) containing the subject active ingredient(s).

SECTION II. DATA REQUIRED BY THIS NOTICE

A. DATA REQUIRED

The data required by this Notice are specified in the Requirements Status and Registrant's Response Form (Insert B). Depending on the results of the studies required in this Notice, additional testing may be required.

B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in Attachment 3, Requirements Status and Registrant's Response Form (Insert B), within the time frames provided.

C. TESTING PROTOCOL

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, Va 22161 (tel: 703-605-6000).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from 2001 L Street, N.W., Washington, D.C. 20036 (Telephone number 202-785-6323; Fax telephone number 202-785-0350).

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160.3(a)(6)].

D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) NOTICES ISSUED BY THE AGENCY

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

B. OPTIONS FOR RESPONDING TO THE AGENCY

The options for responding to this Notice are: 1) voluntary cancellation, 2) delete use(s), (3) claim generic data exemption, (4) agree to satisfy the data requirements imposed by this Notice or (5) request a data waiver(s).

A discussion of how to respond if you chose the Voluntary Cancellation option, the Delete Use(s) option or the Generic Data Exemption option is presented below. A discussion of the various options available for satisfying the data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These forms are the Data-Call-In Response Form (Insert A) and the Requirements Status and Registrant's Response Form (Insert B). The Data Call-In Response Form (Insert A) must be submitted as part of every response to this Notice. Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form (Insert A) and Requirements Status and Registrant's Response Form (Insert B) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person identified in Attachment 1.

1. Voluntary Cancellation - You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient(s) that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form (Insert A), indicating your election of this option. Voluntary cancellation is item number 5 on the Data Call-In Response Form (Insert A). If you choose this option, this is the only form that you are required to complete.

If you choose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

2. Use Deletion - You may avoid the requirements of this Notice by eliminating the uses of your product to which the requirements apply. If you wish to amend your registration to delete uses, you must submit the Requirements Status and Registrant's Response Form (Insert B), a completed application for amendment, a copy of your proposed amended labeling, and all other information required for processing the application. Use deletion is option number 7 on the Requirements Status and Registrant's Response Form (Insert B). You must also complete a Data Call-In Response Form (Insert A) by signing the certification, item number 8. Application forms for amending registrations may be obtained from the Registration Support and Emergency Response Branch, Registration Division, (703) 308-8358.

If you choose to delete the use(s) subject to this Notice or uses subject to specific data requirements, further sale, distribution, or use of your product after one year from the due date of your 90 day response, must bear an amended label.

3. Generic Data Exemption - Under section 3(c)(2)(D) of FIFRA, an applicant for registration of a product is exempt from the requirement to submit or cite generic data concerning an active ingredient(s) if the active ingredient(s) in the product is derived exclusively from purchased, registered pesticide products containing the active ingredient(s). EPA has concluded, as an exercise of its discretion, that it normally will not suspend the registration of a product which would qualify and continue to qualify for the generic data exemption in section 3(c)(2)(D) of FIFRA. To qualify, all of the following requirements must be met:

a. The active ingredient(s) in your registered product must be present solely because of incorporation of another registered product which contains the subject active ingredient(s) and is purchased from a source not connected with you; and,

b. every registrant who is the ultimate source of the active ingredient(s) in your product subject to this DCI must be in compliance with the requirements of this Notice and must remain in compliance; and

c. you must have provided to EPA an accurate and current "Confidential Statement of Formula" for each of your products to which this Notice applies.

To apply for the Generic Data Exemption you must submit a completed Data Call-In Response Form (Insert A), and all supporting documentation. The Generic Data Exemption is item number 6a on the Data Call-In Response Form (Insert A). If you claim a generic data exemption you are not required to complete the Requirements Status and Registrant's Response Form (Insert B). Generic Data Exemption cannot be selected as an option for product specific data.

If you are granted a Generic Data Exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this Data Call-In Notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your and their product(s), unless you commit to submit and do submit the required data within the specified time. In such cases the Agency generally will not grant a time extension for submitting the data.

4. Satisfying the Data Requirements of this Notice - There are various options available to satisfy the data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 6 on the Requirements Status and Registrant's Response Form (Insert B) and option 6b and 7 on the Data Call-In Response Form(Insert A). If you choose option 6b or 7, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

5. Request for Data Waivers. Data waivers are discussed in Section III-D of this Notice and are covered by options 8 and 9 on the Requirements Status and Registrant's

Response Form (Insert B). If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

C. SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form (Insert A) that you agree to satisfy the data requirements (i.e. you select option 6b and/or 7), then you must select one of the six options on the Requirements Status and Registrant's Response Form (Insert A) related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form (Insert B). These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

1. I will generate and submit data within the specified time frame (Developing Data),

2. I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing),

3. I have made offers to cost-share (Offers to Cost Share),

4. I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study),

5. I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study),

6. I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study).

Option 1, Developing Data

If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG), and be in conformance with the requirements of PR Notice 86-5. In addition, certain studies require Agency approval of test protocols in advance of study initiation. Those studies for which a protocol must be submitted have been identified in the Requirements Status and Registrant's Response Form (Insert B) and/or footnotes to the form. If you wish to use a protocol which differs from the options discussed in Section II-C of this Notice, you must submit a detailed description of the proposed protocol and your reason for wishing to use it. The Agency may choose to reject a protocol not specified in Section II-C. If the Agency

rejects your protocol you will be notified in writing, however, you should be aware that rejection of a proposed protocol will not be a basis for extending the deadline for submission of data.

A progress report must be submitted for each study within 90 days from the date you are required to commit to generate or undertake some other means to address that study requirement, such as making an offer to cost-share or agreeing to share in the cost of developing that study. A 90-day progress report must be submitted for all studies. This 90-day progress report must include the date the study was or will be initiated and, for studies to be started within 12 months of commitment, the name and address of the laboratory(ies) or individuals who are or will be conducting the study.

In addition, if the time frame for submission of a final report is more than 1 year, interim reports must be submitted at 12 month intervals from the date you are required to commit to generate or otherwise address the requirement for the study. In addition to the other information specified in the preceding paragraph, at a minimum, a brief description of current activity on and the status of the study must be included as well as a full description of any problems encountered since the last progress report.

The time frames in the Requirements Status and Registrant's Response Form (Insert B) are the time frames that the Agency is allowing for the submission of completed study reports or protocols. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirement(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2, Agreement to Share in Cost to Develop Data --

If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be

your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3, Offer to Share in the Cost of Data Development --

If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form (Insert A) and a Requirements Status and Registrant's Response Form (Insert B) committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burdens of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit, and do submit the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4, Submitting an Existing Study --

If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this

Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, all of the following three criteria must be clearly met:

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(7) " *raw data* means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. *Raw data* may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3(7), means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants must also certify at the time of submitting the existing study that such GLP information is available for post-May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been

the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If EPA has previously reviewed a protocol for a study you are submitting, you must identify any action taken by the Agency on the protocol and must indicate, as part of your certification, the manner in which all Agency comments, concerns, or issues were addressed in the final protocol and study.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such a study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5.

