



Reregistration Eligibility Decision (RED)

Bromacil



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 bromacil which includes the active ingredients bromacil and its lithium salt. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of these chemicals, 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 may also include requirements for additional data (generic) on the active ingredients 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 are due 90 days from the date of receipt of this letter. The second set of required responses are due 8 months from the date of receipt 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 the pesticide law (FIFRA) and the food and drug law (FFDCA). This RED takes into account the new safety standard set by FQPA for establishing and reassessing tolerances. However, it should also 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 representative Jane Mitchell (703) 308-8061. Address any questions on required generic data to the Special Review and Reregistration Division representative Margaret Rice (703) 308-8039.

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

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 703-487-4650).

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 Data Compensation Requirements.** Complete and sign EPA form 8570-31 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

Bromacil

LIST A

CASE 0041

TABLE OF CONTENTS

BROMACIL REREGISTRATION ELIGIBILITY DECISION TEAM	x
ABSTRACT	xiii
I. INTRODUCTION	1
II. CASE OVERVIEW	2
A. Chemical Overview	2
B. Use Profile	2
C. Estimated Usage of Pesticide	5
D. Data Requirements	6
E. Regulatory History	6
III. SCIENCE ASSESSMENT	7
A. Physical Chemistry Assessment	7
B. Human Health Assessment	8
1. Hazard Assessment	8
a. Acute Toxicity	8
b. Subchronic Toxicity	9
c. Chronic Toxicity and Carcinogenicity	9
d. Developmental Toxicity	10
e. Reproductive Toxicity	10
f. Mutagenicity	10
g. Metabolism	11
h. Dermal Absorption	11
2. Dose-Response Assessment	12
a. Reference Dose	12
b. Cancer Classification	12
c. Toxicity Endpoints	12
3. Exposure Assessment	13
a. Dietary Exposure	13
b. Occupational Exposure	18
4. Risk Characterization	20
a. Dietary Risk	20
b. Occupational Risk	20
c. Food Quality Protection Act Considerations	24
C. Environmental Assessment	29
1. Ecological Toxicity Data	29
a. Toxicity to Terrestrial Animals	29
b. Toxicity to Aquatic Animals	31
c. Toxicity to Plants	33

2.	Environmental Fate	34
a.	Environmental Fate Assessment	34
b.	Environmental Fate and Transport	35
c.	Water Resources	39
3.	Exposure and Risk Characterization	44
a.	Ecological Exposure and Risk Characterization	44
IV.	RISK MANAGEMENT AND REREGISTRATION DECISION	60
A.	Determination of Eligibility	60
B.	Determination of Eligibility	60
1.	Eligibility Decision	60
2.	Eligible and Ineligible Uses	61
C.	Regulatory Position	61
1.	Food Quality Protection Act Findings	62
2.	Tolerance Reassessment	63
3.	Cancer Risk Assessment	64
4.	Benefits from Use of Bromacil	64
5.	Ecological Effects Risk Mitigation	65
6.	Spray Drift	66
7.	Endangered Species Program	66
8.	Groundwater Protection Requirements	66
9.	Occupational Labeling Rationale/Risk Mitigation	67
10.	Worker Protection Standard	69
11.	Aerial Application	74
V.	ACTIONS REQUIRED BY REGISTRANTS	74
A.	Manufacturing-Use Products	74
1.	Additional Generic Data Requirements	74
2.	Additional Monitoring of Groundwater	74
B.	Applicator Training Material	75
C.	Vulnerability assessment for Groundwater in pineapple production areas of Puerto Rico	75
D.	End-Use Products	75
1.	Additional Product-Specific Data Requirements	75
2.	Labeling Requirements for End-Use Products	75
E.	Restriction of total acres allowed to be treated for the Toxic-Waste Holding-Pond Liner Treatment	80
F.	Reduction of maximum application rate to no more than 12 lb ai/A for all uses except the undersurface treatment for toxic-waste holding ponds.	80
G.	Specify timing of application.	80
H.	Removal of Recreational Areas from labels.	80
I.	Maximum seasonal application rate.	80
J.	Removal of the Ditch-bank treatment	80
K.	Appropriate Use Rate for Russian thistle and kochia	80
L.	Existing Stocks	81

VI.	APPENDICES	83
	APPENDIX A.	Table of Use Patterns Subject to Reregistration	84
	APPENDIX B.	Table of the Generic Data Requirements and Studies Used to Make the Reregistration Decision	134
	APPENDIX C.	Citations Considered to be Part of the Data Base Supporting the Reregistration of bromacil	143
	APPENDIX D.	Product Specific Data Call-In	153
	Attachment	1. Chemical Status Sheet	166
	Attachment	2. Product Specific Data Call-In Response Forms (Form A inserts) Plus Instructions	167
	Attachment	3. Product Specific Requirement Status and Registrant's Response Forms (Form B inserts) and Instructions	171
	Attachment	4. EPA Batching of End-Use Products for Meeting Data Requirements for Reregistration	179
	Attachment	5. List of Registrant(s) sent this DCI (Insert)	187
	Attachment	6. Confidential Statement of Formula Form and Instructions, Cost Share, and Data Compensation Forms	190
	APPENDIX E.	List of Available Related Documents	197

BROMACIL REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Assessment

Eric Maurer	Economic Analysis Branch
Gabe Patrick	Biological Analysis Branch
James G. Saulmon	Biological Analysis Branch

Environmental Fate and Effects Assessment

Elizabeth Behl	Environmental Fate and Groundwater Branch
Dana Spatz	Environmental Fate and Groundwater Branch
Kevin Costello	Environmental Fate and Groundwater Branch
Ceres Mostaghimi	Environmental Fate and Groundwater Branch
Les Touart	Ecological Effects Branch
Denny McLane	Ecological Effects Branch
Karen Angulo	Science Analysis and Coordination Branch

Health Effects Assessment

Linda Taylor	Toxicology Branch II
John Redden	Risk Characterization and Analysis Branch
Bruce Kitchens	Occupational and Residential Exposure Branch
Brian Steinwand	Science and Analysis Branch
Randy Perfetti	Chemistry Branch, Reregistration Section

Registration Support

Vickie Walters	Fungicide-Herbicide Branch
Lucy Markarian	Registration Support Branch

Risk Management

Virginia Dietrich	Accelerated Reregistration Branch
Mario Fiol	Reregistration Branch

GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
AE	Acid Equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at 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
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FOB	Functional Observation Battery
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
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 ₁₀	Lethal Dose-low. Lowest Dose at which lethality occurs.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOEL	Lowest Observed Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
µg/g	Micrograms Per Gram
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 studies submitted.
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
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
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^*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
SLN	Special Local Need (Registrations Under Section 24 © 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 regarding the pesticide bromacil, case 0041, which includes the active ingredients bromacil and its lithium salt. 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 recently enacted "Food Quality Protection Act of 1996" 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 effect 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 residue.

The Agency has reassessed bromacil food and feed tolerances under the standards of FQPA and determined that, based on available information, there is a reasonable certainty that no harm will result to infants and children or to the general population from aggregate exposure to bromacil residues. EPA evaluated only dietary and drinking water exposure in the aggregate assessment, since other non-occupational exposures to bromacil are unlikely. EPA has no information to indicate that the toxic effects produced by bromacil would be cumulative with those of any other compound, and therefore has considered only bromacil exposures in the aggregate assessment.

In reaching the determination of safety for infants and children, the Agency found that the toxicity data base for bromacil is complete, based on current requirements, and that the effects observed in pre- and post-natal studies did not indicate any increased sensitivity of infants and children to bromacil. Therefore, no additional uncertainty factor was used in the risk assessment.

Further, the Agency has determined that no revisions in tolerances will be required. Sufficient data are available to ascertain the adequacy of the established tolerances listed for citrus and pineapple fruit. No tolerances for residues of bromacil in milk, eggs, animal fat, meat and meat byproducts are required because residues of bromacil expected in meat and milk would be less than levels detected by the current analytical methods.

Bromacil is a broad-spectrum herbicide used for weed control in citrus and pineapple. Both bromacil and its lithium salt are used for weed control in the following non-food uses: drainage systems, outdoor industrial areas, rights-of-way/fence rows/hedge rows, paved areas, non-agricultural uncultivated areas, and power stations. Recreational areas were considered during the risk assessment but are not being supported. The Agency has concluded that all

products registered for all uses are eligible for reregistration when labeled and used as specified in the Reregistration Eligibility Decision.

To reduce potential risks of contamination to groundwater, and toxicity to pesticide applicators, EPA is requiring, among other changes, reductions in the rate of application, use of Personal Protective Equipment, and the establishment of Restricted Entry Intervals. In addition, to reduce risks of acute and chronic effects to non-target plants and animals, EPA is requiring reduced application rates and prohibiting certain aquatic applications. Additional ecological effects studies are required to confirm or complete EPA's risk assessment and conclusions.

Before reregistering products containing bromacil, the Agency is requiring that product specific data, revised Confidential Statement of Formula (CSF) and revised labeling be submitted within eight months of the issuance of this document. These data include product chemistry and acute toxicity testing. After reviewing these data and any revised labels and finding them acceptable and in accordance with section 3(c)(5) of FIFRA, the Agency will reregister each product.

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. The amended Act provides a schedule for the reregistration process to be completed in nine years. 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 pesticide applications. The FQPA did not, however, amend any of the existing reregistration deadlines in section 4 of FIFRA. The Agency will therefore 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 bromacil and its lithium salt including the risk to infants and children for any potential dietary, drinking water, dermal or oral exposures, and cumulative effects as stipulated under the FQPA. The document consists of six sections. Section I is the introduction. Section II describes bromacil and its lithium salt, 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 bromacil and its lithium salt. Section V discusses the reregistration requirements for bromacil. 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 ingredients are covered by this Reregistration Eligibility Decision:

- **Common Name:** Bromacil
- **Chemical Name:** 5-bromo-3-*sec*-butyl-6-methyluracil
- **CAS Registry Number:** 314-40-9
- **OPP Chemical Code:** 012301
- **Empirical Formula:** C₉H₁₃BrN₂O₂
- **Trade and Other Names:** Hyvar® X; Krovar® I DF; Krovar® II DF
- **Basic Manufacturer:** DuPont

-
- **Common Name:** Bromacil lithium salt
 - **Chemical Name:** 5-bromo-3-*sec*-butyl-6-methyluracil, lithium salt
 - **CAS Registry Number:** 53404-19-6
 - **OPP Chemical Code:** 012302
 - **Empirical Formula:** C₉H₁₂BrN₂O₂Li⁺
 - **Trade and Other Names:** Hyvar® L; Hyvar® X-L
 - **Basic Manufacturer:** DuPont

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 these uses of bromacil, and bromacil lithium salt is in Appendix A. Also, a detailed discussion of bromacil uses on citrus and pineapples appears below in section III.B.3.a., Dietary Exposure.

For Bromacil:

Type of Pesticide: systemic herbicide

Use Sites: Terrestrial food crop - pineapple

Terrestrial food and feed crop - citrus fruits including grapefruit and orange

Terrestrial non-food non-crop - agricultural uncultivated areas, airports and landing fields, outdoor industrial areas, nonagricultural outdoor buildings and structures, nonagricultural rights-of-way and fencerows and hedgerows, nonagricultural uncultivated areas and soils, paved areas including private roads and sidewalks, recreational areas, and outdoor refuse and solid waste sites

Aquatic non-food industrial - drainage systems

Target Pests: annual and perennial weeds, brush, woody plants and vines, specifically:

Broadleaves: American elm, aster, bouncingbet, cottonweed, dandelion, dogbane, dogfennel, goldenrod, hackberry, lambsquarters, maple oak, pine, plantain, poplar, puncturevine, ragweed, redbud, sumac, sweetgum, turkey mullein, wild carrot, wild cherry, willow, winged elm;

Grasses: bahiagrass, bermudagrass, bluegrass, brome, broomsedge, Canada bluegrass, cheat, crabgrass, dallisgrass, foxtail, johnsongrass, johnsongrass from seed, orchardgrass, purpletop, quackgrass, redtop, ryegrass, saltgrass, smooth brome, vaseygrass, wild oat;

Other plants: bracken fern, horsetail, nutsedge.

Formulation Types Registered:

Table 1. Bromacil: Formulation Types Registered

Formulation	Percent Active Ingredient
Technical Grade Active Ingredient	
Solid	95
Manufacturing Product	
Dust	40 to 80
End Use Product	
Emulsifiable concentrate	0.6 to 3.3
Granular	0.21 to 10
Liquid ready-to-use	0.6 to 1
Pelleted/Tableted	10

Table 1. Bromacil: Formulation Types Registered

Formulation	Percent Active Ingredient
Pressurized liquid soluble	0.5
Soluble Concentrate/Liquid	0.3 to 40.8
Water dispersible granules (dry flowable)	40 to 80
Wettable powder	40 to 80
Wettable powder/dust	4

Method and Rates of Application:

Equipment - aerosol can; aircraft (fixed-wing and helicopter, only for application to the Yakima Firing Center); boomsprayer; compressed air sprayer; granule applicator; hand-held sprayer; knapsack sprayer; power sprayer; shaker can; spreader; sprinkler can; tank-type sprayer.

Method band treatment; broadcast; prepaving treatment; soil band treatment;

and Rate - soil broadcast treatment; soil treatment; spot treatment; spray; strip. Please refer to Appendix A for rates of application.

Use Practice For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply through any type of irrigation system. Do not apply directly to water or wetlands. Keep out of lakes, streams, and ponds.

For Bromacil Lithium Salt:

Type of Pesticide: systemic herbicide

Use Sites: Terrestrial non-food non-crop - outdoor industrial areas, nonagricultural outdoor buildings and structures, nonagricultural rights-of-way, fencerows, and hedgerows, nonagricultural uncultivated areas and soils.

Aquatic non-food industrial - drainage systems

Target Pests: Annual and perennial weeds, brush, woody plants and vines, specifically:

Broadleaves: aster, bouncingbet, broomweed, cottonwood, dandelion, dogbane, dogfennel, elm, Florida pusley, goldenrod, hackberry, henbit, lambsquarters, maple, mustard, oak, pine, plantain, poplar, puncturevine, purslane, ragweed, redbud, sumac, sweetgum, turkey mullein, wild carrot, wild cherry, willow;

Grasses: bahiagrass, barnyardgrass, bermudagrass, bluegrass, brome, broomsedge, cheat, crabgrass, crowfootgrass, dallisgrass, foxtail, johnsongrass, natalgrass, orchardgrass, pangolagrass, paragrass, purpletop, quackgrass, redtop, ryegrass, saltgrass, sandspur, sprangletop, Texas panicum, torpedograss, vaseygrass, wild oat;

Other plants: annual sedge, bracken fern, horsetail, nutgrass, nutsedge

Formulation Types Registered:

Table 2. Bromacil Lithium Salt: Formulation Types Registered

Formulation	Percent Active Ingredient
Manufacturing Product	
Soluble concentrate/liquid	7.5 to 21.9
End Use Product	
Liquid ready-to-use	2.0 to 2.5
Soluble Concentrate/Liquid	1.2 to 21.9

Method and Rates of Application:

Equipment - Broadcast; Prepaving treatment; Soil treatment; Spot treatment; Spray.

Method and Rate - Boom sprayer; Compression sprayer; Hand held sprayer; Knapsack sprayer; Power sprayer; Sprinkler can; in some cases, not specified on label. Please refer to Appendix A for rates of application.

Use Practice Limitations:

For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark.

C. Estimated Usage of Pesticide

The table below summarizes the best estimates available for certain pesticide uses of bromacil and its lithium salt. 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.