Option 5, Upgrading a Study --

If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option should also be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally your submission of data intended to upgrade studies must be accompanied by a certification

that you comply with each of those criteria as well as a certification regarding protocol compliance with Agency requirements.

Option 6, Citing Existing Studies --

If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core minimum." For ecological effects studies, the classification generally would be a rating of "core." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of Certification with Respect to Citations of Data (in PR Notice 98-5) EPA Form 8570-34 .

D. REQUESTS FOR DATA WAIVERS

There are two types of data waiver responses to this Notice. The first is a request for a low volume/minor use waiver and the second is a waiver request based on your belief that the data requirement(s) are inapplicable and do not apply to your product.

1. Low Volume/Minor Use Waiver -- Option 8 on the Requirements Status and Registrant's Response Form (Insert B). Section 3(c)(2)(A) of FIFRA requires EPA to consider the appropriateness of requiring data for low volume, minor use pesticides. In implementing this provision EPA considers as low volume pesticides only those active ingredient(s) whose total production volume for all pesticide registrants is small. In determining whether to grant a low volume, minor use waiver the Agency will consider the extent, pattern and volume of use, the economic incentive to conduct the testing, the importance of the pesticide, and the exposure and risk from use of the pesticide. If an active ingredient(s) is used for both high volume and low volume uses, a low volume exemption will not be approved. If all uses of an active ingredient(s) are low volume and the combined volumes for all uses are also low, then an exemption may be granted, depending on review of other information outlined below. An exemption will not be granted if any registrant of the active ingredient(s) elects to conduct the testing. Any registrant receiving a low volume minor use waiver must remain within the sales figures in their forecast supporting the waiver request in order to remain qualified for such waiver. If granted a waiver, a registrant will be required, as a condition of the waiver, to submit annual sales reports. The Agency will respond to requests for waivers in writing.

To apply for a low volume, minor use waiver, you must submit the following information, as applicable to your product(s), as part of your 90-day response to this Notice:

a. Total company sales (pounds and dollars) of all registered product(s) containing the active ingredient(s). If applicable to the active ingredient(s), include foreign sales for those products that are not registered in this country but are applied to sugar (cane or beet), coffee, bananas, cocoa, and other such crops. Present the above information by year for each of the past five years.

b. Provide an estimate of the sales (pounds and dollars) of the active ingredient(s) for each major use site. Present the above information by year for each of the past five years.

c. Total direct production cost of product(s) containing the active ingredient(s) by year for the past five years. Include information on raw material cost, direct labor cost, advertising, sales and marketing, and any other significant costs listed separately.

d. Total indirect production cost (e.g. plant overhead, amortized plant and equipment) charged to product(s) containing the active ingredient(s) by year for the past five years. Exclude all non-recurring costs that were directly related to the active ingredient(s), such as costs of initial registration and any data development.

e. A list of each data requirement for which you seek a waiver. Indicate the type of waiver sought and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

f. A list of each data requirement for which you are not seeking any waiver and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

g. For each of the next ten years, a year-by-year forecast of company sales (pounds and dollars) of the active ingredient(s), direct production costs of product(s) containing the active ingredient(s) (following the parameters in item c above), indirect production costs of product(s) containing the active ingredient(s) (following the parameters in item d above), and costs of data development pertaining to the active ingredient(s).

h. A description of the importance and unique benefits of the active ingredient(s) to users. Discuss the use patterns and the effectiveness of the active ingredient(s) relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient(s), providing information that is as quantitative as possible. If you do not have quantitative data upon which to base your estimates, then present the reasoning used to derive your estimates. To assist the Agency in determining the degree of importance of the active ingredient(s) in terms of its benefits, you should provide information on any of the following factors, as applicable to your product(s):

(1) documentation of the usefulness of the active ingredient(s) in Integrated Pest Management, (b) description of the beneficial impacts on the environment of use of the active ingredient(s), as opposed to its registered alternatives, (c) information on the breakdown of the active ingredient(s) after use and on its persistence in the environment, and (d) description of its usefulness against a pest(s) of public health significance.

Failure to submit sufficient information for the Agency to make a determination regarding a request for a low volume minor use waiver will result in denial of the request for a waiver.

2. Request for Waiver of Data --Option 9 on the Requirements Status and Registrant's Response Form (Insert B). This option may be used if you believe that a particular data requirement should not apply because the corresponding use is no longer registered or the requirement is inappropriate. You must submit a rationale explaining why you believe the data requirements should not apply. You must also submit the current label(s) of your product(s) and, if a current copy of your Confidential Statement of Formula is not already on file you must submit a current copy.

You will be informed of the Agency's decision in writing. If the Agency determines that the data requirements of this Notice do not apply to your product(s), you will not be required to supply the data pursuant to section 3(c)(2)(B). If EPA determines that the data are required for your product(s), you must choose a method of meeting the requirements of this Notice within the time frame provided by this Notice. Within 30 days of your receipt of the Agency's written decision, you must submit a revised Requirements Status and Registrant's Response Form (Insert B) indicating the option chosen.

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

A. NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.

2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.

3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.

4. Failure to submit on the required schedule acceptable data as required by this Notice.

5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.

7. Withdrawal of an offer to share in the cost of developing required data.

8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer, or failure of a registrant on whom you rely for a generic data exemption either to:

   a. inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form (Insert A) and a Requirements Status and Registrant's Response Form (Insert B); or,

   b. fulfill the commitment to develop and submit the data as required by this Notice; or,

   c. otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.

9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection

of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

2. EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.

3. EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

C. EXISTING STOCKS OF SUSPENDED OR CANCELED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or canceled if doing so would be consistent with the purposes of the Federal Insecticide, Fungicide, and Rodenticide Act.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding would generally not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You must also explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily canceled products containing an active ingredient(s) for which the Agency has particular risk concerns will be determined on case-by-case basis.

Requests for voluntary cancellation received after the 90 day response period required by this Notice will not result in the Agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due unless you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3 year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study

in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLE UNREASONABLE ADVERSE EFFECTS

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person listed in Attachment 1, the Data Call-In Chemical Status Sheet.

All responses to this Notice (other than voluntary cancellation requests and generic data exemption claims) must include a completed Data Call-In Response Form (Insert A) and a completed Requirements Status and Registrant's Response Form (Insert B) and any other documents required by this Notice, and should be submitted to the contact person identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Data Call-In Response Form (Insert A) need be submitted.