Table 3. Percent of U.S. Crops and Sites Treated Annually with Bromacil, 1990 - 1992^{1,2}

Site	Acres Grown ³ (x 1000)	Acres Treated ⁴ (x 1000)	Percentage Treated	Pounds AI Applied (x 1000)	Major Region or State
Grapefruit	144	50 - 100	35 - 69	100 - 300	FL, AZ, TX, CA
Lemons	63	5 - 15	8 - 24	5 - 25	AZ, CA
Limes	7	1 - 2	14 - 28	3 - 4	FL
Oranges	622	250 - 450	40 - 72	600 - 1,000	FL, AZ, TX, CA
Tangerines	24	10 - 15	42 - 62	10 - 15	AZ, CA, FL
Rights of way ⁵	6,661	135 - 165	2 - 3	605 - 655	Nationwide
Totals		451-747		1,323 - 1,999	

¹ Data based on proprietary and non-proprietary sources, USDA, and state statistics.

² There are no known site specific usage data available for pineapple.

³ Acres grown based on USDA, Agricultural Census, and state statistics.

⁴ Includes highways, railroads, pipelines, (from industrial sources, USDA, and state statistics).

⁵ Multiple acres treated represents the total number of acre treatments.

D. Data Requirements

The Agency required registrants to submit studies as specified in the regulations, noted in 40 CFR Section 158. Data from these studies are sufficient to characterize the risks associated with the uses described in this document. See Appendix B for a complete list of data requirements that support the reregistration of bromacil and its lithium salt.

E. Regulatory History

The following table summarizes information about the history and current status of products containing Bromacil and its salts.

Table 4. Bromacil and Salts: Summary of Registration Status

Active Ingredient	Year Registered	Current Status	Active Products ¹
Bromacil	1961	active	95
Dimethylamine salt	1969	canceled	none
Sodium salt	1969	canceled	none
Lithium salt	1970	active	24

¹ As of April 1996.

Bromacil was first registered in the United States for use as a herbicide in an end-use product in 1961. The 95% technical formulation, DuPont Bromacil Technical, was registered in 1967. Products containing the dimethylamine and sodium salts of bromacil were registered in 1969. Products containing these salts are now canceled, and are not discussed further in this document. A product containing the lithium salt of bromacil (Du Pont X-L Herbicide) was first registered in 1970.

A Registration Standard for bromacil was issued in September 1982 (NTIS PB87-110276). The Registration Standard required the submission of product chemistry, residue chemistry, toxicology, ecological effects and environmental fate studies. A Data Call-In (DCI) was issued in September of 1991 for bromacil requiring additional product chemistry, residue chemistry, toxicology, ecological effects and environmental fate studies. This RED reflects a reassessment of all data which were submitted to support the reregistration of bromacil.

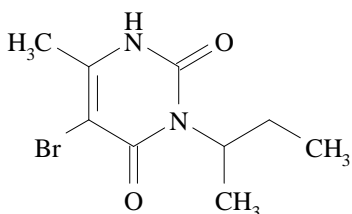
Additional controls have been placed on the use of bromacil by the state regulatory agencies of Florida and California as a result of bromacil being detected in groundwater. Florida prohibited the use of bromacil on vulnerable soils within one of its major citrus-growing areas, the Central Ridge, by rule (Rule 5E-8.038 in volume 19, Number 44, November 5, 1993, page 6424, *Florida Administrative Weekly*).

California's State Management Plan for controlling the occurrence of pesticides in the groundwater requires the use of Pesticide Management Zones (PMZs). California has set up several bromacil-specific PMZs. A PMZ is a one square mile area that has been determined to be vulnerable to ground water pollution. In these PMZs bromacil can only be applied to crops by permit and in accordance with a ground water protection advisory. This advisory contains specific information to reduce the potential for movement of the chemical into ground water. (*Sampling for Pesticide Residues in California Well Water, 1994 Update Well Inventory Data Base*, Ninth Annual Report to the Legislature, State Department of Health Services, Office of Environmental Health Hazard Assessment, and the State Water Resources Control Board, California Environmental Protection Agency).

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

The physical and chemical characteristics of bromacil (5-bromo-3-sec-butyl-6-methyluracil) and bromacil lithium salt are described below:



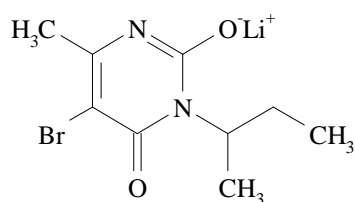
Bromacil

Empirical Formula: C₉H₁₃BrN₂O₂

Molecular Weight: 261.1

CAS Registry No.: 314-40-9

OPP Chemical Code: 012301



Bromacil lithium salt

Empirical Formula: C₉H₁₂BrLiN₂O₂

Molecular Weight: 267.1

CAS Registry No.: 53404-19-6

OPP Chemical Code: 012302

Below is a description of the physical and chemical properties of the technical grade of bromacil. The lithium salt of bromacil is not included since the technical grade of the lithium salt is not isolated during commercial production.

Color	White to light tan
Physical State	Crystalline solid at 25°C
Melting Point	158-159°C at 760 mmHg
Solubility	Water at 815 ppm at 25°C Organic solvents at 20°C in the following proportions: n-hexane 0.023 g/100 g toluene 3.0 g/100 g acetonitrile 4.65 g/100 g acetone 11.4 g/100 g methylene chloride 12.0 g/100 g

B. Human Health Assessment

1. Hazard Assessment

The toxicological data base on bromacil is adequate to support reregistration eligibility. The Agency believes bromacil and its lithium salt are toxicologically equivalent, therefore this assessment applies to both active ingredients.

a. Acute Toxicity

The Agency has characterized the acute toxicity of technical grade bromacil based on laboratory data. The following table summarizes the findings from acute toxicity studies submitted to the Agency. Acute toxicity categories are assigned for each route of exposure and range from IV (considered least toxic) to I (considered most acutely toxic). Data pertaining to the acute eye and dermal irritation and dermal sensitization are not required to support the reregistration of the technical grade active ingredient (TGAI), these data are presented for informational purposes:

Table 5 . Acute Toxicity Studies for Bromacil

GUIDELINE	TEST	RESULTS	CATEGORY
81-1 (Accession # 00022077)	Oral LD50--rat	5.126 g/kg ♂/3.998 g/kg ♀	IV
81-2 (Accession # 00013272)	Dermal LD50--rabbit	> 5000 mg/kg	IV
81-3 (Accession # 00022080).	Inhalation LC50--rat	> 14.4 mg/L	IV
81-4 (Accession # 00022079)	Eye irritation--rabbit ^{1,2}	mild irritant	III
81-5 (Accession # 00022081)	Dermal irritation--rabbit ¹	Primary Irritation Score= 0.8	IV

¹ This study is required for manufacturing-use and end-use products (40 CFR 158) and is provided for informational purposes only.

² The lithium salt of bromacil falls into Toxicity Category II for eye irritation.

The acute toxicity of bromacil by most routes of exposure has been categorized in the lowest possible toxicity category, category IV. Only ocular exposure was in category III: bromacil is mildly irritating to the eye. A dermal sensitization study in Guinea pigs (MRID 41304107) is currently in the review process, and a detailed review will be issued at a later date.

b. Subchronic Toxicity

A 90-day subchronic feeding study is not available but is not being required since the existing chronic data adequately characterize risk associated with subchronic duration of exposure.

c. Chronic Toxicity and Carcinogenicity

In a chronic toxicity study, Beagle dogs were given 0, 25, 150, or 625 ppm bromacil in the feed for one year. Body-weight gains were decreased in both sexes at 625 ppm. Although testicular atrophy and degeneration were observed in males at all dose levels, these effects were determined to be unrelated to treatment based on (1) the lack of a dose response for the unilateral, the bilateral, and the combined unilateral/ bilateral lesions and (2) the lack of an increase in the incidence or severity with a 25-fold increase in dose. The NOEL was 150 ppm (4.65 ♂/4.6 ♀ mg/kg/day). The LOEL was 625 ppm (17.8 ♂/17.3 ♀ mg/kg/day), based on decreased body-weight gains (MRID 41869701).

A combined chronic toxicity and carcinogenicity study was conducted with Crl:CD (BR) rats. The doses given in the diet for two years were 0, 50, 250, or 2500 ppm. The NOEL was 250 ppm [9.82 ♂/13.3 ♀ mg/kg/day]. The LOEL was 2500 ppm (103♂/144♀ mg/kg/day), based on decreased body-weight gains. Additional effects observed were (1) increased incidence in the high-dose males of cystic follicles and ultimo branchial cysts of the thyroid, hyperplasia and clear cell foci of the adrenal cortex, and retinal atrophy; (2) increased incidence of epithelial hyperplasia of the thymus in the high-dose females; and (3) dose-related increasing trends in thyroid C-cell adenomas and thyroid follicular cell adenomas and/or carcinomas combined in the males (MRID 41261701).

In a carcinogenicity study, CD-1 mice were given bromacil in the diet for 18 months. The doses were 0, 250, 1250, or 5000 ppm bromacil in the diet (0, 40, 196, or 871 mg/kg/day for males; 0, 67, 330, or 1131 mg/kg/day for females). The NOEL for systemic effects was not determined, based on liver lesions at all dose levels in males. The systemic LOEL was 40 mg/kg/day, based on the following liver effects: increased incidence in hepatocellular hypertrophy, single cell and centrilobular necrosis, hepatocellular lysis with RBC accumulation, and centrilobular vacuolation. There was a significant increase in combined hepatocellular adenomas and/or carcinomas at 871 mg/kg/day in males only, and there was a significant dose-related trend for hepatocellular carcinoma and for combined hepatocellular adenomas and/or carcinoma in males (MRID 00072782).

d. Developmental Toxicity

A developmental toxicity study with Crl:CD BR rats used doses of 0, 20, 75, 200, or 500 mg/kg/day given by gavage on gestation days 7-16. The maternal toxicity NOEL was 20 mg/kg/day. The maternal toxicity LOEL was 75 mg/kg/day, based on decreased body-weight gain and decreased food consumption during the first two days of dosing. The developmental toxicity NOEL was 75 mg/kg/day. The developmental toxicity LOEL was 200 mg/kg/day, based on increased incidence of rudimentary lumbar ribs and extra thoracic vertebrae. Significant increases in skeletal developmental variations due to retarded development; i.e., retarded or partial ossification of the axial skeleton [interparietal, parietal, and supraoccipital skull bones, bipartite and dumbbelled centrum of the vertebrae, sternum and hyoid] and the partial ossification of the appendicular skeleton [pubis and ischium] were observed at the highest dose tested (MRID 40984802).

In a developmental toxicity study in Hra:(NZW)SPF rabbits, doses of 0, 30, 100, 300, or 500 mg/kg/day were given by gavage on gestation days 7-19. The NOEL for maternal toxicity was 100 mg/kg/day. The LOEL for maternal toxicity was 300 mg/kg/day, based on decreased body-weight gain and food consumption. There were no effects on maternal reproductive parameters. The NOEL for developmental toxicity was 100 mg/kg/day. The LOEL for developmental toxicity was 300 mg/kg/day, based on the increase in the percentage of late post-implantation loss. There was a significant reduction in the number of female pups at the 300 and 500 mg/kg/day dose levels, and there was a significant increase in the mean percentage of skeletal variations at the highest dose level (MRID 40984801). The Agency does not consider bromacil to be a developmental toxicant.

e. Reproductive Toxicity

In a two generation reproduction study, Crl:CD BR rats were fed doses of 0, 50, 250, or 2500 ppm bromacil. No effects on reproductive performance were seen. The parental NOEL was 250 ppm (12.5 mg/kg/day). The LOEL was 2500 ppm (125 mg/kg/day), based on significantly increased incidence of hydronephrosis. The reproductive NOEL was > 125 mg/kg/day (MRID 41804601).

f. Mutagenicity

Bromacil did not induce a mutagenic response in the Ames assay, with and without activation (MRID 42465701). In an *in vivo* micronucleus assay in mice, bromacil was negative (MRID 42465801). Bromacil was not genotoxic in the unscheduled DNA synthesis assay (MRID 42465901). The Agency does not consider bromacil to be mutagenic.

Additional data submitted under section 6(a)(2) of FIFRA by E.I. DuPont de Nemours and Company has received a cursory review (MRID 44005401 and 02) by the Agency. This submission is currently in the review process and a detailed review will be issued at a later date.

The Registrant is required to submit all the full mutagenicity studies addressed in MRID 44005401. A summary of the Registrant's analysis follows.

Krovar® DF is formulated from 40% bromacil, 40% diuron and 20% inert ingredients. Krovar® DF was evaluated in an in vivo mouse micronucleus mutagenicity assay and was found to be positive for clastogenic activity (study not submitted).

Subsequently, bromacil was tested in an in vitro chromosome aberrations mutagenicity assay in human lymphocytes and was found to be positive for clastogenic activity (MRID 44005402).

Bromacil was also tested in an in vivo micronucleus assay and was found to be negative for clastogenic activity (study not submitted).

In addition, diuron technical (98%) was tested in male and female rat bone marrow cells following single oral doses of 50, 500, and 5000 mg/kg by oral intubation. Signs of systemic toxicity and body weight loss were observed in the rats at the 5000 mg/kg level. Diuron was considered positive for clastogenic activity (study not submitted).

The Agency's Mutagenicity Risk Assessment Guidelines give more weight to in vitro test results. The evidence presented by the registrant indicates that the positive mutagenicity of Krovar® DF is most likely due to the diuron and not the bromacil.

The weight of evidence suggests that bromacil is not mutagenic. This is supported by the studies addressed in the first paragraph of this section. Agency does not consider bromacil to be mutagenic.

g. Metabolism

Metabolic studies were conducted with rats given single [low and high] and multiple [low] doses of radiolabelled bromacil. The major route of elimination was via the urine following all dosing schedules except the multiple low dose in males where urine and fecal elimination were approximately equal. Bromacil was absorbed readily from the gastrointestinal tract, extensively metabolized [primarily by hydroxylation at the 6-methyl position and on the sec-butyl moiety], and rapidly excreted. The hydroxylated metabolites were eliminated as glucuronide conjugates. Radiolabel was found in all tissues examined, but there was no evidence of accumulation. The major metabolite of bromacil in the urine of rats was 5-bromo-6-hydroxymethyl-3-sec-butyl-uracil. Trace levels of the parent compound and two other (unidentified) metabolites were excreted in the urine (MRID 42825201).

h. Dermal Absorption

The Agency established an interim estimate of 20% dermal absorption for bromacil using a non-guideline absorption study and surrogate data from other pesticides. A discussion of these

data and the Agency's rationale follow. The registrant, in a document entitled *Detailed Risk Mitigation Proposals for Bromacil Reregistration*, cites a 1965 skin absorption study in rabbits and, using several conservative assumptions, estimates dermal absorption of bromacil during a workday (8 hours) to be 4.6%. In addition, a preliminary literature search for *in vitro* human absorption values suggests 14% absorption of 5-fluorouracil, a surrogate substituted uracil. On this basis the registrant has suggested using an interim 20% absorption value in the worker risk assessment while they conduct a 28-day dermal toxicity study in rats.

Using data/information on other pesticides for which there are dermal absorption data whose solubilities are similar to bromacil, and given that bromacil is neither volatile nor a dermal irritant, the Agency can reasonably assume dermal absorption of these materials to be similar. For example, maneb, is a solid, as is bromacil and has a molecular weight and solubility similar to that of bromacil. Dermal penetration of maneb is expected to be no greater than one percent. For these reasons, the Agency believes the interim estimate of 20% absorption of bromacil is reasonable.

2. Dose-Response Assessment

a. Reference Dose

The Agency determined the RfD for bromacil to be 0.1 mg/kg/day, based on the NOEL of 9.82 mg/kg/day in the chronic rat toxicity study. An uncertainty factor of 100 was used to account for the inter-species extrapolation and intra-species variability (Ghali, 1994). The World Health Organization/Joint Meeting on Pesticide Residues has not evaluated bromacil.

b. Cancer Classification

The Office of Pesticide Programs Carcinogenicity Peer Review Committee classified bromacil as Group C - possible human carcinogen - and recommended that the Reference Dose (RfD) approach be used for quantification of human risk. This decision was based on the increased incidence of liver tumors in male mice, and positive trends in thyroid tumors in male rats, and to a lesser extent on analysis of structural activity relationship to similar compounds. Bromacil is not considered mutagenic.

c. Toxicity Endpoints

Based upon its review of the toxicology data base for bromacil, the Agency selected a toxicological endpoint and dose level of concern appropriate for risk assessment (*Toxicology Endpoint Selection Document*, November 15, 1994). This endpoint is maternal toxicity, from the rat developmental toxicity study (MRID 41804601) described above. Short- (1 to 7 days) and intermediate- (1 week to several months) term occupational risk assessments are appropriate, due to the low NOEL and the lack of a 21-day dermal toxicity study. An acute dietary risk assessment is not appropriate, because the effects noted in the above study would not be expected with just

one dose. Also, there was no evidence to indicate that bromacil was associated with major developmental or reproductive toxicity.

The Agency selected this endpoint for the following reason. In the developmental toxicity study in rats, bromacil was tested at 0, 20, 75, 200, and 500 mg/kg/day. The maternal NOEL was 20 mg/kg/day, the maternal LOEL was 75 mg/kg/day based on a decrease in body weight and food consumption during the dosing period. A significant increase in liver weight at 500 mg/kg/day was observed. The developmental NOEL was 75 mg/kg/day, and the developmental toxicity LOEL was 200 mg/kg/day, based on an increased incidence of rudimentary lumbar ribs and an extra thoracic vertebra.

The LOEL at 75 mg/kg/day is an indication of maternal stress. The maternal effect noted was a minimal effect involving decreases in body weight gain and food consumption during only the first two days of dosing. Thus, the actual maternal NOEL level is likely to be considerably higher than 20 mg/kg/day.

3. Exposure Assessment

This section describes the process the Agency used to estimate human exposure to bromacil from the diet and from occupational use.

a. Dietary Exposure

A dietary risk assessment is required when a chemical is registered for use on crops used either as food for people or feed for livestock. Bromacil meets this criteria. It is registered for food/feed use on citrus and pineapple. Formulations may be applied as soil broadcast or banded sprays to citrus or pineapple and broadcast foliar applications to pineapples using ground equipment. The bromacil lithium salt is not registered for use on any crops.

The residue chemistry data base identifying and quantifying the residues of bromacil is adequate and supports reregistration of bromacil as a food use pesticide on citrus and pineapple. Tolerances for residues of bromacil at 0.1 ppm in/on citrus and pineapples have been established and are expressed in terms of bromacil *per se* [Source: 40 CFR §180.210]. No tolerances exist for residues of bromacil in animal commodities; and no food/feed additive tolerances have been established.

Directions for Use on Citrus and Pineapples

Three end-use products (EPs) of bromacil are presently registered to E.I. du Pont de Nemours & Co. that may be used on food/feed crops grown in the U.S. The bromacil EPs are presented below:

Table 6. DuPont Products Registered for Use on Food/Feed Crops

EPA Reg. No.	Formulation Class	Product Name
352-287	80% WP	Hyvar® X Herbicide
352-351 ¹	53% WP (MAI) ²	Krovar® II Herbicide
352-352 ¹	40% WP (MAI) ²	Krovar® I Weed Killer
352-440 ¹	53% DF (MAI) ²	Krovar® II DF Herbicide
352-505	40% DF (MAI) ²	Krovar® I DF Herbicide
352-546	80% DF	Hyvar® DF Herbicide

¹These products were voluntarily canceled by DuPont effective May 2, 1996.

² Multiple active ingredient product.

All registered formulations of bromacil prohibit their application through any type of irrigation system. The 80% WP, and the 40% DF specify a 12-hour reentry interval. A reentry interval is not specified for the 80% DF. Preharvest intervals are not specified in any of the labels.

The 40%, 53%, and 80% WP and DF bromacil formulations are registered for band or broadcast ground treatment beneath and/or between established bearing citrus trees at 1.1-6.4 lb ai/A/application or 0.8-3.2 lb ai/A/application as split treatments; the 53% WP may also be used in FL as a split application at up to 4.2 lb ai/A/application. Spray applications must be made in a minimum of 40 gal of water/A. The application rates are dependent on soil types; higher rates are recommended for silt loam or clay loam soils and lower rates are recommended for sand or loamy sand soils. The maximum seasonal use rate for citrus varies among labels and depends upon location, soil conditions, and orchard age. For established bearing trees (> 4 years), all labels (except the 53% WP) specify a maximum seasonal rate in FL of 6.4 lb ai/A/year on soils of low permeability and 4.2 lb ai/A/year on highly permeable soils; the 53% WP allows a maximum seasonal rate in FL of 8.5 lb ai/A/year. For other citrus producing regions (AZ/CA/LA/TX), the 80% WP and DF and the 53% DF labels do not specify a maximum seasonal use rate, the 53% WP specifies a maximum of 5.3 lb ai/A/year, and the 40% WP and DF formulations specify maximum use rates of 6.4 lb ai/A/year for TX and LA and 2.4 lb ai/A/year for CA and AZ. The maximum seasonal use rates on citrus for specific regions and conditions must be standardized between the labels.

All labels specify that grazing of cattle in treated areas is prohibited. Treated areas may be planted to citrus trees one year after the last application. Replanting of treated areas to any crop other than citrus within two years after application is prohibited. The 53% C and 80% WP and DF formulation labels also prohibit applications to citrus in Kern County, CA because of the threat to groundwater.

The 80% WP and the 80% DF are registered for multiple applications to pineapples grown in HI and FL. The first treatment may be made at 1.6-4.8 lb ai/A as a ground broadcast application before plants begin to grow. The remaining treatments may be made either as directed interline applications prior to floral differentiation at 1.6-3.2 lb ai/A or as broadcast treatments

at 1.6 lb ai/A after the plant is 8 months old but prior to floral differentiation. The formulations are also registered for application to ratoon crops at 0.8-3.2 lb ai/A to be applied using ground equipment after harvesting the planting crop but before differentiation. The maximum seasonal application rates are 8 lb ai/A and 3.2 lb ai/A to the planting and ratoon crops, respectively. In Puerto Rico, bromacil is registered for use on pineapples at 0.8-3.2 lb ai/A to be applied immediately after planting and before plants begin to grow. Replanting of treated areas to any crop other than pineapples within two years after application is prohibited.

Plant Metabolism

The qualitative nature of the residue in plants is adequately understood based on acceptable orange and pineapple metabolism studies. Results from the orange metabolism study indicate that bromacil undergoes hydroxylation at the 6-methyl group to produce Metabolite A (5-bromo-3-sec-butyl-6-hydroxy-methyluracil), which is readily conjugated with glucose and is converted to a malonyl ester of glucose conjugate of Metabolite A. In pineapple the metabolism of bromacil proceeds from hydroxylation of the *sec*-butyl side chain followed by conjugation of the hydroxylated metabolites. The residue of concern and the residue to be regulated in citrus and pineapple fruit is bromacil *per se* (MRIDs 13202, 002415, 014750, 42967501, 43460601)

Animal Metabolism

The nature of the residue in animals is adequately understood based on an acceptable ruminant metabolism study reflecting oral dosing. In ruminants, bromacil is hydroxylated at the 6-methyl and the *sec*-butyl side chains and the 6-hydroxymethyl derivative is further conjugated. A poultry metabolism study is presently not required since bromacil is not registered for use on crops that are used as poultry feed (MRIDs 002192, 42998901).

Residue Analytical Methods - Plants and Animals

Adequate methods are available for tolerance enforcement and data collection. A GLC method with microcoulometric detection is available for tolerance enforcement and is listed in *Pesticide Analytical Method* (PAM) Vol. II as Method I. Additional methods include a GLC method with electron-capture detection (ECD), published in PAM Vol. II as Method B, and an improved GLC method using a thermionic nitrogen/phosphorus detector (GLC/ECD) used for data collection. These methods have not undergone validation by the Agency (MRID 013999, 014217, 019944, 42967301, 43078801).

The registrant submitted data on a GLC/ECD method for determining residues of bromacil *per se* in/on oranges and pineapple. The submitted method is a modification of Method B published in PAM Vol. II and has a more sensitive limit of detection (LOD = 0.01 ppm) than any of the enforcement methods. In addition, the registrant has submitted data on a confirmatory GLC/MSD data collection method for citrus and pineapple that may be used if bromacil residues are present at or above a level of 0.01 ppm.

Enforcement analytical methods for residues in animals are not required as no tolerances exist for bromacil in animal commodities.

The *FDA PESTDATA* data base dated 1/94 (PAM Vol. I, Appendix II) indicates that bromacil is completely recovered (> 80%) using PAM, Vol. I *Multiresidue Protocol D* and not recovered using *Protocol E* Sections 211.1 or 212.1.

Storage Stability

The requirements for storage stability data are satisfied for the purposes of reregistration. The submitted storage stability data indicate that residues of bromacil *per se* are stable at -15 C for up to 18 months in citrus and pineapple fruits and in pineapple beverage juice and bran at ≤15 C for 99 and 139 days, respectively.

The registrant did not provide information regarding the duration of storage of citrus samples that were used for tolerance assessment. However, since residues of bromacil were not observed in the citrus metabolism study and residue samples used for tolerance assessment bore nondetectable (< 0.05 ppm) residues of bromacil *per se*, it can be concluded that the citrus fruit field trials are validated by acceptable storage stability data (MRID 42967401, 43461601).

Magnitude of the Residue in Plants

The reregistration requirements for magnitude of the residue in plants using bromacil are fulfilled. Adequate field trial data depicting residues of bromacil following applications made according to the maximum registered use patterns have been submitted for citrus and pineapple. Geographical representation is adequate and a sufficient number of trials reflecting representative formulation classes were conducted.

Citrus Fruits Group

Oranges, Lemons, Grapefruit, and Tangelos: The Agency concluded that acceptable data on citrus (oranges, lemons, grapefruit, and tangelos) are available. Residues of bromacil *per se* were < 0.05 ppm in/on citrus harvested up to 8 months after treatment with 3.2-8.0 lbs ai/A/season of bromacil in tests performed in CA, TX, and FL. Also, additional data on citrus were submitted in support of an amended use to increase the maximum seasonal use rate from 6.4 lb ai/A/season to 8.5 lb ai/A/season in FL. Residues of bromacil *per se* were < 0.05 ppm in/on citrus harvested 7, 14, 21, and 28 days after the last treatment with 6.4-8.5 lb ai/A/season of bromacil in 4 tests performed in FL. The available data support the established 0.1 ppm crop group tolerance for residues of bromacil in/on citrus fruits (MRID 13203, 13206, 13321, 30632, 50468, 137865).

Miscellaneous Commodities

Pineapple: Recently submitted field data from three tests in HI indicate that residues of bromacil will not exceed the established tolerance of 0.1 ppm in/on pineapples harvested 125-215

days following the last of two applications of the bromacil 80% WP formulation at 10 lb ai/A (1.25x the maximum seasonal rate) or 20 lb ai/A (2.5x). Residues of bromacil *per se* were nondetectable (< 0.04 ppm) in/on five control samples and seven treated samples. No additional data are required; however, the registrant must specify a PHI in all relevant labels. As pineapple forage is no longer listed as a regulated commodity in the updated (9/95) Table II of *Subdivision O, Residue Chemistry*, data in/on pineapple forage are no longer required (MRID 13205,13293, 43461601).

Magnitude of the Residue in Processed Food/Feed

The reregistration requirements for magnitude of the residue in processed food/feed commodities are fulfilled for citrus and pineapple. A summary of the available data and reregistration status is presented below for each commodity.

Citrus Fruits: Acceptable data on citrus processed commodities are available. Residues of bromacil *per se* were < 0.04 ppm in/on citrus dried pulp. Data for citrus molasses were not submitted but the Agency concluded that if residues do occur in dried citrus pulp and molasses they will not exceed the tolerance for the raw agricultural commodity. Also, additional data on citrus processed commodities were submitted in support of an amended use to increase the maximum seasonal use rate of bromacil in FL. Residues of bromacil in orange fruit, peel, pulp, and juice were nondetectable (< 0.05 ppm). Residues do not concentrate in any citrus processed commodities. No food/feed additive tolerances are required for the processed commodities of citrus (MRID 13203, 13206, 13321, 30632, 137865).

In a pineapple processing study (MRID 43461601), residues of bromacil were nondetectable (< 0.04 ppm) in/on pineapple harvested 215 days after two broadcast applications of bromacil (80% WP), first at 12 lb ai/A before planting followed by a second application prior to floral induction at 8 lb ai/A for a total seasonal rate of 20 lb ai/A (2.5x). Residues were also nondetectable in/on juice and bran processed from the pineapples. Although the pineapple fruit used to obtain processing data did not bear measurable residues, the Agency concluded that the pineapple processing study is adequate because the registrant indicated that the plants treated at 2.5x exhibited signs of phytotoxicity. No food/feed additive tolerances are required for pineapple juice or bran.

Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

There are no established tolerances for bromacil residues in eggs, milk, animal fat, meat, and meat by-products. A 1970 study reported residues of bromacil *per se* of ≤0.116 ppm in milk from a dairy cow fed bromacil at 30 ppm in the diet (MRID 05002192).

The Agency has concluded that ruminant feeding studies and animal tolerances are not required because residues of bromacil expected in milk and meat would be < 0.0001 ppm, a level that would not be detected by the current analytical methods. This conclusion is based on I) a maximum theoretical dietary burden of 0.033 ppm for cattle calculated by assuming 33% of the

diet consisting of dried citrus pulp, ii) the level of bromacil fed to the animals in the ruminant metabolism study (9.2 ppm; 280x); and iii) the low TRR levels in milk (0.04 ppm) and tissue samples (0.02 ppm) from the metabolism study.

In addition, because no poultry feed items presently have tolerances for bromacil, conventional feeding studies are not required for poultry and no tolerances are required for poultry meat and eggs.

Confined Rotational Crops

Pineapple and citrus crops are normally not rotated, therefore, the requirement for confined rotational crop studies does not apply.

Summary of Residue Chemistry Assessment

Adequate plant metabolism and magnitude of the residue data are available for citrus and pineapple. Adequate processing studies have been submitted and residues of bromacil do not concentrate in processed commodities of citrus and pineapple. The qualitative nature of the residue in ruminants is adequately understood and data on nature of the residue in poultry are not required because no poultry feed items presently have tolerances for bromacil. Livestock feeding studies and animal tolerances are not required. In addition, the Agency has FDA's surveillance monitoring data (FY78-FY88) and Total Diet Study data (1982-1986). Therefore, a reliable risk assessment for the uses of bromacil can be conducted.

The compound 5-bromo-3-(2-hydroxy-1-methylpropyl)-6-methyluracil (Metabolite D) comprises a significant portion of the residue in pineapples. It was observed at a level 12 times that of the bromacil concentration in pineapple fruit. Therefore, while the residue to be included in the tolerance expression for pineapples will be bromacil, the Agency will use a 12X factor for the risk assessment. In the crop field trials no bromacil was observed at a limit of quantification of 0.04 ppm; therefore, the exposure which will be used will be 0.5 ppm. The present tolerances use up only ca. 1% of the new RfD for bromacil. Therefore, significantly less than 100% RfD will be taken up even when this additional residue is incorporated into the risk assessment.

b. Occupational Exposure

An occupational exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators) during use or to persons entering treated sites after application is complete. Bromacil meets these criteria.