The Office of Compliance (OC) of the Office of Enforcement and Compliance Assurance (OECA), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

CHLOROTHALONIL DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Generic Data Call-In Notice because you have product(s) containing Chlorothalonil.

This Generic Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of Chlorothalonil. This attachment is to be used in conjunction with (1) the Generic Data Call-In Notice, (2) the Generic Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 2), (4) a list of registrants receiving this DCI (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), and (6) the Cost Share and Data Citation Forms in replying to this Chlorothalonil Generic Data Call In (Attachment F). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the generic database for Chlorothalonil are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional product chemistry data on Chlorothalonil are needed. These data are needed to fully complete the reregistration of all eligible Chlorothalonil products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact at (703) 308-8169.

All responses to this Notice for the generic data requirements should be submitted to:

Jill Bloom, Chemical Review Manager
Reregistration Branch 2
Special Review and Registration Division (7508C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: 0097

SPECIFIC INSTRUCTIONS FOR THE GENERIC DATA CALL-IN RESPONSE FORM (INSERT A)

This Form is designed to be used to respond to call-ins for generic and product specific data for the purpose of reregistering pesticides under the Federal Insecticide Fungicide and Rodenticide Act. Fill out this form each time you are responding to a data call-in for which EPA has sent you the form entitled "Requirements Status and Registrant's Response."

Items 1-4 will have been preprinted on the form Items 5 through 7 must be completed by the registrant as appropriate Items 8 through 11 must be completed by the registrant before submitting a response to the Agency.

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggesting for reducing this burden, to Chief, Information Policy Branch, PM-223, U S Environmental Protection Agency, 401 M St , S W , Washington, D C 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D C 20503.

INSTRUCTIONS

Item 1. This item identifies your company name, number and address.

Item 2. This item identifies the ease number, ease name, EPA chemical number and chemical name.

Item 3. This item identifies the date and type of data call-in.

Item 4. This item identifies the EPA product registrations relevant to the data call-in. Please note that you are also responsible for informing the Agency of your response regarding any product that you believe may be covered by this data call-in but that is not listed by the Agency in Item 4. You must bring any such apparent omission to the Agency's attention within the period required for submission of this response form.

Item 5. Cheek this item for each product registration you wish to cancel voluntarily. If a registration number is listed for a product for which you previously requested voluntary cancellation, indicate in Item 5 the date of that request. You do not need to complete any item on the Requirements Status and Registrant's Response Form for any product that is voluntarily canceled.

Item 6a. Check this item if this data call-in is for generic data as indicated in Item 3 and if you are eligible for a Generic Data Exemption for the chemical listed in Item 2 and used in the subject product. By electing this exemption, you agree to the terms and conditions of a Generic Data Exemption as explained in the Data Call-In Notice.

If you are eligible for or claim a Generic Data Exemption, enter the EPA registration Number of each registered source of that active ingredient that you use in your product.

Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and-any other outstanding Data Call-In Notice), and incorporate that product into all your products, you may complete this item for all products listed on this form If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources are registered), you may not claim a Generic Data Exemption and you may not select this item.

Item 6b. Check this Item if the data call-in is a generic data call-in as indicated in Item 3 and if you are agreeing to satisfy the generic data requirements of this data call-in. Attach the Requirements Status and Registrant's Response Form (Insert A) that indicates how you will satisfy those requirements.

Item 7a. Check this item if this call-in if a data call-in as indicated in Item 3 for a manufacturing use product (MUP), and if your product is a manufacturing use product for which you agree to supply product-specific data. Attach the Requirements Status and Registrants' Response Form (Insert A) that indicates how you will satisfy those requirements.

Item 7b. Check this item if this call-in is a data call-in for an end use product (EUP) as indicated in Item 3 and if your product is an end use product for which you agree to supply product-specific data. Attach the Requirements Status and Registrant's Response Form (Insert A) that indicates how you will satisfy those requirements.

Item 8. This certification statement must be signed by an authorized representative of your company and the person signing must include his/her title. Additional pages used in your response must be initialed and dated in the space provided for the certification.

Item 9. Enter the date of signature.

Item 10. Enter the name of the person EPA should contact with questions regarding your response.

Item 11. Enter the phone number of your company contact.

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SPECIFIC INSTRUCTIONS FOR COMPLETING THE REQUIREMENTS STATUS AND REGISTRANTS RESPONSE FORM (INSERT B)

Generic Data

This form is designed to be used for registrants to respond to call-in- for generic and product-specific data as part of EPA's reregistration program under the Federal Insecticide Fungicide and Rodenticide Act. Although the form is the same for both product specific and generic data, instructions for completing the forms differ slightly. Specifically, options for satisfying product specific data requirements do not include (1) deletion of uses or (2) request for a low volume/minor use waiver. These instructions are for completion of generic data requirements.

EPA has developed this form individually for each data call-in addressed to each registrant, and has preprinted this form with a number of items. DO NOT use this form for any other active ingredient.

Items 1 through 8 (inclusive) will have been preprinted on the form. You must complete all other items on this form by typing or printing legibly.

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggesting for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

INSTRUCTIONS

Item 1. This item identifies your company name, number, and address.

Item 2. This item identifies the case number, case name, EPA chemical number and chemical name.

Item 3. This item identifies the date and type of data call-in.

Item 4. This item identifies the guideline reference numbers of studies required to support the product(s) being reregistered. These guidelines, in addition to requirements specified in the Data Call-In Notice, govern the conduct of the required studies.

Item 5. This item identifies the study title associated with the guideline reference number and whether protocols and 1, 2, or 3-year progress reports are required to be

submitted in connection with the study. As noted in Section III of the Data Call-In Notice, 90-day progress reports are required for all studies.

If an asterisk appears in Item 5, EPA has attached information relevant to this guideline reference number to the Requirements Status and Registrant's Response Form (Insert B).

Item 6. This item identifies the code associated with the use pattern of the pesticide. A brief description of each code follows:

A.	Terrestrial food
B.	Terrestrial feed
C.	Terrestrial non-food
D.	Aquatic food
E.	Aquatic non-food outdoor
F.	Aquatic non-food industrial
G.	Aquatic non-food residential
H.	Greenhouse food
I.	Greenhouse non-food crop
J.	Forestry
K.	Residential
L.	Indoor food
M.	Indoor non-food
N.	Indoor medical
O.	Indoor residential

Item 7. This item identifies the code assigned to the substance that must be used for testing. A brief description of each code follows.

EP	End-Use Product
MP	Manufacturing-Use Product
MP/TGAI	Manufacturing-Use Product and Technical Grade Active Ingredient
PAI	Pure Active Ingredient
PAI/M	Pure Active Ingredient and Metabolites
PAI/PAIRA	Pure Active Ingredient or Pure Active Ingredient Radiolabelled
PAIRA	Pure Active Ingredient Radiolabelled
PAIRA/M	Pure Active Ingredient Radiolabelled and Metabolites
PAIRA/PM	Pure Active Ingredient Radiolabelled and Plant Metabolites
TEP	Typical End-Use Product
TEP _ *	Typical End-Use Product, Percent Active Ingredient Specified
TEP/MET	Typical End-Use Product and Metabolites
TEP/PAI/M	Typical End-Use Product or Pure Active Ingredient and Metabolites

TGAI/PAIRA	Technical Grade Active Ingredient or Pure Active Ingredient Radiolabelled
TGAI	Technical Grade Active Ingredient
TGAI/TEP	Technical Grade Active Ingredient or Typical End-Use Product
TGAI/PAI	Technical Grade Active Ingredient or Pure Active Ingredient
MET	Metabolites
IMP	Impurities
DEGR	Degradates

***See: guideline comment**

Item 8. This item identifies the time frame allowed for submission of the study or protocol identified in item 2. The time frame runs from the date **of your** receipt of the Data Call-In Notice.

Item 9. Enter the appropriate Response Code or Codes to show how you intend to comply with each data requirement. Brief descriptions of each code follow. The Data Call-In Notice contains a fuller description of each of these options.

1. (Developing Data) I will conduct a new study and submit it within the time frames specified in item 8 above. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice and that I will provide the protocol and progress reports required in item 5 above.

2. (Agreement to Cost Share) I have entered into an agreement with one or more registrants to develop data jointly. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to sharing in the cost of developing data as outlined in the Data Call-ln Notice.

3. (Offer to Cost Share) I have made an offer to enter into an agreement with one or more registrants to develop data jointly. I am submitting a copy of the form "Certification of Offer to Cost Share in the Development of Data" that describes this offer/agreement. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to making an offer to share in the cost of developing data as outlined in the Data Call-In Notice.

4. (Submitting Existing Data) I am submitting an existing study that has never before been submitted to EPA. By indicating that I have chosen this option, I certify that this study meets all the requirements pertaining to the conditions for submittal of existing data outlined in the Data Call-In Notice and I have attached the needed supporting information along with this response.

5. (Upgrading a Study) I am submitting or citing data to upgrade a study that EPA has classified as partially acceptable and potentially upgradeable. By indicating that I have chosen this option, I certify that I have met all the requirements pertaining to the conditions for submitting or citing existing data to upgrade a study described in the Data Call-In Notice. I am indicating on attached correspondence the Master Record Identification Number (MRID) that EPA has assigned to the data that I am citing as well as the MRID of the study I am attempting to upgrade.

6. (Citing a Study) I am citing an existing study that has been previously classified by EPA as acceptable, core, core minimum, or a study that has not yet been reviewed by the Agency. I am providing the Agency's classification of the study.

7. (Deleting Uses) I am attaching an application for amendment to my registration deleting the uses for which the data are required.

8. (Low Volume/Minor Use Waiver Request) I have read the statements concerning low volume-minor use data waivers in the Data Call-In Notice and I request a low-volume minor use waiver of the data requirement. I am attaching a detailed justification to support this waiver request including, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

9. (Request for Waiver of Data) I have read the statements concerning data waivers other than low volume minor-use data waivers in the Data Call-In Notice and I request a waiver of the data requirement. I am attaching an identification of the basis for this waiver and a detailed justification to support this waiver request. The justification includes, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

Item 10. This item must be signed by an authorized representative of your company. The person signing must include his/her title, and must initial and date all other pages of this form.

Item 11. Enter the date of signature.

Item 12. Enter the name of the person EPA should contact with questions regarding your response.

Item 13. Enter the phone number of your company contact.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment 1 of this Notice, the Data Call-In Chemical Status Sheet, to submit certain product specific data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 5; or

2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3, Requirements Status and Registrant's Response Form, (see section III-B); or

3. Why you believe EPA should not require your submission of product specific data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 5).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 03-31-99).

This Notice is divided into six sections and six Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

Section I - Why You Are Receiving This Notice
Section II - Data Required By This Notice
Section III - Compliance With Requirements Of This Notice
Section IV - Consequences Of Failure To Comply With This Notice
Section V - Registrants' Obligation To Report Possible Unreasonable Adverse Effects
Section VI - Inquiries And Responses To This Notice

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Product-Specific Data Call-In Response Form (Insert A)
3 - Requirements Status and Registrant's Response Form (Insert B)
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient and reevaluated the data needed to support continued registration of the subject active ingredient. The Agency has concluded that the only additional data necessary are product specific data. No additional generic data requirements are being imposed. You have been sent this Notice because you have product(s) containing the subject active ingredient.

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The product specific data required by this Notice are specified in Attachment 3, Requirements Status and Registrant's Response Form (Insert B). Depending on the results of the studies required in this Notice, additional testing may be required.

II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in Insert B, Requirements Status and Registrant's Response Form (Insert B), within the time frames provided.

II-C. TESTING PROTOCOL

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, Va 22161 (tel: 703-605-6000).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 2001 L Street, N.W., Washington, D.C. 20036 (Telephone number 202-785-6323; Fax telephone number 202-785-0350).

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160.3(a)(6)].

II-D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) NOTICES ISSUED BY THE AGENCY

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for product specific data must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

The options for responding to this Notice for product specific data are: (a) voluntary cancellation, (b) agree to satisfy the product specific data requirements imposed by this notice or (c) request a data waiver(s).

A discussion of how to respond if you chose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These forms are the Data-Call-In Response Form (Insert A), and the Requirements Status and Registrant's Response Form (Insert B). The Data Call-In Response Form must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form (Insert B) must be submitted for each product listed on the Data Call-In Response Form (Insert A) unless the voluntary cancellation option is selected or unless the product is identical to another (refer to the instructions for completing the Data Call-In Response Form(Insert A). Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form (Insert A) and Requirements Status and Registrant's Response Form (Insert B), initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

1. Voluntary Cancellation - You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form (Insert A), indicating your election of this option. Voluntary cancellation is item number 5 on the Data Call-In Response Form (Insert B). If you choose this option, this is the only form that you are required to complete.

If you chose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

2. Satisfying the Product Specific Data Requirements of this Notice There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 5 on the Requirements Status and Registrant's Response Form(Insert A) and item numbers 7a and 7b on the Data Call-In Response Form(Insert B). Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements.

3. Request for Product Specific Data Waivers. Waivers for product specific data are discussed in Section III-D of this Notice and are covered by option 7 on the Requirements Status and Registrant's Response Form (Insert B). If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form (Insert A) that you agree to satisfy the product specific data requirements (i.e. you select item number 7a or 7b), then you must select one of the six options on the Requirements Status and Registrant's Response Form (Insert A) related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form(Insert A). These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified time frame (Developing Data)
(2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1, Developing Data -- If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced here in and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines(PAG), and be in conformance with the requirements of PR Notice 86-5.