Handler (Mixer/Loader/Applicators) Exposures

There is potential exposure to mixers, loaders, applicators, or other handlers during usual use-patterns associated with bromacil. Eight major exposure scenarios were identified for bromacil:

- (1) mixing/loading the liquid flowable, wettable powder, or dry flowable formulations for groundboom or aerial application;
- (2) applying as a spray with power sprayer equipment to treat rights-of-ways and under toxic-waste holding-pond liners;
- (3) applying as a spray with groundboom equipment;
- (4) applying using aerial fixed wing aircraft;
- (5) applying using aerial helicopter;
- (6) mixing/loading and applying with a low pressure handwand;
- (7) mixing/loading and applying with a push-type spreader; and
- (8) mixing/loading and applying granulars with a whirly bird spreader.
- (9) mixing/loading and applying with a backpack/knapsack sprayer.

For these nine bromacil handler exposure scenarios, the Agency used the V1.1 version of the *Pesticide Handler's Exposure Data Base (PHED)* except for the low pressure handwand scenario version where version V1.01 was used. Table 7 includes the equipment used for each exposure scenario and the daily treatment area. In addition, application is permitted using shaker or sprinkler cans and by aerosol, but no assessment was performed on these application methods. Exposure from these methods is expected to be less than for the above scenarios because the total amount of bromacil applied would be considerably less using these methods than the above methods.

The Agency used the same exposure values identified for rights-of-way spray applications for the toxic-waste holding-pond applications, except the maximum treatment area for the holding-ponds is assumed to be nearly five times that for rights-of-ways applications. A tractor drawn solid broadcast application has been identified for a pelleted formulation. The Agency is using the groundboom spray application exposure (and liquid mixer/loader exposure) as the worst case scenario for the pelleted use in absence of pelleted exposure data. All further risk characterization and PPE requirements for the tractor drawn mixer/loader/applicator are based on the mixing, loading, and application of the groundboom spray scenario. The Agency expects the estimated exposures for groundboom spray to overestimate any exposure that might result from applying the pelleted formulation.

Post-Application Exposure

Post-application exposure is likely since bromacil is broadcast in pineapple plantations and citrus orchards. However, exposure is expected to be relatively low since bromacil is generally directed at the target weeds therefore contact with treated surfaces is likely to be limited mostly to feet, lower legs, and, in some circumstances, hands. For these reasons, post-application

exposure data are not required for brush and weed control in crop areas, right-of-ways, paved areas, non-agricultural uncultivated areas, power stations, recreational areas, and orchard floors.

4. Risk Characterization

a. Dietary Risk

Acute Dietary Risk

An acute dietary risk assessment is not required because acutely toxic effects are not expected at concentrations of bromacil which are likely to be found in food (see Dose-Response Assessment section).

Chronic Dietary Risk

Residue Information

Tolerances for bromacil are published in 40 CFR §180.210. Tolerances had been established in/on citrus and pineapples at 0.1 ppm. The available data support the established tolerances and there are no suggested revocations or amendments to existing tolerances. Tolerance level residues and 100 percent crop treated assumptions were made for all commodities. No anticipated residue (AR) information was used in this analysis. No tolerances exist for residues of bromacil in animal commodities and no food/feed additive tolerances have been established and none are needed.

Results

A DRES chronic exposure analysis was performed using tolerance level residues and 100 percent crop treated information to estimate the TMRC for the general population and 22 subgroups.

Existing tolerances result in a TMRC which represents < 1% of the RfD for the U.S. general population. The highest subgroup, children 1-6 years old occupies 1% of the RfD.

The analysis for bromacil is a worst case estimate of dietary exposure with all residues at tolerance level and 100 percent of the commodities assumed to be treated with bromacil. Based on the risk estimates calculated in this analysis, it appears that chronic dietary risk, including cancer, from the uses recommended through reregistration, is not of concern.

b. Occupational Risk

The exposure scenarios are presented in the following tables along with the corresponding exposure/risk assessment. The baseline dermal unit exposures for all handlers represents the current label requirements: scenarios 1a, 1b, 1c, 1d, and 3 are based on single layer clothing and chemical resistant gloves while using open pour and open cockpit/cab; scenarios 2a, 2b, 4, 5, 6, 7, and 8 are based on single layer clothing and no gloves (baseline also represent the registrant's

proposed rate reduction from 24 lb ai/acre to 12 lb ai/acre). The additional PPE (Table 4: scenarios 2a, 2b, 4, 6 and 8) represents dermal unit exposures when chemical resistant gloves are worn. The risk mitigation for scenario 1b (mixing/loading wettable powder formulations) is water soluble packets and single layer clothing and no gloves.

Margins of exposure (MOEs) were calculated using the following formula:

$$MOE = \frac{NOEL}{EXPOSURE} = \frac{20MG/KG/DAY}{DailyDermalExposure(mg/kg/day)}$$

Risk to Handlers (Mixers, Loaders, Applicators, etc.)

Bromacil has the potential for significant exposure to mixer/loaders and applicators. From a review of the labels, the Agency identified nine possible handler exposure scenarios.

With the addition of chemical-resistant gloves or, in one instance, engineering controls, all exposure scenarios (except the toxic-waste holding-pond scenario at the maximum acreage, the mixing/loading for aerial application, and the mixing/loading dry flowables for groundboom at the maximum application rate of 25 lb ai/A) resulted in MOEs greater than or equal to 100 (see Table 9). For the toxic-waste holding-pond scenario at the maximum acreage (48 acres), the MOE is less than 100 (see Table 8) even when the applicator is wearing chemical-resistant gloves.

For this scenario, the Agency assumes that five acres is an area typically treated for this treatment and believes areas as large as 48 acres are treated only occasionally based on information provided by the registrant.

The mixing/loading of dry flowables and wettable powders resulted in MOEs less than 100. However, these MOEs are based upon a developmental toxicity study in rats in which the maternal NOEL was established at 20 mg/kg/day and the maternal LOEL at 75 mg/kg/day. The maternal effect noted was a minimal effect involving decreases in body weight gain and food consumption during only the first two days of dosing. Thus, the actual maternal NOEL level is likely to be considerably higher than 20 mg/kg/day. In addition, both the maternal and developmental NOELs in the rabbit study were established at a higher dose level, 100 mg/kg/day. Consideration of the minimal, transitory effects noted at the rat maternal LOEL (75 mg/kg/day) and the much higher dosage (200 mg/kg/day) required to elicit pronounced developmental effects, leads to a conclusion that the actual MOEs for these scenarios is at least 100.

Table 7. Unit Exposure Values and Daily Exposure Estimates for Uses of Bromacil

Exposure Scenario (Scenario Number)	Dermal Unit Exposure ^a (mg/lb ai)		Inhalation Unit Exposure ^c (µg/lb ai)	Application Rate (lb ai/acre) ^d Based on Registrant Risk Reduction	Daily Max. Treated ^e (acres)	Baseline Daily Absorbed Dermal Exposure ^f (mg/day)	Baseline Daily Inhalation Exposure ^g (mg/day)	Baseline Daily Absorbed Total Exposure ^h (mg/day)
	Current Label Baseline ^a	Add PPE Recommended ^b	Current Label Baseline(No Respirator)					
Mixer/Loader Exposure								
Mixing/Loading All Liquids for Groundboom Application (1a)	0.04 (gloves)	N/A	1.2	Max: 12 Typical: 4.5	80	Max: 7.7 Typical: 2.9	Max: 1.2 Typical: 0.43	Max: 8.9 Typical: 3.3
Mixing/Loading Wettable Powder for Groundboom Application (1b)	0.2 (gloves)	0.02 (Eng. Cntrl.)	43.4	Max: 12 Typical: 4.5	80	Max: 38.4 Typical: 14.4	Max: 41.7 Typical: 15.6	Max: 80.1 Typical: 30.0
Mixing/Loading Dry Flowables for Groundboom Application (1c)	0.07 (gloves)	N/A	0.8	Max: 12 Typical: 4.5	80	Max: 13.4 Typical: 5.0	Max: 0.77 Typical: 0.29	Max: 14.2 Typical: 5.3
Mixing/Loading Dry Flowables for Aerial Application (1d)					350	Max: 58.8 Typical: 22.1	Max: 3.4 Typical: 1.26	Max: 62.2 Typical: 23.4
Applicator Exposure								
Rights-of-way Sprayer (2a)	1.2 (no gloves)	0.4	3.9	Max: 12 Typical: 4.5	10	Max: 28.8 Typical: 10.8	Max: 0.47 Typical: 0.18	Max: 29.3 Typical: 11.0
Toxic-Waste Holding-Pond Liner Treatment (2b)	1.2 (no gloves)	0.4	3.9	Max: 25	Max: 48 Typical: 5 Min: .1	Max: 288 Typical: 30 Min: 0.6	Max: 4.7 Typical: .49 Min: .01	Max: 292.7 Typical: 30.5 Min: 0.61
Groundboom Sprayer (3)	0.01 (gloves)	N/A	0.4	Max: 12 Typical: 4.5	80	Max: 1.9 Typical: 0.72	Max: 0.032 Typical: 0.14	Max: 1.9 Typical: 0.86
Aerial Fixed-wing (4)	0.005 (no gloves)	N/A	0.068	Max: 12 Typical: 4.5	350	Max: 4.2 Typical: 1.6	Max: 0.29 Typical: 0.11	Max: 4.5 Typical: 1.7
Aerial Helicopter (5)	0.0021 (no gloves)	N/A	1.32	Max: 12 Typical: 4.5	350	Max: 1.8 Typical: 0.7	Max: 5.5 Typical: 2.1	Max: 7.3 Typical: 2.8
Mixer/Loader Applicator Exposure								
Low Pressure Handwand (6)	103 (no gloves)	4.9	31	Max: 12 Typical: 4.5	1	Max: 247.2 Typical: 92.7	Max: 0.37 Typical: 0.14	Max: 247.6 Typical: 92.8
Push-type Spreader (7)	2.9 (no gloves)	N/A	6.3	Max: 12 Typical: 4.5	1	Max: 7.0 Typical: 2.6	Max: 0.076 Typical: 0.028	Max: 7.1 Typical: 2.6
Whirly-bird Spreader (8)	10.4 (no gloves)	8.2	61.8	Max: 12 Typical: 4.5	0.5	Max: 12.5 Typical: 4.7	Max: 0.37 Typical: 0.14	Max: 12.9 Typical: 4.9
Backpack/Knapsack Sprayer (9)	2.6 (no gloves)	N/A	30.2	Max: 12 Typical: 4.5	1	Max: 6.24 Typical: 2.34	Max: 0.36 Typical: 0.14	Max: 6.6 Typical: 2.5

Note: Baseline includes registrant's risk mitigation, while the additional PPE is Agency's Recommendation. N/A - Not applicable, MOE greater than 100 for baseline protection.

^aThe baseline is based on the following current labels: Scenario 1a - single layer clothing and chemical resistant gloves HYVAR L (Reg. No. 352-425); Scenario 1b - single layer clothing and chemical resistant gloves HYVAR X (Reg. No. 352-287); Scenario 1c - single layer clothing and chemical resistant gloves KROVAR II DF (Reg. No. 352-440); Scenarios 2a and 2b - single layer clothing and no gloves HYVAR XL (Reg. No. 352-346); Scenario 3 - single layer clothing and chemical resistant gloves HYVAR L (Reg. No. 352-425); Scenarios 4 and 5 - enclosed cockpit (open cockpit data are not available), single layer clothing, no gloves; Scenario 6 - single layer clothing and no gloves HYVAR XL (Reg. No. 352-346); Scenarios 7 and 8 - single layer clothing and no gloves (Reg. No.352-412); Scenario 9 (Reg. No.334-245).

^bThe additional PPE is for dermal unit exposure representing single layer clothing and chemical resistant gloves while using open pour except Scenario 1b. Note: Scenario 1b represents workers wearing single layer clothing and no gloves while using water soluble packets as an engineering control measure (inhalation = 0.2 ug/lb ai).

^cInhalation exposure values are reported as geometric means (lognormal distributions). No adjustment has been made to simulate workers wearing dust/mist respirators.

^dMaximum application rate is based on the registrants mitigation proposal to reduce the rate from 24 to 12 lb ai/A, except for the toxic-waste holding-pond where the Max rate is 25 lb ai/A.

^eValues represent the maximum and typical area which can be used in a single day to complete treatments for each exposure scenario of concern.

^fDaily absorbed dermal exposure (mg/day) = Exposure (mg/lb ai) * Max. or Typical Appl. Rate (lb ai/acre) * Max., Typical, or Min. Treated (acres/day) * 0.2 (dermal absorption).

^gDaily inhalation exposure (mg/day) = Exposure (ug/lb ai) * (1mg/1000 ug) conversion * Max. or Typical Rate (lb ai/acre) * Max., Typical, or Min. Treated (acres/day).

^hDaily absorbed total exposure (mg/day) = Daily absorbed dermal exposure (mg/day) + Daily inhalation exposure (mg/day).

Table 8. Daily Dose, Margins of Exposure and Risk Mitigation Measures for Uses of Bromacil

Exposure Scenario (Scenario Number)	Baseline Daily Absorbed Dermal Dose ^{a,c} (mg/kg/day)	Baseline Daily Inhalation Dose ^{b,d} (mg/kg/day)	Baseline Total Daily Absorbed Dose ^e (mg/kg/day)	Baseline Total MOE ^f	Risk Mitigation		
					Additional PPE recommended ^g		
					Daily Absorbed Dermal Dose (mg/kg/day)	Total Absorbed Daily Dose ^e (mg/kg/day)	Total MOE
Mixer/Loader Risk							
Mixing/Loading All Liquids for Groundboom Application (1a)	Max: 0.13 Typical: 0.048	Max: 0.02 Typical: 0.0072	Max: 0.15 Typical: 0.055	Max: 133 Typical: 364	N/A	N/A	N/A
Mixing/Loading Wettable Powder for Groundboom Application (1b)	Max: 0.64 Typical: 0.24	Max: 0.70 Typical: 0.26	Max: 1.3 Typical: 0.50	Max: 15 Typical: 40	Maximum: 0.064 Typical: 0.024	Max: 0.067 Typical: 0.025	Max: 299 Typical: 800
Mixing/Loading Dry Flowables for Groundboom Application (1c)	Max: 0.22 Typical: 0.083	Max: 0.013 Typical: 0.0048	Max: 0.24 Typical: 0.088	Max: 83 Typical: 227	Not Feasible	Not Feasible	Not Feasible
Mixing/Loading Dry Flowables for Aerial Application (1d)	Max: 0.98 Typical: 0.37	Max: 0.06 Typical: 0.02	Max: 1.04 Typical: 0.39	Max: 19 Typical: 51	Not Feasible	Not Feasible	Not Feasible
Applicator Risk							
Rights-of-way Sprayer (2a)	Max: 0.48 Typical: 0.18	Max: 0.0078 Typical: 0.003	Max: 0.49 Typical: 0.183	Max: 41 Typical: 109	Max: 0.16 Typical: N/A	Max: 0.17 Typical: N/A	Max: 118 Typical: N/A
Toxic-Waste Holding-Pond Liner Treatment(2b)	Max: 4.8 Typical: 0.5 Min: 0.01	Max: 0.08 Typical: .0008 Min: .00004	Max: 4.9 Typical: 0.5 Min: 0.01	Max: 4.1 Typical: 40 Min: 2000	Max: 1.6 Typical: 0.2 Min: N/A	Max: 1.7 Typical: 0.2 Min: N/A	Max: 11.8 Typical: 100 Min: N/A
Groundboom Sprayer (3)	Max: 0.032 Typical: 0.012	Max: 0.00053 Typical: 0.0023	Max: 0.032 Typical: 0.014	Max: 625 Typical: 1,429	N/A	N/A	N/A
Aerial Fixed-wing (4)	Max: 0.07 Typical: 0.03	Max: 0.005 Typical: 0.002	Max: 0.08 Typical: 0.03	Max: 250 Typical: 667	N/A	N/A	N/A
Aerial Helicopter (5)	Max: 0.03 Typical: 0.01	Max: 0.09 Typical: 0.04	Max: 0.12 Typical: 0.05	Max: 167 Typical: 400	N/A	N/A	N/A
Mixer/Loader/Applicator Risk							
Low Pressure Handwand (6)	Max: 4.1 Typical: 1.5	Max: 0.0062 Typical: 0.0023	Max: 4.1 Typical: 1.5	Max: 4.9 Typical: 13.3	Max: 0.20 Typical: 0.073	Max: 0.20 Typical: 0.075	Max: 100 Typical: 267
Push-type Spreader (7)	Max: 0.12 Typical: 0.043	Max: 0.013 Typical: 0.00047	Max: 0.12 Typical: 0.043	Max: 167 Typical: 465	N/A	N/A	N/A
Whirly-bird Spreader (8)	Max: 0.21 Typical: 0.08	Max: 0.006 Typical: 0.0024	Max: 0.22 Typical: 0.082	Max: 91 Typical: 244	Max: 0.16 Typical: N/A	Max: 0.17 Typical: N/A	Max: 118 Typical: N/A
Backpack/Knapsack Sprayer (9)	Max: 0.10 Typical: 0.04	Max: 0.006 Typical: 0.002	Max: 0.106 Typical: 0.042	Max: 188 Typical: 476	N/A	N/A	N/A

N/A - Not applicable, MOE greater than 100 for baseline protection.