The time frames in the Requirements Status and Registrant's Response Form (Insert A) are the time frames that the Agency is allowing for the submission of completed study reports. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2, Agreement to Share in Cost to Develop Data -- Registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending on the same data. If this is the case, data may be generated for just one of the products in the group. The registration number of the product for which data will be submitted must be noted in the agreement to cost share by the registrant selecting this option. If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the

terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3, Offer to Share in the Cost of Data Development -- This option only applies to acute toxicity and certain efficacy data as described in option 2 above. If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment 7. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form (Insert A) and a Requirements Status and Registrant's Response Form (Insert B) committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burdens of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit, and do submit the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4, Submitting an Existing Study -- If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, **all of the following three criteria must be clearly met**:

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(j) " 'raw data' means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3(k), means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants must also certify at the time of submitting the existing study that such GLP information is available for post-May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5.

Option 5, Upgrading a Study -- If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data

submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option should also be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria as well as a certification regarding protocol compliance with Agency requirements.

Option 6, Citing Existing Studies -- If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core minimum." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form 8570-34, Certification with Respect to Citations of Data (in PR Notice 98-5).

Registrants who select one of the above 6 options must meet all of the requirements described in the instructions for completing the Data Call-In Response Form (Insert A) and the Requirements Status and Registrant's Response Form (Insert B), as appropriate.

III-D. REQUESTS FOR DATA WAIVERS

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant

to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the Requirements Status and Registrant's Response Form. Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency would grant a waiver only under extraordinary circumstances. You should also be aware that submitting a waiver request will not automatically extend the due date for the study in question. Waiver requests submitted without adequate supporting rationale will be denied and the original due date will remain in force.

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.

2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.

3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.

4. Failure to submit on the required schedule acceptable data as required by this Notice.

5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.

7. Withdrawal of an offer to share in the cost of developing required data.

8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer or failure of a registrant on whom you rely for a generic data exemption either to:

    a. inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form(Insert A) and a Requirements Status and Registrant's Response Form(Insert B);

b. fulfill the commitment to develop and submit the data as required by this Notice; or

c. otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.

9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

IV-B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

2. EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.

3. EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or canceled if doing so would be consistent with the purposes of the Act.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding would generally not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You must also explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden the Agency

will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily canceled products containing an active ingredient for which the Agency has particular risk concerns will be determined on case-by-case basis.

Requests for voluntary cancellation received after the 90 day response period required by this Notice will not result in the Agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due unless you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3 year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLEUNREASONABLE ADVERSE EFFECTS

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person(s) listed in Attachment 1, the Data Call-In Chemical Status Sheet.

All responses to this Notice (other than voluntary cancellation requests and generic data exemption claims) must include a completed Data Call-In Response Form (Insert A) and a completed Requirements Status and Registrant's Response Form (Insert B) for product specific data) and any other documents required by this Notice, and should be submitted to the contact person(s) identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Data Call-In Response Form (Insert A) need be submitted.

The Office of Compliance Monitoring (OCM) of the Office of Pesticides and Toxic Substances (OPTS), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachments

1 - Data Call-In Chemical Status Sheet
2 - Product-Specific Data Call-In Response Form (Insert A)
3 - Requirements Status and Registrant's Response Form (Insert B)
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice

CHLOROTHALONIL DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing Chlorothalonil.

This Product Specific Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of Chlorothalonil. This attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), (6) a list of registrants receiving this DCI (Attachment 6) and (7) the Cost Share and Data Compensation Forms in replying to this Chlorothalonil Product Specific Data Call-In (Attachment 7). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for Chlorothalonil are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on Chlorothalonil are needed for specific products. These data are required to be submitted to the Agency within the time frame listed. These data are needed to fully complete the reregistration of all eligible Chlorothalonil products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding this product specific data requirements and procedures established by this Notice, please contact Karen Jones at (703) 308-8047 .

All responses to this Notice for the Product Specific data requirements should be submitted to:

Karen Jones
Chemical Review Manager Team 81
Product Reregistration Branch
Special Review and Reregistration Branch 7508W
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: **0097**

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORM FOR PRODUCT SPECIFIC DATA

Item 1-4. Already completed by EPA.

Item 5. If you wish to **voluntarily cancel** your product, answer "**yes**." If you choose this option, you will not have to provide the data required by the Data Call-In Notice and you will not have to complete any other forms. Further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provision of the Data Call-In Notice (Section IV-C).

Item 6. Not applicable since this form calls in product specific data only. However, if your product is **identical** to another product and you qualify for a **data exemption**, you must respond with "**yes**" to Item 7a (MUP) or 7B (EUP) on this form, provide the **EPA registration numbers of your source(s)**; you would **not** complete the "Requirements Status and Registrant's Response" form. Examples of such products include **repackaged** products and **Special Local Needs (Section 24c)** products which are identical to federally registered products.

Item 7a. For each **manufacturing use product** (MUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "**yes**."

Item 7b. For each **end use product** (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "**yes**." If you are requesting a **data waiver**, answer "**yes**" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with **Option 7** (Waiver Request) for each study for which you are requesting a waiver. See Item 6 with regard to identical products and data exemptions.

Items 8-11. Self-explanatory.

NOTE: You may provide **additional information** that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

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INSTRUCTIONS FOR COMPLETING THE REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORM FOR PRODUCT SPECIFIC DATA

Item 1-3 Completed by EPA. Note the **unique identifier number** assigned by EPA in Item 3. This number **must be used in the transmittal document for any data submissions** in response to this Data Call-In Notice.

Item 4. The guideline reference numbers of studies required to support the product's continued registration are identified. These guidelines, in addition to the requirements specified in the Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart C.

Item 5. The study title associated with the guideline reference number is identified.

Item 6. The use pattern(s) of the pesticide associated with the product specific requirements is (are) identified. For most product specific data requirements, all use patterns are covered by the data requirements. In the case of efficacy data, the required studies only pertain to products which have the use sites and/or pests indicated.

Item 7. The substance to be tested is identified by EPA. For product specific data, the product as formulated for sale and distribution is the test substance, except in rare cases.

Item 8. The due date for submission of each study is identified. It is normally based on **8 months after issuance of the Reregistration Eligibility Document** unless EPA determines that a longer time period is necessary.

Item 9. **Enter <u>only one</u> of the following response codes <u>for each data requirement</u> to show how you intend to comply with the data requirements listed in this table.** Fuller descriptions of each option are contained in the Data Call-In Notice.

1. I will generate and submit data by the specified due date (**Developing Data**). By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice. By the specified due date, I will also submit: (1) a completed **"Certification with Respect to Citations of Data (in PR Notice 98-5)" form (EPA Form 8570-34)** and (2) two

completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

2. I have entered into an agreement with one or more registrants to develop data jointly (**Cost Sharing**). I am submitting a **copy of this agreement**. I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. By the specified due date, I will also submit: (1) a completed **"Certification with Respect to Citations of Data (in PR Notice 98-5)" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

3. I have made offers to share in the cost to develop data (**Offers to Cost Share**). I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting **evidence that I have made an offer** to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed **"Certification of Attempt to Enter into an Agreement with other Restraints for Development of Data " (EPA Form 8570-32)**. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (**Submitting an Existing Study**). I certify that this study will meet all the requirements for submittal of existing data outlined in Option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that

this study will fill the data requirement for which I have indicated this choice. By the specified due date, I will also submit a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** to show what data compensation option I have chosen. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgradable (**Upgrading a Study**). I will submit **evidence of the Agency's review** indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (**Citing an Existing Study**). If I am citing another registrant's study, I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the **MRID or Accession number(s)** for the cited data on a "Product Specific Data Report" form or in a similar format. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

7. I request a waiver for this study because it is inappropriate for my product (**Waiver Request**). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my **only** opportunity to state

the reasons or provide information in support of my request. If the Agency approves my waiver request, I will **not** be required to supply the data pursuant to Section 3(c)(2)(B) of FIFRA. If the Agency denies my waiver request, I **must choose** a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within **30 days** of my receipt of the Agency's written decision, submit a revised "Requirements Status and Registrant's Response" Form indicating the option chosen. I also understand that the deadline for submission of data as specified by the original data call-in notice will not change. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

Items 10-13. Self-explanatory.

NOTE: You may provide **additional information** that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

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EPA'S BATCHING OF **CHLOROTHALONIL** PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing **Chlorothalonil** as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to

participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

One hundred and ten active products were found which contain Chlorothalonil as an active ingredient. These products have been placed into seventeen batches and a "no batch" category in accordance with the expected acute toxicity of the active and inert components. Furthermore, the following bridging strategies are deemed acceptable for this chemical:

- Products in batch 16 may cite all acute data performed with technical chlorothalonil.

- Products in batches 14, 13, 12, 11, 9, 8, 7, 3 and 2 may cite category 3/4 acute data performed with technical chlorothalonil.

_ Products in batch 2 may also cite category 3/4 acute data performed with batch 3 products.

_ Products in batch 7 may also cite category 3/4 acute data performed with batch 8 products.

- The “No batch” product 67572-2 may cite category 3/4 acute data performed with technical chlorothalonil.

NOTE: The technical acute toxicity values included in this document are for informational purposes only. The data supporting these values may or may not meet the current acceptance criteria.

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
1	577-544	0.70	Liquid
	577-546	0.70	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
2	961-277	5.0	Solid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
	7001-329	5.0	Solid
	7401-331	5.0	Solid
	9198-115	5.0	Solid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
3	16-159	12.9	Liquid
	270-285	11.24	Liquid
	802-581	12.5	Liquid
	829-287	12.5	Liquid
	909-95	12.5	Liquid
	5887-176	12.5	Liquid
	7401-65	12.5	Liquid
	28293-236	12.5	Liquid
	59144-18	12.5	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
4	67071-2	14.7	Solid
	67071-15	14.7	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
5	5905-472	19.15	Liquid
	9779-337	19.15	Liquid
	50534-159	19.1	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
6	7401-339	29.6	Liquid
	7401-340	29.6	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
7	239-2522	29.6	Liquid
	9688-97	30.8	Liquid
	50534-33	29.6	Liquid
	50534-35	30.8	Liquid
	60063-9	29.6	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
8	1022-546	40.4	Liquid
	1448-372	40.4	Liquid
	9779-333	38.5	Liquid
	50534-8	40.4	Liquid
	50534-9	40.4	Liquid
	50534-34	40.4	Liquid
	50534-115	40.4	Liquid
	50534-161	40.4	Liquid
	50534-198	40.4	Liquid
	50534-204	38.5	Liquid
	50534-211	38.5	Liquid
	50534-213	40.4	Liquid
	50534-216	40.4	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
8	60063-4	40.4	Liquid
	60063-5	40.4	Liquid
	60063-6	40.4	Liquid
	61451-1	40.4	Liquid
	67071-4	40.4	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
9	4-290	50.0	Solid
	7401-330	50.0	Solid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
10	21346-2	51.0	Liquid
	50534-197	50.0	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
11	50534-220	51.0	Liquid
	50534-221	51.0	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
12	1448-366	54.0	Liquid
	9779-320	54.0	Liquid
	50534-188	54.0	Liquid
	50534-209	54.0	Liquid
	50534-224	54.0	Liquid
	60063-7	54.0	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
13	60063-2	75.0	Solid
	60063-3	75.0	Solid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
14	829-232	75.0	Solid
	2935-514	75.0	Solid
	50534-4	75.0	Solid
	50534-23	75.0	Solid
	50534-29	75.0	Solid
	50534-116	75.0	Solid
	50534-189	75.0	Solid
	50534-205	75.0	Solid
	50534-207	75.0	Solid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
15	50534-201	82.5	Solid
	50534-202	82.5	Solid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
16	5905-527	90.0	Solid
	9779-280	90.0	Solid
	9779-328	90.0	Solid
	50534-157	90.0	Solid
	50534-195	90.0	Solid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
	50534-218	90.0	Solid
	60063-10	90.0	Solid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
17	1448-363	98.0	Solid
	50534-7	96.0	Solid
	50534-24	96.0	Solid
	50534-114	96.0	Solid
	50534-117	96.0	Solid
	50534-200	97.0	Solid
	60063-1	98.0	Solid
	60063-8	98.0	Solid
	61451-2	96.0	Solid
	66451-1	96.0	Solid
	67071-3	98.0	Solid

No Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
	70-223	20.0	Solid
	100-800	72.0	Solid
	192-195	12.5	Liquid
	264-571	28.0	Liquid
	538-114	9.50	Solid
	538-141	11.25	Solid
	7401-62	3.75	Liquid
	7401-67	6.0	Liquid
	9404-79	5.0	Solid

No Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
	9779-339	24.0	Liquid
	10182-423	11.0	Liquid
	10404-60	40.0	Liquid
	45639-196	38.6	Liquid
	48234-7	50.0	Solid
	50534-191	27.0	Solid
	50534-199	5.0	Liquid
	50534-203	40.0	Liquid
	50534-206	27.0	Solid
	50534-208	14.5	Liquid
	50534-219	27.0	Solid
	67572-2	0.087	Liquid

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FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

SCIENTIFIC ADVISORY PANEL MEETING

A Set of Scientific Issues Being Considered by the Agency in Connection with Chlorothalonil: Mechanism for the Formation of Renal and Forestomach Tumors.