^aThe baseline is based on the following current labels: Scenario 1a - single layer clothing and chemical resistant gloves HYVAR L (Reg. No. 352-425); Scenario 1b - single layer clothing and chemical resistant gloves HYVAR X (Reg. No. 352-287); Scenario 1c - single layer clothing and chemical resistant gloves KROVAR II DF (Reg. No. 352-440); Scenarios 2a and 2b - single layer clothing and no gloves HYVAR XL (Reg. No. 352-346); Scenario 3 - single layer clothing and chemical resistant gloves HYVAR L (Reg. No. 352-425); Scenarios 4 and 5 - enclosed cockpit (open cockpit data are not available), single layer clothing, no gloves; Scenario 6 - single layer clothing and no gloves HYVAR XL (Reg. No. 352-346); Scenarios 7 and 8 - single layer clothing and no gloves (Reg. No. 352-412); Scenario 9 (Reg. No. 334-245).

^bThe baseline inhalation unit exposure values represents handlers wearing no respirators while using open pour and open cabs/cockpits.

^cDaily absorbed dermal dose (mg/kg/day) = [Exposure (mg/lb ai) * 0.2 (dermal absorption) * Max. or Typical Appl. Rate (lb ai/acre) * Max. Treated (acres/day)] / 60 kg (body weight).

^dDaily inhalation dose (mg/kg/day) = [Exposure (ug/lb ai) * (1mg/1000ug) conversion * Max. or Typical Appl. Rate (lb ai/A) * Max. Treated (acres/day)] / 60 kg (body weight).

^eTotal Daily Absorbed Dose (mg/kg/day) = Daily absorbed dermal dose (mg/kg/day) + Daily inhalation dose (mg/kg/day).

^fTotal MOE = NOEL (20 mg/kg/day) / Total Daily Absorbed Dose (mg/kg/day).

^gThe additional PPE is for dermal unit exposures representing single layer clothing and chemical resistant gloves except for Scenario 1b. Note: Scenario 1b represents workers wearing single layer clothing and no gloves while using water soluble packets as an engineering control measure (inhalation = 0.2 ug/lb ai).

Risk From Post-Application Exposures

No post-application exposure data are available for bromacil. EPA believes that the post-application exposures are likely, particularly following applications to citrus, pineapples, and recreation areas. These exposures may occur during activities, such as mowing and scouting in citrus orchards, scouting in pineapple plantations, and recreational activities in recreation areas. Since bromacil is generally directed at the target weeds, contact with treated surfaces is likely to be limited mostly to feet, lower legs, and, in some circumstances, hands.

c. Food Quality Protection Act Considerations

The Food Quality Protection Act of 1996 (FQPA) amended the FFDCA by setting a new safety standard for the establishment of tolerances. In determining whether a tolerance meets the new safety standard, section 408(b)(2)(C) directs EPA to consider information concerning the susceptibility of infants and children to pesticide residues in food, and available information concerning aggregate exposure to infants and children of such residues, as well as the potential for cumulative effects from pesticide residues and other substances that have a common mechanism of toxicity.

The FQPA amendments to section 408(b)(2)(C) require EPA to apply an additional 10-fold uncertainty (safety) factor unless reliable data demonstrate that the additional factor is unnecessary to protect infants and children.

Section 408(b)(2)(D) establishes factors that the Agency must consider in determining whether the safety standard is met in deciding to issue or reassess tolerances. These factors include the consideration of available information on the aggregate exposures to the pesticide from dietary sources including drinking water as well as non-occupational exposures such as those derived from pesticides used in and around the home. The Agency must also consider the potential cumulative effects of the pesticide for which a tolerance is being sought as well as other substances that have a common mechanism of toxicity.

Because bromacil has food uses, specific consideration of the risks to infants and children, as well as aggregate exposures and potential cumulative effects is warranted.

Potential Risk to Infants and Children

In determining whether a safety factor different than the additional 10-fold is or is not appropriate for assessing risks to infants and children, EPA considers all reliable data and makes a decision using a weight of evidence approach taking into account the completeness and adequacy of the toxicity data base, the nature of the effects observed in pre and post-natal studies, and other information such as epidemiological data.

For the purpose of assessing the pre- and post-natal toxicity of bromacil, EPA has evaluated two developmental and one reproduction study. Based on current data requirements, these three studies when considered along with other required toxicity studies, constitute a

complete data base for evaluating pre- and post-natal effects for food use chemicals. However, as EPA fully implements the requirements of FQPA, additional data related to the special sensitivity of young organisms may be required.

Developmental and Reproductive Effects

The effects observed in the bromacil developmental and reproduction studies can be summarized as follows:

A developmental toxicity study with Crl:CD BR rats used doses of 0, 20, 75, 200, or 500 mg/kg/day given by gavage on gestation days 7-16. The maternal toxicity NOEL was 20 mg/kg/day. The maternal toxicity LOEL was 75 mg/kg/day, based on decreased body-weight gain and decreased food consumption during the first two days of dosing. The developmental toxicity NOEL was 75 mg/kg/day. The developmental toxicity LOEL was 200 mg/kg/day, based on increased incidence of rudimentary lumbar ribs and an extra thoracic vertebra. Significant increases in skeletal developmental variations due to retarded development, i.e., retarded or partial ossification of the axial skeleton [interparietal, parietal, and supraoccipital of the skull bones, bipartite and dumbbelled centrum of the vertebrae, sternum and hyoid] and the partial ossification of the appendicular skeleton [pubis and ischium] were observed at the highest dose tested.

In a developmental toxicity study in Hra:(NZW)SPF rabbits, doses of 0, 30, 100, 300, or 500 mg/kg/day were given by gavage on gestation days 7-19. The NOEL for maternal toxicity was 100 mg/kg/day. The LOEL for maternal toxicity was 300 mg/kg/day, based on decreased body-weight gain and food consumption. There were no effects on maternal reproductive parameters. The NOEL for developmental toxicity was 100 mg/kg/day. The LOEL for developmental toxicity was 300 mg/kg/day, based on the increase in the percentage of late post-implantation loss. There was a significant reduction in the number of female pups at the 300 and 500 mg/kg/day dose levels, and there was a significant increase in the mean percentage of skeletal variations at the highest dose level.

In a two generation reproduction study, Crl:CD BR rats were fed doses of 0, 50, 250, or 2500 ppm bromacil. No effects on reproductive performance were seen. The parental NOEL was 250 ppm (12.5 mg/kg/day). The LOEL was 2500 ppm (125 mg/kg/day), based on significantly increased incidence of hydronephrosis. The reproductive NOEL was > 2500 ppm (125 mg/kg/day).

The developmental data for bromacil indicate developmental effects occurred at doses that were the same as or higher than doses which cause maternal toxicity. The Agency would generally be concerned when developmental/reproductive effects are seen at doses lower than those which cause maternal effects. No effects on reproductive performance were seen in the two generation rat study. The developmental studies in conjunction with the reproduction study do not indicate any additional sensitivity of young organisms to bromacil.

Uncertainty Factor

Based on reliable data outlined above, the Agency concludes that an additional uncertainty factor is not warranted for the bromacil chronic risk assessment, nor is the use of an additional uncertainty factor indicated for estimating risk from acute exposure detailed below.

Aggregate Exposure/Risk

In examining aggregate exposure, 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 include drinking water, and non-occupational exposures, e.g., to pesticides used in and around the home. For estimating acute and chronic risks the Agency considers aggregate exposures from the diet and from drinking water. Exposures from uses in and around the home that may be of a short term, intermediate or other duration may also be aggregated as appropriate for specific chemicals.

Bromacil has no residential or other non-occupational uses that might result in exposure to adults or children. Therefore, the only considerations for aggregate exposure are those from food and drinking water.

Acute Risk

The acute toxicity of bromacil by the oral, dermal, and inhalation routes of exposure is very low. The Agency has identified no acute toxicity endpoints of concern. Acute dietary and drinking water risk assessments were not conducted for bromacil because acute toxic effects are not expected at the concentrations of bromacil which are likely to be found in food or drinking water.

Chronic Risk

Dietary Exposure

A chronic dietary exposure analysis was performed, using tolerance level residues and assuming that 100 percent of the crops were treated, to estimate the Theoretical Maximum Residue Contribution (TMRC) for the general population and 22 subgroups.

Existing tolerances result in a TMRC which represents < 1% of the RfD for the U.S. general population. The highest subgroup, children 1-6 years old occupies 1% of the RfD.

The analysis for bromacil is a worst case estimate of dietary exposure with all residues assumed to be at tolerance levels and 100 percent of the commodities assumed to have been treated with bromacil.

Tolerances have been established in/on citrus and pineapples at 0.1 ppm. The available data for bromacil support the established tolerances listed in 40 CFR §180.210. No revocations or amendments are required at this time. No tolerances exist for residues of bromacil in animal commodities and no food/feed additive tolerances have been established or need to be established.

Drinking Water Exposure

Extensive data exists as evidence that bromacil leaches to ground water as a result of normal agricultural use. Data currently available to the EPA indicate that bromacil has been detected in ground water in 5 states, with concentrations in many Florida wells exceeding 100 ppb.

The data the Agency has on bromacil in South Florida surface water suggests that it is probably unlikely that the annual average concentrations of bromacil will exceed the lifetime health advisory or that peak or short term average concentrations will exceed the 1-10 day health advisory in surface water sources for drinking water in South Florida. The Agency has no other data on bromacil in surface waters.

Although bromacil residues in water are found above the HAL (90 ppb), the Agency has determined that an adult drinking 2 liters of water per day over a lifetime containing 100 ppb of bromacil reaches < 4% of the RfD, and a 10 kg child drinking 1 liter of water containing 100 ppb of bromacil reaches 10% of the RfD. Furthermore, as the infant's/child's body weight increases with age, the percent of the RfD for consumption of bromacil-contaminated water decreases.

Non-occupational Exposures

No other sources of chronic exposure to bromacil have been identified.

Conclusion Regarding Chronic Aggregate Exposure to Bromacil

Considering chronic exposures from all sources of bromacil (in this case only food residues and drinking water residues are relevant), aggregate risks will be < 6% of the RfD for the general population (< 2% from food and < 4% from water), and < 11% of the RfD for infants and children (1% from food and 10% from water).

The Agency concludes that aggregate risks to the general U.S. population, and to the population subgroup of infants and children, resulting from bromacil uses are not of concern.

Cumulative Effects

In assessing the potential risk from cumulative effects of bromacil and other pesticides and substances with a common mode/mechanism of toxicity, the Agency first considered structural similarities and common effects that exist between bromacil and other substituted uracil compounds such as terbacil and lenacil. The Agency then considered other compounds which

could potentially result in effects similar to bromacil: induced cystic thyroid follicles; or bromacil-induced enlargement of centrilobular cells of the liver.

A comparison of the available toxicological database for bromacil and terbacil revealed no clear commonality of effects. The toxicology database for lenacil was not considered because there are currently no registered uses and no tolerances for lenacil. Consequently, no dietary or non-occupational exposure to lenacil is anticipated. A summary of the most prominent clinical signs from terbacil and bromacil follows.

The following clinical signs were observed in the bromacil toxicology database: decreased body weight, focal atrophy of seminiferous tubules (testicular abnormalities), hydronephrosis, suggestive histological evidence for antithyroid activity (cystic follicles in the thyroid and enlargement of centrilobular cells of the liver) and a positive trend in thyroid tumors for male rats (basis of C classification for carcinogenicity).

The following clinical signs were observed in the terbacil toxicology database: decrease in body weight, increase in liver weights, vacuolization and hypertrophy of hepatocytes, hypertrophy of centrilobular hepatocytes in males, decreased pituitary weights in males and females, increase in thyroid/body weight ratio, and elevated alkaline phosphatase.

Based on these data, the Agency has determined that there does not appear to be a common mode/mechanism of toxicity between bromacil and terbacil. With both chemicals, there is marginal evidence of liver effects (principally enlargement of centrilobular cells). Enlargement of liver cells is not a specific enough effect to be considered a common mode/mechanism of toxicity. The thyroid effects observed with bromacil were cystic follicles. Terbacil induced an increase in relative thyroid weights but no increase in absolute thyroid weights. An increase in relative weight without a corresponding increase in absolute weight has very little meaning, especially without any supporting histological or hormonal evidence. This conclusion was based on the marginal liver effects noted in the databases, and the absence of thyroid effects in the terbacil database (with the exception of increases in relative thyroid weights).

In evaluating other chemicals with effects similar to bromacil, the Agency determined that the available data on bromacil are not sufficient to conclude that bromacil induces thyroid tumors through an antithyroid mode/mechanism of toxicity. Bromacil induces a positive trend in thyroid follicular cell tumors for male rats with no significant pairwise increases in thyroid tumors at any dose level. The available studies showed no changes in either T³, T⁴ or TSH levels, which would be prime indicators of antithyroid activity. In addition, there were no data available other than histological indications (cystic thyroid follicles and enlargement of liver cells) to indicate that bromacil is either affecting the thyroid directly by interfering with iodide uptake or thyroid hormone production and release or affecting the thyroid indirectly through the liver (increase in metabolism and excretion of thyroid hormones, thereby inducing the thyroid to grow in order to produce more hormones). Therefore, available data do not suggest that bromacil has a common mode/mechanism of toxicity with any other chemical that is known to have antithyroid activity.

Therefore, the risk assessment has taken into account only exposures resulting from bromacil uses.

C. Environmental Assessment

1. Ecological Toxicity Data

Review of the toxicity data found that chronic data were lacking for both aquatic and terrestrial animals. All of the acute studies fulfill the guideline requirements except the 72-3(b) acute estuarine and marine toxicity study with mollusk. In summary, the following guideline requirements are not fulfilled:

- Avian Reproduction Quail [71-4 (a)].
- Avian Reproduction Duck [71-4 (b)].
- Acute Estuarine/Marine Toxicity Mollusk [72-3(b)].
- Early Life-Stage Fish [72-4(a)].
- Life-Cycle Aquatic Invertebrate [72-4(b)].
- Aquatic Plant Growth [122-2].

The following assessment for ecological risk has been conducted for rates up to 32 lb ai/A, the maximum label rate allowed for bromacil-containing products prior to this reregistration review and issuance of the reregistration eligibility decision.

a. Toxicity to Terrestrial Animals

(1) Birds and Reptiles, Acute and Subacute

In order to establish the oral and dietary toxicity of bromacil to birds and reptiles, the following tests are required using the technical grade material: one avian single-dose oral (LD₅₀) study on one species (preferably mallard or bobwhite quail) (TABLE 9), and two subacute dietary studies (LC₅₀) on one species of waterfowl (preferably the mallard duck) and one species of upland game bird (preferably bobwhite quail) (TABLE 10).