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) has completed its review of the set of scientific issues being considered by the Agency in connection with Chlorothalonil: Mechanism for the Formation of Renal and Forestomach Tumors. The review was conducted in an open meeting held in Arlington, Virginia, on July 30, 1998. The meeting was chaired by Dr. Ernest E. McConnell (ToxPath, Inc.) Other Panel Members present were: Dr. Rory Conolly (Chemical Industry Institute of Toxicology-CIIT); Dr. Michael Cunningham (National Institute of Environmental Health Sciences-NIEHS); Dr. Amira Eldefrawi (University of Maryland School of Medicine); Dr. Gordon Hard (American Health Foundation); Dr. Genevieve M. Matanoski (The Johns Hopkins University); Dr. Fumio Matsumura (University of California) and; Dr. Christopher Portier (National Institute of Environmental Health Sciences-NIEHS.

Public Notice of the meeting was published in the Federal Register on June 19, 1998.

Oral statements were received from the following:

Dr. William Busey (Environmental Pathology Laboratories, Inc.)

Dr. John Foster (Zeneca)

Dr. Ashley Wickramaratne (Zeneca)

No written statements were received.

General Comments from SAP Members

Several points were raised during the Agency presentation, public comment, Panel general discussion, and response to Agency questions that represented issues or viewpoints on the chlorothalonil deliberation. In particular, several aspects related to chlorothalonil's activity in the rodent kidney were covered during general Panel discussion.

1. In response to questioning by the Panel, the Agency stated that tubule cytotoxicity in the rat kidney commenced at a very early time-point and was sustained through the period of compound administration, matching data available on increased tubule cell proliferation. Cell proliferation studies had not been conducted in the dog, but chlorothalonil did not induce histopathological changes in this species.

2. The Panel noted that a CD-1 mouse study, positive for renal tumors, had not been included in the Agency's data presentation.

3. Discussion on tubule hyperplasia, recognized as a precursor lesion to renal tubule tumors, confirmed that it preceded tumor development and had been observed in interim and subchronic studies in a dose-response pattern. Based on experience with other renal carcinogens (genotoxic and non-genotoxic), the incidence of chemically-induced renal tubule hyperplasia would not be expected to be 100 percent in any given study.

4. The Panel considered information on the activity of γ-glutamyltranspeptidase (GGT) in the kidneys of neonatal rats and healthy human fetal tissue compared with adult activity for each species. Whereas neonatal rats possessed activity twice as that of mature rats, human fetal tissue contained less GGT activity than adults, suggesting that infants may be less susceptible to chemicals acting through this metabolic pathway. However, this was a single study and no comparative species information exists for β-lyase at immature ages. More plentiful data have been recorded on GGT activity in the plasma of infants, but the derivation of plasma GGT activity is from liver and not kidney. β-lyase was likely to be an inducible enzyme but GGT was probably not inducible in the kidney because it is localized to the brush border of renal tubules.

5. Attention was drawn to an *in vitro* study using the β-lyase inhibitor, aminooxyacetic acid, which exerted no modifying effect on chlorothalonil toxicity. This result might suggest that the β-lyase pathway was not involved in chlorothalonil metabolism. Additional information, however, indicated that the concentration of chlorothalonil used in this *in vitro* study represented an overwhelming and lethal dose. On the other hand, research from several laboratories with halogenated alkenes/alkanes has indicated that involvement of the cysteine conjugate β-lyase pathway can lead to formation of thiols that are electrophilic agents capable of reacting with DNA.

6. The Panel expressed the position that data analysis consider the dose-response curves for renal tumors and tubule hyperplasia to determine whether the multiple dose-points fitted a straight line or not. Likewise, it was considered important to evaluate the dose-response behavior for cell proliferation. Furthermore, the draft EPA cancer risk assessment guidelines suggested use of a benchmark dose analysis to select the point-of-departure. The suggested point-of-departure in the rat could then be transformed into a human equivalent dose.

7. Another point concerned a positive *in vitro* comet assay using human peripheral blood lymphocytes in which chlorothalonil produced a positive result indicative of single-and double-strand DNA breaks and alkaline-labile sites. Several Panel members considered that the result of this study should be discounted because of the toxic doses employed and the lack of accompanying data on *in vivo* exposure levels.

8. A number of concerns related to chlorothalonil activity in the kidney were raised by a Panel member. One aspect concerned published *in vitro* data on rat hepatocytes indicating that chlorothalonil may have the capability of producing cytotoxicity by a mechanism involving oxidative stress. The Panel member acknowledged that there was sufficient precedence in the literature to support the conjugation of chlorothalonil with glutathione (GSH) in the intestine, but that data were not available to demonstrate whether this was the only metabolic pathway for chlorothalonil. It has been reported that 30% of the radioactivity in rat urine following

administration of ^{14}C-chlorothalonil represents di- and tri- thiol metabolites and their methylated derivatives (produced by further metabolism of the cysteine conjugates through the β-lyase pathway), but the remaining 70% of radioactivity was yet to be identified and characterized. The Panel member considered there to be no available evidence inferring that the GSH conjugates of chlorothalonil were nephrotoxic. The member also registered concern that, at least with another chemical, 2-bromo-(diglutathion-S-yl)-hydroquinone, the differences between species in renal activity of GGT did not correlate with the species susceptibility to the toxicity of this compound. For example, guinea pigs possess even less GGT than do humans, but were very susceptible to the renal toxicity of 2-bromo-(diglutathion-S-yl)-hydroquinone, indicating the activity of GGT may not be related to the toxicity of the metabolite. The Panel member concluded this may have implications for chlorothalonil.

9. In summary, there was a majority view of Panel members that the cytotoxicity/regenerative cell proliferation pathway was plausible and the likely mode of action for chlorothalonil. In addition, risk assessment based on differential enzyme activities in rats vs. humans is not appropriate. It was agreed that data gaps exist for chlorothalonil on such points as identification of the toxic metabolite(s), their potential for accumulation in the kidney, and potential for binding to DNA. However, one Panel member concluded that there was no compelling evidence that chlorothalonil carcinogenicity is mediated through a cytotoxic mechanism, nor was there evidence that it is cytotoxic via the proposed GSH metabolite. The one Panel member differed with the remainder of the Panel and concluded that risk assessment based on the differential enzyme activities in rats vs. humans is appropriate.

Questions to the Scientific Advisory Panel

The Agency posed the following questions to the SAP regarding Chlorothalonil: Mechanism for the Formation of Renal and Forestomach Tumors.

1. Based on our review of the dose response data, does the Panel agree that the proposed mode of action for chlorothalonil is scientifically reasonable, valid, and supported by the data?

There was a majority view amongst Panel members that the mode of action for chlorothalonil's activity in the rodent kidney, based on sustained cytotoxicity and regenerative cell proliferation during compound administration, as presented by the Agency, was plausible and likely to be valid. In this respect, chlorothalonil appeared to be acting in a mode similar to chloroform in the rodent kidney. However, it was acknowledged that many data gaps still exist, particularly related to the identity of the ultimate metabolic end-points and their ability or not to react with renal tubule DNA. There was no consensus on whether the mechanism of cell death induced by chlorothalonil occurred only through disruption of mitochondrial respiration. One dissenting view held that data from *in vitro* and *in vivo* studies could be interpreted as indicating chlorothalonil to be a DNA-reactive agent causing DNA damage and cell death through an oxidative mechanism. Such a view would increase concern about the potential carcinogenicity of chlorothalonil for humans and warrant risk assessment by use of a linearized low-dose extrapolation model.

For the rodent forestomach tumors induced by chlorothalonil, there was general agreement amongst the Panel that chlorothalonil was similar to a group of non-genotoxic rodent forestomach carcinogens that were either mucosal irritants or disruptors of the gastric mucosal barrier, causing repeated injury to the forestomach lining with inflammation, and sustained increased cell proliferation. This leads to hyperplasia and ultimately, neoplasia, representing an indirect or secondary mechanism of carcinogenesis.

2. Based on the proposed mode of action, is a non -linear approach for risk assessment appropriate. The proposed mode of action points towards an MOE approach. Does the Panel agree?

Assuming a mode of action involving sustained cytotoxicity and regenerative cell proliferation, a margin-of-exposure (MOE) approach would be in order. However, a view was expressed that the rodent data should be analyzed with, for example, the Weibull model to determine whether the data points adhered to a linear or non-linear pattern. This view held that the exercise would guide a sounder scientific and public health decision.

3. If the Panel agrees to the MOE approach, is the selection of the 1.5 mg/kg/day dose level an appropriate point of departure?

Several studies have pointed to 1.5 mg/kg/d being an appropriate point-of-departure based on the lack of forestomach lesions and an absence in the kidney of increased tubule cell proliferation and hyperplasia. However, the Panel believed that this question could only be answered after non-linearity had been tested by an appropriate statistical model, as recommended in the response to Question 2. One Panel member strongly recommended the use of a benchmark dose rather than a no-observable-adverse-effect-level (NOAEL) for determining the point-of-departure dose.

4. One of the important aspects of the proposed mechanism of chlorothalonil-induced renal tumors is the involvement of one or more enzymes involved in the metabolism of chlorothalonil to nephrotoxic metabolites. Data presented suggest species differences in activities of gamma-glutamyl transpeptidase (GGT) and cysteine conjugate β-lyase between rats and humans such that humans may be less sensitive to nephrotoxicity of chlorothalonil. Does the Panel agree?

There was a general view from the Panel that the research indicating quantitative differences in γ-glutamyltranspeptidase (GGT) and β-lyase activity between rats and humans underlined the plausibility that humans may be less susceptible than rats to renal carcinogens acting through metabolic pathways involving these enzymes. One Panel member was less convinced because the data supporting this mechanism are incomplete and mice have less GGT activity than rats and only about twice the amount present in human kidney. In addition, this species still showed a carcinogenic response, albeit weak.

5. The Agency is not in possession of any data to suggest whether the activities of renal GGT and cysteine conjugate β-lyase are significantly different in human infants and children from that of adult humans or animals. Does the Panel have any comment on the relative activities of GGT and cysteine conjugate β-lyase among animals and humans, and whether potential differences in the response of the kidney to nephrotoxicity of chlorothalonil should be expected among human subpopulations?

Although data showing lower levels of GGT in human fetal kidney tissue might suggest a lower susceptibility in the young compared to adults, it was generally agreed that not enough information existed on this aspect to provide a meaningful answer to the question.

FOR THE CHAIRPERSON:

Certified as an accurate report of findings:

Paul I. Lewis

Designated Federal Official

FIFRA/Scientific Advisory Panel

DATE:_____

Pesticide Registration Forms are available at the following EPA internet site:

http://www.epa.gov/opprd001/forms/.

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)
2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.
3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.
   DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.'

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@epamail.epa.gov.

The following Agency Pesticide Registration Forms are currently available via the internet at the following locations:

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf.
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf.
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf.
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf.
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf.
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf.
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf.

8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf.
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf.
8570-34	Certification with Respect to Citations of Data (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.

Pesticide Registration Kit www.epa.gov/pesticides/registrationkit/.

Dear Registrant:

For your convenience, we have assembled an online registration kit which contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.
2. Pesticide Registration (PR) Notices
   a 83-3 Label Improvement Program--Storage and Disposal Statements
   b. 84-1 Clarification of Label Improvement Program
   c. 86-5 Standard Format for Data Submitted under FIFRA
   d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
   e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
   f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
   g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
   h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

   Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_Notices.
3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader.)
   a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
   b. EPA Form No. 8570-4, Confidential Statement of Formula
   c. EPA Form No. 8570-27, Formulator's Exemption Statement
   d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
   e. EPA Form No. 8570-35, Data Matrix
4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader.)
   a. Registration Division Personnel Contact List

Biopesticides and Pollution Prevention Division (BPPD) Contacts

Antimicrobials Division Organizational Structure/Contact List

c. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)

d. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)

e. 40 CFR Part 158, Data Requirements for Registration (PDF format)

f. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information.

These include:

1. The Office of Pesticide Programs' Web Site
2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) the following address:

   National Technical Information Service (NTIS)
   5285 Port Royal Road
   Springfield, VA 22161

The telephone number for NTIS is (703) 487-4650. Please note that EPA is currently in the process of updating this booklet to reflect the changes in the registration program resulting from the passage of the FQPA and the reorganization of the Office of Pesticide Programs. We anticipate that this publication will become available during the Fall of 1998.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their Web site.
4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at 1-800-858-7378 or through their Web site.

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

Date of receipt
EPA identifying number
the Product Manager assignment

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying File Symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a CAS number if one has been assigned.

Documents Associated with this RED

The following is a list of available documents that may further assist in responding to this Reregistration Eligibility Decision document. These documents may be obtained by the following methods.

Electronic
File Format: Portable Document Format (.PDF) requires Adobe® Acrobat or compatible reader. Electronic copies are available on our website at www.epa.gov/REDs, or contact Jill Bloom at (703) 308-8169

1. A full copy of this RED document
2. A copy of the fact sheet for Chlorothalonil
3. A copy of Appendix A - Use Table

The following documents are part of the Administrative Record for this RED document and may included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the respective Chemical Status Sheet.

1. Health and Environmental Effects Science Chapters.

2. Detailed Label Usage Information System (LUIS) Report.