Table 9: Avian Acute Oral Toxicity Findings

Surrogate Species	% A.I.	LD ₅₀ mg/kg	MRID No. Author/Year	Toxicity Category
Northern Bobwhite	96.6	2250	40951501 Grimes, J., 1986	Practically nontoxic

Table 10: Avian Subacute Dietary Toxicity Findings

Surrogate Species	% A.I.	LC ₅₀ ppm	MRID No. Author/Year	Toxicity Category
Northern Bobwhite	80	> 10,000	00013295 Dieterich, W.H., 1965	Practically nontoxic
Mallard	80	> 10,000	00013295 Dieterich, W.H., 1965	Practically nontoxic

The results summarized in the above two tables indicate that bromacil is practically nontoxic to avian and reptilian species on an acute oral and subacute dietary basis. The guideline requirements for the avian acute oral toxicity and avian subacute dietary toxicity studies are fulfilled. (MRID 40951501 and 00013295)

(2) Birds and Reptiles, Chronic

Avian reproduction studies are required when birds or reptiles may be exposed to bromacil repeatedly or continuously due to persistence, bioaccumulation, or multiple applications, or if mammalian reproduction tests indicate reproductive hazard. The field dissipation study shows the half-life of bromacil in soil is two months, and the labels allow for repeat application. Avian reproduction studies are not available. These studies are required in order to address the potential for adverse chronic or reproductive effects to birds and reptiles from bromacil.

(3) Acute and Chronic Effects to Mammals

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, the rat acute oral LD₅₀ is used to determine toxicity to mammals. This LD₅₀ is reported in the table below.

Table: 11 Mammalian Acute Oral Toxicity Findings

Surrogate Species	LD ₅₀ mg/kg	MRID # Author/year	Toxicity Category
Rat (small mammal surrogate) female	3998	00022077 Raltech Science Services Lab.	Practically nontoxic

The available mammalian data summarized in Table 12 indicate that bromacil is practically nontoxic to small mammals on an acute oral basis. (MRID #00022077)

(4) Insects

A honey bee acute contact LD₅₀ study is required if the proposed use will result in honey bee exposure.

TABLE 12: Nontarget Insect Acute Contact Toxicity Findings

Surrogate Species	% AI	LD ₅₀ µg a.i./bee	MRID No. Author/Year	Toxicity Category
Honey Bee	technical	193.3	00018842 Atkins, E.L.Jr.; Anderson, L.D.; Greywood, E.A. 1969	Relatively nontoxic

The data summarized in Table 12 indicate that there is sufficient information to characterize bromacil as relatively nontoxic to bees. The guideline requirement for the honey bee acute contact LD₅₀ study is fulfilled. (MRID 00018842)

b. Toxicity to Aquatic Animals

(1) Freshwater Fish

Acute Toxicity

In order to establish the toxicity of a pesticide to freshwater fish and amphibians, 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).

TABLE: 13 Freshwater Fish Acute Toxicity Findings

Surrogate Species	% A.I.	LC ₅₀ ppm a.i.	MRID No. Author/year	Toxicity Category
Rainbow trout	96.6	36 ppm	40951503 Wetzel, J., 1986	Slightly toxic
Bluegill sunfish	95	127	40951502 Wetzel, J., 1986	Practically nontoxic

The results of the 96-hour acute toxicity studies (Table 13) indicate that bromacil is slightly toxic to fish and amphibians. The guideline requirements for freshwater fish acute toxicity are fulfilled. (MRID 40951503 and 40951502)

Chronic Toxicity

Bromacil labels allow repeat applications and bromacil is persistent in water. Therefore, it can be expected that bromacil will be in water on a recurrent basis. The EEC in water is greater than 0.01 of the LC₅₀ for fish. The refined EEC calculations show that the aquatic concentrations associated with a 4.2 lbs a.i./A rate of bromacil application are expected to change very little over a 56 day period (day of application-0.35 ppm, 96 hours-0.349 ppm, 21 days-0.348 ppm, 56 days-0.347 ppm). Therefore, chronic testing is required.

The fish early life-stage study has not been submitted. These data are needed in order to determine the chronic risk to freshwater vertebrates.

A fish life-cycle test is required if studies of other organisms indicate the reproductive physiology of fish and/or amphibians may be affected. The fish life-cycle guideline requirement is reserved pending the results from the fish early life-stage study.

(2) 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.

TABLE 14: Freshwater Invertebrate Toxicity Findings.

Surrogate Species	% A.I.	EC ₅₀ (ppm)	MRID NO. Author/Year	Toxicity Category
<i>Daphnia magna</i>	96.6	121	40951504 Hall, C. 1986	Practically nontoxic

There is sufficient information, as summarized in Table 14, to characterize bromacil as practically nontoxic to aquatic invertebrates on an acute basis. The guideline requirement for freshwater invertebrate toxicity is fulfilled. (MRID 40951504)

As described above for fish, relatively high concentrations of bromacil are expected in water bodies receiving runoff. Therefore, the *Daphnia* life-cycle test is needed to complete the ecological effects assessment. This requirement has not been fulfilled.

(3) 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. The terrestrial food and feed uses, terrestrial nonfood use, and aquatic nonfood uses of bromacil may result in exposure to the estuarine environment. Therefore, estuarine and marine organism testing is required.

The requirements under this category include a 96-hour LC₅₀ for an estuarine fish, a 96-hour LC₅₀ for shrimp, and either a 48-hour embryo-larvae study or a 96-hour shell deposition study with oysters.

TABLE 15: Estuarine/Marine Acute Toxicity Findings.

Surrogate Species	% A.I.	LC ₅₀ /EC ₅₀ (C.L.)	MRID No. Author/Year	Toxicity Category
Eastern oyster embryo larvae	95.1	130 (NR)	41588703 Boeri, R. L.	Practically nontoxic
Mysid	95.1	12.9 (67-148)	41588701 Boeri R. L.	Practically nontoxic
Sheepshead minnow	95.1	162 (145.8-272.0)	41588702 Boeri, R.L. 1989	Practically nontoxic

There is sufficient information, as summarized in Table 15, to characterize bromacil as practically nontoxic to estuarine species on an acute basis. The guideline requirement is fulfilled for both the mysid and the sheepshead minnow. (MRID 41588701 and 41588702)

The guideline requirement is not fulfilled for the eastern oyster. The eastern oyster 48 hour embryo-larvae test did not meet the guideline requirements because control organisms in this study showed over 23% abnormality in shell development, and the laboratory failed to report the incidence of misshapen or malformed shell development. These abnormal effects may have masked effects of the herbicide. (MRID 41588703)

Chronic toxicity data are also necessary for completion of the estuarine and marine ecological effects assessment because relatively high concentrations of bromacil may persist.

These data include an estuarine fish early life-stage test and mysid life-cycle test. The data requirement has not been fulfilled.

c. Toxicity to Plants

(1) Terrestrial

Currently, terrestrial plant testing (seedling emergence and vegetative vigor) is required for herbicides that have terrestrial nonresidential outdoor use patterns and that have endangered or threatened plant species associated with the site of application. The above conditions apply for bromacil and lithium bromacil.

Tier 2 toxicity data on the technical/TEP (95.5% active ingredient) material for the most sensitive species is given in Table 16 below:

TABLE 16: Nontarget Terrestrial Plant Toxicity for Bromacil Technical (95.5% A.I.)

Surrogate Species	Seedling emergence EC ₂₅ lb a.i./A ¹	Vegetative vigor EC ₂₅ lb a.i./A ²
Dicot- Soybean	0.618 (0.356-> 20.0) ³	0.0184 (0.0143-0.0221) ³ (NOEC 0.0117)
Monocot-Wheat	0.0731 (0.573-0.0873)	0.0684 (0.00522-0.811) (NOEC 0.0469)
Monocot-Onion	(NOEL 0.0469)	(NOEC > 0.0938)
Monocot-Corn	(Not Reported)	0.173 (0.138-0.199) (NOEC 0.0938)
Monocot-Sorghum	0.185 (0.160-0.205)	0.284 (0.0682-0.413) (NOEC 0.188)
Dicot-Tomato	(NOEL > 0.0234)	0.0232 (0.0149-0.0285) (NOEC .0234)
Dicot-Sugarbeet	0.038 (Unknown) (NOEC 0.0234)	0.0213 (0.0104-0.0297) (NOEC 0.0234)
Dicot-Cucumber	(NOEC 0.0469)	0.0106 (0.00717-0.0136) (NOEC 0.0117)
Dicot-Rape	0.0154 (0.000364-0.0233)	0.0156 (0.00987-0.0206) (NOEC 0.0117)

¹Effects on seedling emergence are based on height.

²Effects on vegetative vigor are based on height.

³95% confidence interval.

For seedling emergence, rape is the most sensitive dicot and wheat is the most sensitive monocot. The guideline is fulfilled.

(2) Aquatic

Currently, aquatic plant testing is required for any herbicide that has outdoor non-residential terrestrial uses that may result in off-site movement by runoff (solubility > 10 ppm in water), or is applied directly to aquatic use sites (i.e. drainage systems and irrigation ditches, etc.) as is currently the case for bromacil. The following species should be tested: *Selenastrum capricornutum*, *Lemna gibba*, *Skeletonema costatum*, *Anabaena flos-aquae*, and a freshwater diatom.

Tier 2 toxicity data on the technical material is listed in Table 17 below:

TABLE 17: Nontarget Aquatic Plant Toxicity Findings

Surrogate Species	% A.I.	EC ₅₀
<i>Navicula pelliculosa</i> (Freshwater diatom) NT ¹	N/A	N/A
<i>Lemna gibba</i> NT ¹	N/A	N/A
<i>Selenastrum capricornutum</i>	96.5%	6.8 (5.9-7.8) ² ppb
<i>Skeletonema costatum</i> NT ¹	N/A	N/A
<i>Anabaena flos-aquae</i> NT ¹	N/A	N/A

¹NT indicates that these species were not tested.

²95% confidence interval.

The results summarized in the above table indicate that bromacil is very highly toxic to *Selenastrum capricornutum*. The following species must be tested: *Lemna gibba*, *Skeletonema costatum*, *Anabaena flos-aquae*, and a freshwater diatom. The value of the studies is considered to be high because these surrogate species were chosen to represent all aquatic plants. Without these studies, the susceptibility of potentially more sensitive plants would not be considered. The guideline requirements are fulfilled for bromacil but not for the lithium salt. (MRID # 42516401).

2. Environmental Fate

a. Environmental Fate Assessment

The environmental fate data base for bromacil is largely complete. Bromacil is a persistent and highly mobile herbicide.

The primary routes of dissipation appear to be photolysis in water under alkaline conditions and microbial degradation in anaerobic soil. In the laboratory studies, bromacil was stable to hydrolysis, photodegradation in water at pH's 5 and 7, photodegradation on soil, and aerobic soil metabolism. However, bromacil in pH 9 buffered solution did photodegrade fairly rapidly with a half-life of 4-7 days. Under anaerobic conditions, bromacil appeared to degrade with a half-life of approximately one month, though this study had several major deficiencies that call into question the validity of this information. Laboratory mobility data, in addition to ground water monitoring information, have clearly demonstrated that bromacil is highly mobile in soil. Bromacil's persistence was confirmed with half-lives of 124-155 days in the field dissipation studies; however its tendency to leach was not apparent from the two studies. The timing and amount of rainfall/irrigation in these studies is a possible explanation. Bromacil accumulates only slightly in fish and deperates rapidly. There is evidence that bromacil will contaminate groundwater, and will move off-site and contaminate surface water.

b. Environmental Fate and Transport

(1) Degradation

Hydrolysis. Bromacil is stable to hydrolysis at environmental pHs. Ring-labeled [2-¹⁴C]bromacil at 20 ppm was stable to hydrolysis in sterile aqueous pH 5, 7, and 9 buffer solutions that were incubated in the dark at 25 ± 1 °C for 30 days. At 30 days post-treatment, bromacil comprised 94.4-96.4%, 94.6-99.0%, and 96.5-97.0% of the recovered radioactivity in the pH 5, 7, and 9 solutions, respectively. Unidentified [¹⁴C]peaks from TLC analyses of the test solutions revealed three minor degradates, one of which (Peak II) reached a maximum of 3.9% of the recovered radioactivity in the pH 7 solution at 30 days. The radioactivity in the trapping solutions was ≤0.01% of the applied (MRID 40951505).

Photodegradation in Water. Bromacil is stable to photolysis in water at pH 5 and 7, but degrades at pH 9 with a half-life of 4-7 days. Apparently, once ionized (pK_a 9.1), there is a shift in the absorption spectrum of bromacil thereby making it susceptible to photolysis. Degradates in the pH 9 system have not been identified.

In the first photodegradation in water study, ring-labeled [2-¹⁴C]bromacil at 20 ppm was stable in sterile aqueous pH 5 and 7 buffered solutions and degraded rapidly in sterile aqueous pH 9 buffered solutions that were irradiated continuously with a xenon arc lamp at 25 ± 1 °C for 15 days.

Bromacil photodegraded with a calculated half-life of 326 days in the pH 5 test solution. Bromacil decreased from an average of 97.2-98.0% of the applied radioactivity immediately post-treatment to 89.0-92.7% of the applied at 17 days post-treatment (15 days of irradiation).

Bromacil photodegraded with a calculated half-life of 102 days in the pH 7 test solution. Bromacil decreased from an average of 97.1-99.2% of the applied radioactivity immediately post-treatment to 78.2-80.8% of the applied at 17 days post-treatment (15 days of irradiation). A maximum of eight unidentified degradates were isolated in the pH 7 solution, each present at ≤8.1% of the recovered radioactivity.

Bromacil photodegraded with a calculated half-life of 7 days in the pH 9 test solution. Bromacil decreased from an average concentration of 96.4-98.0% of the applied radioactivity immediately post-treatment to 15.8-18.9% of the applied at 7 days, and 3.4-4.4% of the applied at 17 days post-treatment (15 days of irradiation). The radioactivity in the pH 9 test solution was not further characterized. In the dark control test solutions, the average concentrations of bromacil were ≥96.4% of the applied radioactivity at 17 days post-treatment (15 days of irradiation). In all test solutions, [¹⁴C]volatiles were ≤0.5% of the applied for the irradiated and dark solutions during the study. (MRID 40951507)

In a second photodegradation in water study, ring-labeled [2-¹⁴C]bromacil at 20 ppm photodegraded with a half-life of 103.1 hours (4.3 days) in a sterile aqueous pH 9 buffered

solution that was irradiated continuously with a xenon arc lamp at $25 \pm 1^\circ\text{C}$ for 15 days. Bromacil was 99.94% of the applied immediately post-treatment, 50.89% at 3 days, 15.86% at 7 days, and 0.81% at 15 days post-treatment. The test solution was not analyzed for degradates during the study. (MRID 40951508)

Photodegradation on Soil. Bromacil is stable to photolysis on soil. Ring-labeled [2- ^{14}C]bromacil at 0.13 mg/mL (equivalent to 0.12 lb ai/A), photodegraded with a calculated half-life of 166 days on silty clay loam soil that was irradiated for 12 hours per day with a xenon arc lamp for 30 days at $25 \pm 1^\circ\text{C}$.

Based on TLC analysis of the irradiated samples, bromacil decreased from 104.6% of the applied immediately post-treatment to 90.4% of the applied after 30 days. Two unidentified degradates (Unknowns I and II) each comprised $\leq 2.5\%$ of the applied in the irradiated samples. At 30 days post-treatment, unextracted [^{14}C]residues totaled 3.6% of the applied; no [^{14}C]volatiles were detected during the course of the study.

The calculated half-life for the dark controls was 273 days. Based on TLC analysis, bromacil decreased from 104.6% of the applied immediately post-treatment to 96.7% of the applied after 30 days; Unknowns I and II were each $\leq 2.0\%$ of the applied. At 30 days post-treatment, unextracted [^{14}C]residues totaled 1.3% of the applied; no [^{14}C]volatiles were detected. (MRID 40951509)

Aerobic Soil Metabolism. Microbial degradation of bromacil in aerobic soil is slow, with a half-life of 275 days. Ring-labeled [2- ^{14}C]bromacil at 9 ppm degraded with a half-life of 275 days in silty clay loam soil that was incubated in the dark at $25 \pm 1^\circ\text{C}$ and 75% of field moisture capacity for up to 12 months. Bromacil decreased from 98.5% of the applied radioactivity immediately post-treatment to 53.1% at 184 days, 48.6% at 240 days, and 38.6% at 12 months. Carbon dioxide was the major degradate, totaling 40.3% of the applied at 12 months post-treatment. In extracts of sterilized silty clay loam soil, bromacil comprised 87.5% of the applied at 12 months post-treatment. Metabolites were a maximum of 1.6% of applied radioactivity. Five nonvolatile degradates were identified:

- 1) 5-bromo-6-methyluracil (**Metabolite G**) was a maximum of 3.4% of applied radioactivity at 304 days post-treatment;
- 2) 5-bromo-3-(alpha-hydroxymethylpropyl)-6-methyluracil (**Metabolite C**) was a maximum of 1.5% of applied radioactivity at 154 and 184 days;
- 3) 5-bromo-3-sec-butyl-6-hydroxymethyluracil (**Metabolite A**) was a maximum of 0.6% of applied radioactivity at 184 days post-treatment;
- 4) 5-bromo-3-(2-hydroxy-1-methylpropyl)-6-methyluracil (**Metabolite D**) was a maximum of 0.8% of applied radioactivity at 304 days; and,

- 5) 3-sec-butyl-6-methyluracil (**Metabolite F**) was a maximum of 0.7% of applied radioactivity at 304 days.

(MRID 40951510)

Anaerobic Aquatic Metabolism. This study provides ancillary information and cannot be upgraded. The study is unsatisfactory because it did not adequately characterize the degradation of bromacil under anaerobic conditions, which is apparently a major route of dissipation. The sampling intervals were inadequate to accurately establish the half-life of the test substance (> 50% degraded between two samplings). Between day 28 and day 93, the percent applied radioactivity identified as bromacil decreased from 78.1% to 1.3%.

The 39 day half-life calculated by the registrant was based on an assumption that there was a 28 day lag phase and that the degradation was first-order linear between 28 and 93 days. Only these two sampling intervals were used to calculate the half-life. The Agency believes the data are inadequate to accurately define the pattern of decline of bromacil and the patterns of formation and decline of the metabolites.

The major degradate was 3-sec-butyl-6-methyluracil (Metabolite F) and was a maximum of 80.7% of the applied at day 304 post-treatment. This product is likely formed through reductive dehalogenation, a reaction favored under anaerobic conditions.

Since the sampling intervals were inadequate to accurately establish the half-life, the problems with this study could not be resolved with the submission of additional data. A new anaerobic aquatic metabolism study using appropriate study intervals is necessary to determine whether anaerobic aquatic metabolism is a major route of dissipation for bromacil, and to accurately establish the half-life. (MRID 40951511)

(2) Mobility

Column Leaching. Bromacil is very mobile in sand, sandy loam, clay loam and silt loam soils. Aged bromacil residues are very mobile in silt loam soils.

Based on column leaching studies, unaged [¹⁴C]bromacil was very mobile in columns of sand, sandy loam, clay loam, and silt loam soils that were treated with ring-labeled [2-¹⁴C]bromacil at 5.49 mg ai/column (approximately equivalent to 27 kg ai/ha) and leached with 20 inches of 0.01 M CaCl₂ solution. [¹⁴C]Residues in the leachates of all four soils totaled 91.2-99.6% of the applied; [¹⁴C]residues remaining in the soil columns were 2.46-9.37% of the applied and were distributed throughout the length of the columns. Based on HPLC analyses of the leachates, bromacil comprised 89.0-94.1% of the applied, and unidentified residues ("other") totaled < 0.05-6.7% of the applied.

Aged Column Leaching. Based on a column leaching study, aged [¹⁴C]bromacil residues were very mobile in a column of silt loam soil that was treated with ring-labeled [2-¹⁴C]bromacil

at 63 ppm, incubated for 30 days, and leached with 20 inches of 0.01 M CaCl₂ solution. [¹⁴C]Residues in the leachate totaled 87.3% of the applied radioactivity; [¹⁴C]residues remaining in the soil column were 19.5% of the applied and were mostly (11.3% of applied) in the upper 2 inches of the column. Extractable [¹⁴C]residues remaining in the soil column were 11.8% of the applied; of these, bromacil comprised 11.3% of the applied and unidentified residues ("other") were 0.5% of the applied. Following leaching, bromacil was the only compound identified in the leachate, comprising 82.8% of the applied radioactivity; unidentified ("other") residues comprised 4.5% of the applied.

The mobility of 3-sec-butyl-6-methyluracil (Metabolite F), the major and persistent metabolite identified in the Anaerobic Aquatic Metabolism study, was not addressed. However, this metabolite is not of toxicological concern. Therefore, based on the environmental fate profile of bromacil, (i.e., its persistence and mobility) and the toxicity information on Metabolite F, no additional mobility data are needed at this time. (MRID 40951512)

(3) Accumulation

Accumulation in Fish. Bromacil is only slightly accumulated in bluegill sunfish. Accumulated residues depurate very rapidly.

Bromacil residues accumulated very slightly in bluegill sunfish that were exposed to ring-labeled [2-¹⁴C]bromacil at 1.0 or 10.6 ppm for 28 days under flow-through aquarium conditions. Total [¹⁴C]residues were highest in the viscera tissues of fish exposed to either test concentration, with bioconcentration factors of 6.8 and 8.3X, respectively.

In fish exposed to 10.6 ppm of ring-labeled [2-¹⁴C]bromacil, the maximum bioconcentration factors were 4.6X for muscle, 6.8X for viscera, 2.1X for carcass, and 2.5X for whole fish. Maximum mean concentrations of total [¹⁴C]residues were 49.2 ppm in muscle (day 21), 72.2 ppm in viscera (day 28), 22.3 ppm in carcass (day 21), and 26.4 ppm in whole fish (day 21). Depuration was rapid, with > 96% of the accumulated [¹⁴C]residues eliminated from the fish tissues by day 3 of the depuration period.

In fish exposed to 1.0 ppm of ring-labeled [2-¹⁴C]bromacil, maximum bioconcentration factors were 4.6X for muscle, 8.3X for viscera, 2.2X for carcass, and 2.8X for whole fish. Maximum mean concentrations of total [¹⁴C]residues were 4.8 ppm in muscle (day 21), 8.6 ppm in viscera (day 7), 2.3 ppm in carcass (day 14), and 2.9 ppm in whole fish (day 7). Depuration was rapid, with > 96% of the accumulated [¹⁴C]residues eliminated from the fish tissues by day 3 of the depuration period.

During the 28-day exposure period, total [¹⁴C]residues, comprised of bromacil exclusively, ranged from 0.91 to 1.21 ppm for the low dose and 8.8 to 11.4 ppm for the high dose aquaria. Although identification of accumulated residues is generally required, this information is not needed in this case due to the very low bioconcentration factors and high depuration rates for bromacil. (MRID 40951513)

(4) Field Dissipation

In the field, bromacil was persistent, but did not demonstrate the degree of mobility that was predicted by the laboratory studies and the available ground water monitoring data. In loamy soils, bromacil was somewhat persistent and demonstrated low to moderate mobility under field conditions. One possible explanation for the limited mobility at the two sites could be the amount and timing of rainfall and/or irrigation.

Bromacil (Hyvar X Herbicide, 80% WP), applied in a single ground application at 12 lb ai/A, dissipated with half-lives of 155 days from the upper 10 cm of a bare ground plot of silty clay loam soil located in Delaware, and 124 days from the upper 10 cm of a bare ground plot of loam soil located in California. Bromacil was detected in the upper 10 cm of the Delaware and California plots through 538 and 415 days posttreatment, respectively. In general, bromacil was not detected below the 40 cm soil depth at both test sites.

- 1) **Newark, Delaware.** Average concentrations of bromacil in the 0- to 10-cm depth were 9.71 ppm immediately post-treatment, 4.69 ppm at 30 days, 3.59-4.17 ppm at 90-181 days, 1.97 ppm at 359 days, and 0.41 ppm at 538 days post-treatment. In the 10- to 20-cm depth, average concentrations of bromacil varied with no discernible pattern, and were a maximum of 0.36 ppm at 243 days post-treatment. In the 20- to 40-cm depth, bromacil was an average of 0.17 ppm immediately post-treatment, 0.05 ppm at 14 days, and was generally ≤ 0.03 ppm from 30-538 days post-treatment. In general, bromacil was not detected below the 40-cm soil depth.
- 2) **Madera, California.** Average concentrations of bromacil in the 0- to 10-cm depth were 8.28 ppm immediately post-treatment, 4.65 ppm at 29 days and 4.07 ppm at 59 days, 2.85-3.31 ppm at 89-179 days, and 0.48 ppm at 415 days post-treatment. In the 10- to 20-cm depth, average concentrations of bromacil were 0.31 ppm immediately post-treatment, then < 0.01 -0.30 ppm with no discernible pattern through 415 days post-treatment. In the 20- to 40-cm depth, bromacil was an average of 0.09 ppm immediately post-treatment and generally was not detected by 15 days post-treatment, although it was 0.02-0.04 ppm in isolated samples taken at 179-415 days post-treatment. In general, bromacil was not detected below the 40-cm soil depth. (MRID 41677101)

c. Water Resources

(1) Ground Water

Extensive data exists as evidence that bromacil leaches to ground water as a result of normal agricultural use. Less data is available to determine the impact of bromacil applications from use on rights-of-way. Data currently available to the EPA indicate that bromacil has been detected in ground water in 5 states, with concentrations in many Florida wells exceeding 100 ppb. Because of this, bromacil exceeds the following levels of concern:

- 1) **Human Health.** Bromacil has been detected in ground water at concentrations that exceed the lifetime health advisory level (HAL) of 90 ppb, and has maintained concentrations above that level in many wells. Wells in Sebring, Florida have shown levels of bromacil near the HAL 30 months after detections were originally found above 90 ppb.
- 2) **Ground Water Quality.** Bromacil has been shown conclusively from groundwater monitoring data to leach to ground water, diminishing the quality of the resource. In areas of the Central Ridge of Florida, such as DeSoto City, ground water contaminated with bromacil has remained contaminated for several years. In addition, concentrations of bromacil in these Florida wells do not consistently decrease with time, even with reductions in the application rate of the chemical.
- 3) **Non-target Plants.** Bromacil is highly toxic to aquatic plants, with an EC₅₀ for *Selenastrum capricornatum* of 6.8 ppb. This is of particular concern in Florida, where because of high water tables, ground water discharges into drainage canals, which ultimately drain into surface water bodies. In addition, bromacil has been found in ground water at concentrations that exceed levels-of-concern for non-target terrestrial plants, as determined by seedling-emergence studies. This could be a concern in areas where contaminated ground water is used for irrigation.

Small-Scale Retrospective Ground Water Monitoring Studies. DuPont conducted retrospective ground water monitoring studies in three citrus-growing regions (Central Ridge, Flatwoods and Coastal) of Florida between 1987 and 1990. Bromacil was detected in ground water at all three study sites, as described below.

- 1) **Central Ridge.** Bromacil was detected in all 10 wells at this site, with well depths ranging from 14 to 54 feet. Five of these wells had at least one detection above the 90 ppb Health Advisory Level (HAL), with a maximum concentration of 156 ppb. Concentrations of bromacil at this site did not decrease with time in these monitoring wells, although the application rate of bromacil was decreased throughout the study.
- 2) **Flatwoods.** Bromacil was detected in all three of the monitoring wells installed at this site, with a maximum detection of 21.8 ppb.
- 3) **Coastal.** Bromacil was detected in three of the four monitoring wells at this site, with a maximum concentration of 147 ppb. The three wells with detections were screened from 5 to 10 feet. The well without detections was screened from 50 to 60 feet.

State Ground Water Monitoring Studies.

- 1) **Florida.** Although bromacil is used in many states, the greatest use has been on citrus crops in Florida. In addition, the most extensive ground water monitoring for bromacil has been in Florida. As a result of this monitoring, it has become clear that contamination of ground water with bromacil has occurred to varying degrees throughout the citrus-growing regions of the state.

The region with the greatest concern is the Central Ridge of Florida. In response to a large number of bromacil detections in drinking water wells at levels above the HAL (90 ppb), the State of Florida has suspended use of bromacil in this region, pending evaluation of mitigation measures proposed by DuPont. DuPont is conducting a prospective field-scale ground water monitoring study to determine if additional reduction of the application rate will prevent bromacil from contaminating ground water at levels greater than the HAL in this area.

Bromacil has been one of the pesticides tracked in Florida's Pesticide Contamination Monitoring System. This system keeps a running total of ground water samples analyzed for bromacil, and the number of samples with concentrations above and below the 90 ppb health advisory level. As of May 1995, 2837 wells were sampled for bromacil; 899 had detections below the HAL, and 57 had detections above the HAL. Of this number, 679 of the wells with detections below the HAL, and 55 with detections above the HAL were from Highlands County, in the Central Ridge. Polk County recorded 121 wells with detections below the HAL, and 1 above the HAL. Lake County followed with 70 wells with detections below the HAL, then Hardee County with 16 wells with detections below and one with detections above the HAL.

A separate study performed in Collier County, in the Flatwoods region of southern Florida, had detections well above the HAL in shallow ground water. In a report on this study¹, detections of bromacil in ground water are listed at concentrations as high as 1422 ppb. These samples were collected at the very top of the water table, from wells with one-foot screens. The State of Florida does not consider bromacil to be a ground water concern in the Flatwoods region, as there is generally a low-permeability spodic layer near the surface, perching this uppermost saturated zone. However, as a result, the contaminated shallow ground water is available for transport into surface water through drainage ditches.

- 2) **Texas.** While bromacil use is greatest in Florida, significant amounts are also applied in California and Texas for both citrus and right-of-way uses. Contacts at the Texas Department of Agriculture and Texas Natural Resource Conservation Commission

¹ Dwinell, S., 1990. "Movement of Bromacil in a Collier County Citrus Grove: Evaluation of the GLEAMS Model". Florida Dept. of Envir. Regulation.

reported that the State of Texas does not have records of bromacil analysis of ground water samples more recent than 1988. The Agency's "Pesticides in Ground Water Data base" reports that bromacil was detected in 6 of 230 wells sampled in Texas between 1983 and 1989.

- 3) California.** In 1994, the Department of Pesticide Regulation of the California Environmental Protection Agency (CalEPA) reported that bromacil was one of 5 pesticides for which detections were "verified" in California groundwater as a result of non-point agricultural use within the past year. CalEPA defines a detection as "verified" when (a) the pesticide (or breakdown product) is detected in two discrete samples taken from a single well during a 30-day period AND (b) the second sample is analyzed either by the same laboratory using different analytical methods or by two laboratories using the same method (analytical methods must have been approved by the department of pesticide regulators. Bromacil was detected in two other wells but these detections could not be verified because bromacil was not detected in the second discrete samples from these wells. Bromacil detection was verified in 4 wells in 2 counties in 1994 where it had not been previously detected, and found but not verified in two new wells in two other counties.

In California, the quality of groundwater is managed by the use of Pesticide Management Zones (PMZs). A PMZ is an approximately square-mile area designated as sensitive to ground water contamination. PMZs are created based on verified detections in groundwater of a particular pesticide residue. PMZs are chemical specific; there are bromacil PMZs, simazine PMZs, diuron PMZs, etc.

California has designated bromacil a "restricted material" for crop uses. Use of bromacil on crops in bromacil PMZs requires a permit. Noncrop use of bromacil is not allowed under any conditions in bromacil PMZs.

CalEPA monitors compliance within PMZs to ensure pesticides are not reapplied in these areas, and to determine if previously detected residues are still present in the soil. About 10% of existing PMZs are retested each year. In 1994, soils were sampled in non-crop and row areas and analyzed for bromacil. Residues of bromacil were reported in three of five PMZs at levels ranging from 50 to 240 ppb. These residues were considered to have resulted from normal agricultural use before the PMZ was established.

In addition to the Update Report², CalEPA provided a copy of a data base of bromacil analyses in ground water, which consisted of over 6800 entries. Among these are 282 positive detections in 12 counties. The highest concentration recorded in the data base was 20 ppb from a well in Tulare County.

² California Environmental Protection Agency, Department of Pesticide Regulation, 1994. "Sampling for Pesticide Residues in California Well Water: 1994 Update, Well Inventory Data base."

(2) Surface Water

Substantial amounts of bromacil could be available for runoff to surface waters for several months post-application (aerobic soil metabolism half-life of 275 days, terrestrial field dissipation half-lives of 124 to 155 days). The low soil/water partitioning of bromacil (SCS/ARS data base K_{oc} of 32) indicates that most bromacil runoff will be via dissolution in runoff water as opposed to adsorption to eroding soil.

Bromacil is susceptible to direct aqueous photolysis at pH 9 where a substantial portion of it is anionic ($pK_a = 9.1$). However, it is not susceptible to direct aqueous photolysis at pH 5 or 7, to abiotic hydrolysis or to volatilization from water (Henry's Law Constant = 1.1×10^{-9} atm*m³/mol). The stability of bromacil to abiotic processes (except at highly alkaline pHs) coupled with only a moderate susceptibility to microbiological degradation under aerobic conditions indicates that bromacil will be persistent in the water column of non-alkaline surface waters with long hydrological residence times. Bromacil appears to be more susceptible to degradation by microbes under anaerobic conditions which suggests that bromacil will be less persistent in typically anaerobic sediments than in typically aerobic water columns. However, the low soil/water partitioning of bromacil indicates that most of the bromacil in surface water will be dissolved in the water column as opposed to adsorbed to suspended and bottom sediment. Reported BCF values for bromacil in the bluegill sunfish were low and depuration rates were high. Therefore, the bioaccumulation potential of bromacil appears to be low.

Although several degradates of bromacil have been identified in laboratory studies under aerobic conditions, none are classified as major since none represent $\geq 10\%$ of applied radioactivity at any time during the studies. However, under anaerobic conditions, 3-sec-butyl-6-methyluracil was identified as a major degradate. The available data are not sufficient to assess its persistence and mobility.

The South Florida Water Management District (Miles and Pfeuffer 1994) summarized bromacil 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 from the 27 sites from November 1988 through November 1993. Bromacil was detected (above detection limits generally ranging from 0.002 to 0.25 ppb) in 56 samples. Of the 56 detects, two were greater than 10 ppb (14 and 11.1 ppb), nine were between 2 and 10 ppb, twelve were between 1 and 2 ppb, and the remaining 33 detects were below 1 ppb.

The Louisiana Department of Agriculture and Forestry reported 3 detections (detection limit not specified) of bromacil ranging from 0.4 to 1.73 ppb in 84 samples collected in 1992 from 6 Louisiana water districts. The Louisiana Department of Agriculture and Forestry reported 12 detections (detection limit not specified) of bromacil ranging from 0.13 to 2.63 ppb in 48 samples collected monthly May-October 1993 from 8 locations in 5 Louisiana water districts. Three of the 12 detections were greater than 1 ppb.

Bromacil 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. It has lifetime and 1 and 10 day drinking water health advisories of 90 µg/L and 5000 ppb, respectively. The data the Agency has on bromacil in South Florida surface water suggest that it is probably unlikely that the annual average concentrations of bromacil will exceed the lifetime health advisory or that peak or short term average concentrations will exceed the 1-10 day health advisory in surface water sources for drinking water in South Florida. The Agency does not have any other data on bromacil in surface waters. The Agency believes bromacil is unlikely to pose any substantial risks to surface source drinking water anywhere.

In summary, bromacil is mobile in soil, persistent in both soil and water and degrades more rapidly under anaerobic conditions than under other conditions.

3. Exposure and Risk Characterization

a. Ecological Exposure and Risk Characterization

Explanation of the Risk Quotient (RQ) and the Level of Concern (LOC):

The Levels of Concern (LOC) are criteria used to indicate potential risk to nontarget organisms. The criteria indicate that a chemical, when used as directed, has the potential to cause undesirable effects on nontarget organisms. There are two general categories of LOC (acute and chronic) for each of the four nontarget faunal groups and one category (acute) for each of two nontarget floral groups. In order to determine if an LOC has been exceeded, a RQ must be derived and compared to the LOC's. A RQ is calculated by dividing an appropriate exposure estimate (e.g. the estimated environmental concentration [EEC]) by an appropriate toxicity test effect level (e.g. the LC₅₀). The acute effect levels typically are:

- EC₂₅ (terrestrial plants),
- EC₅₀ (aquatic plants and invertebrates),
- LC₅₀ (fish and birds), and
- LD₅₀ (birds and mammals)

The chronic test results are the NOEC for avian and mammal reproduction studies, and either the NOEC for chronic aquatic studies, or the Maximum Allowable Toxicant Concentration (MATC), which is the geometric mean of the NOEC and the LOEC for chronic aquatic studies.

When the RQ exceeds the LOC for a particular category, risk to that particular category is presumed to exist. Risk presumptions are presented in Table 18 along with the corresponding LOCs.

TABLE 18 Levels of Concern (LOC) and associated Risk Presumption

1. Mammals, Birds, Reptiles		
<u>IF THE</u>	<u>LOC</u>	<u>PRESUMPTION</u>
acute RQ>	0.5	High acute risk.
acute RQ>	0.2	Risk that may be mitigated through restricted use.
acute RQ>	0.1	Endangered species may be affected acutely.
chronic RQ>	1.0	Chronic risk, endangered species may be affected chronically.
2. Fish, Amphibians, Aquatic invertebrates		
<u>IF THE</u>	<u>LOC</u>	<u>PRESUMPTION</u>
acute RQ>	0.5	High acute risk.
acute RQ>	0.1	Risk that may be mitigated through restricted use.
acute RQ>	0.05	Endangered species may be affected acutely.
chronic RQ>	1.0	Chronic risk, endangered species may be affected chronically.
3. Plants.		
<u>IF THE</u>	<u>LOC</u>	<u>PRESUMPTION</u>
RQ>	1.0	High acute risk
RQ>	1.0	Endangered plants may be affected.

Currently, no separate criteria for restricted use or chronic effects for plants exist.

(1) Exposure and Risk to Nontarget Terrestrial Animals

(a) Birds and Reptiles

The risk quotient (RQ) used to determine if the level of concern has been exceeded is the EEC divided by the LC₅₀. However, the available studies did not determine an LC₅₀ value. Since the mallard study shows no toxic effects for mallard ducks at the highest level tested (10,000 ppm) and in the quail study the quail appear to be near their effect threshold, a conservative LC₅₀ was derived based on two assumptions: 1) that the slope was 5.78 (this was the average from Hill et al. 1975), and 2) that the LC₁₀ was 10,000 ppm. Table 20 shows RQs calculated from an estimated LC₅₀ of 16,662 ppm. This estimate was derived using the following formula from Hill (et al. 1975):

$$\text{Log LC}_{50} = (5 - \text{probit/slope}) + \text{logLC}_{10}$$

Tables 19-20 show the RQs for each application rate for liquid and granular formulations.

TABLE 19: Acute Avian and Reptilian RQs For Liquid Formulations.

Crop	App. Rate (lbs a.i./A)	Bird Food Items	Conc. Expected at 1 lb/A ¹ (ppm)	EEC (ppm) ²	Est. LC ₅₀ (ppm) ³	RQ Acute (EEC/Est LC ₅₀)
Grapefruit; Orange	3.2	Short grass	240	768.00	16,662	0.05
		Long grass	110	352.00	16,662	0.02
		Broadleaf plants	135	432.00	16,662	0.03
		Fruit	15	48.00	16,662	0.00
Citrus	4.24	Short grass	240	1,017.60	16,662	0.06
		Long grass	110	466.40	16,662	0.03
		Broadleaf plants	135	572.40	16,662	0.03
		Fruit	15	63.60	16,662	0.00
Pineapple	6	Short grass	240	1,440.00	16,662	0.09
		Long grass	110	660.00	16,662	0.04
		Broadleaf plants	135	810.00	16,662	0.05
		Fruit	15	90.00	16,662	0.01
Recreational Areas; Rights-of-Way; Non-agricultural uncultivated areas; Industrial Outdoors	24	Short grass	240	5,760.00	16,662	0.35
		Long grass	110	2,640.00	16,662	0.16
		Broadleaf plants	135	3,240.00	16,662	0.19
		Fruit	15	360.00	16,662	0.02

¹These are derived by Fletcher (et al. 1994).

²EEC was calculated by multiplying the concentration expected at 1 lb/A by the application rate.

³The LC₅₀ was estimated based on the assumption of the probit method of determining the LD₅₀. The two most important assumptions are that the typical slope value is 5.78 and 10,000 ppm is equal to the LC₁₀. Based on this formula: $\text{Log LC}_{50} = (5 - \text{probit/slope}) + \text{logLC}_{10}$ the LC50 is 16,662 ppm.

TABLE 20: Avian and Reptilian RQ for Granular Formulations

Weight	Acute LD50/Square Foot	
	Broadcast RQ ¹	Band RQ
Application Rate of 8.712 lbs./A		
50 g	0.11	The label indicates that the application rate is proportionally reduced based on the band width. Therefore, the band RQ and broadcast RQ will be the same.
180 g	0.03	
1000 g	0.01	
Application Rate of 16 lbs./A		
50 g	0.20	The label indicates that the application rate is proportionally reduced based on the band width. Therefore, the band RQ and broadcast RQ will be the same.
180 g	0.06	
1000 g	0.01	
Application Rate of 24 lbs./A		
50 g	0.30	The label indicates that the application rate is proportionally reduced based on the band width. Therefore, the band RQ and broadcast RQ will be the same.
180 g	0.08	
1000 g	0.01	
Application Rate of 32 lbs./A		
50 g	0.40	The label indicates that the application rate is proportionally reduced based on the band width. Therefore, the band RQ and broadcast RQ will be the same.
180 g	0.40	
1000 g	0.40	

The equation for calculating the risk quotient is:

$$SingleDoseLD_{50}s/Ft^2 = \frac{ProductApp.Rate(lbs/acre) \times (453,590mg/lb/43,560ft^2/A)}{LD_{50}mg/kg \times WeightOfAnimal}$$

Restricted use RQs are exceeded at the 24 and 32 lb. a.i./A rates, and the endangered species RQs are exceeded at the 8.7, 24, and 32 lb. a.i./A rates.

Chronic RQs could not be determined because chronic/reproductive studies were not available. Bromacil is expected to persist (field dissipation study shows bromacil half-life of 2 months), and multiple applications are expected. Also, mammalian chronic studies show effects at concentrations expected in the environment. Based on this, an avian reproduction study is required to complete the ecological effect assessment.

(b) Mammals.

The following equation was used to determine the RQ's:

$$EEC / (LD_{50} / \% \text{ Body weight consumed}) = RQ$$

TABLES 21-22 shows the RQs for different kinds of food for the various liquid formulation application rates of bromacil. TABLE 21 applies to herbivores and insectivores, and TABLE 22 applies to granivores. The EECs are expressed in ppm.

TABLE 21: Risk Quotients for Herbivores/Insectivores

Body weight (g)	%Body wt consumed	Rat LD ₅₀ mg/kg	Est. mg/kg/d in diet	EEC Grass	EEC Forage & sm Insects	EEC Ig. Insects	RQ Grass	RQ Forage & sm. Insects	RQ Ig. Insects
Application Rate of 3.2 Lbs a.i./A.									
15	95	3998	4,208.42	768	432	48	0.18	0.10	0.01
35	66	3998	6,057.58	768	432	48	0.13	0.07	0.01
1000	46	3998	8,691.30	768	432	48	0.09	0.05	0.01
Application Rate of 4.24 lbs a.i./A.									
15	95	3998	4,208.42	1018	572	63.6	0.24	0.14	0.02
35	66	3998	6,057.58	1018	572	63.6	0.17	0.09	0.01
1000	46	3998	8,691.30	1018	572	63.6	0.12	0.07	0.01
Application Rate of 6 lbs a.i./A.									
15	95	3998	4,208.42	1440	810	90	0.34	0.19	0.02
35	66	3998	6,057.58	1440	810	90	0.24	0.13	0.01
1000	46	3998	8,691.30	1440	810	90	0.17	0.09	0.01
Application Rate of 24 lbs a.i./A. ¹									
15	95	3998	4,208.42	5760	3240	360	1.37	0.77	0.09
35	66	3998	6,057.58	5768	3240	360	0.95	0.53	0.06
1000	46	3998	8,691.30	5768	3240	360	0.66	0.37	0.04

TABLE 22: Risk Quotients for Granivores					
Body Weight (g)	% Body Wt Consumed	Rat LD₅₀ mg/kg	Est. mg/kg/d in Diet	EEC seeds	RQ
Application Rate of 3.2 lbs a.i./A					
15	21	3998	19,038.10	48	0.00
35	15	3998	26,653.33	48	0.00
1000	3	3998	133,266.67	48	0.00
Application Rate of 4.24 lbs a.i./A.1					
15	21	3998	19,038.10	63.6	0.00
35	15	3998	26,653.33	63.6	0.00
1000	3	3998	133,266.67	63.4	0.00
Application Rate of 6 lbs a.i./A					
15	21	3998	19,038.10	90	0.00
35	15	3998	26,653.33	90	0.00
1000	3	3998	133,266.67	90	0.00
Application Rate of 24 lbs a.i./A					
15	21	3998	19,038.10	360	0.02
35	15	3998	26,653.33	360	0.01
1000	3	3998	133,266.67	360	0.00

Table 23 presents risk quotients for granular formulations based on the LD₅₀/ft² rather than the EEC/LC₅₀ which is used for other formulations.

TABLE 23: Mammalian RQ for Granular Formulations

Mammal Type Weight	Acute LD50/Square Foot	
	Broadcast	Band
Application Rate of 8.712 lbs./A		
Herbivore 15 g	0.36	The label indicates that the application rate is proportionally reduced based on the band width. Therefore, the band RQ and broadcast RQ will be the same.
Insectivore 15 g	0.36	
Granivore 15 g	0.36	
Application Rate of 16 lbs./A		
Herbivore 15 g	0.67	The label indicates that the application rate is proportionally reduced based on the band width. Therefore, the band RQ and broadcast RQ will be the same.
Insectivore 15 g	0.67	
Granivore 15 g	0.67	
Application Rate of 24 lbs./A		
Herbivore 15 g	1.00	The label indicates that the application rate is proportionally reduced based on the band width. Therefore, the band RQ and broadcast RQ will be the same.
Insectivore 15 g	1.00	
Granivore 15 g	1.00	
Application Rate of 32 lbs./A		
Herbivore 15 g	1.33	The label indicates that the application rate is proportionally reduced based on the band width. Therefore, the band RQ and broadcast RQ will be the same.
Insectivore 15 g	1.33	
Granivore 15 g	1.33	

The equation for calculating the risk quotient is:

$$SingleDoseLD_{50}s/ft^2 = \frac{ProductApp.Rate(lbs/acre) \times (453,590mg/lb/43,560ft^2/A)}{LD_{50}mg/kg \times WeightOfAnimal}$$

TABLE 24 summarizes the results of TABLE 23 and provides the range of mammalian acute RQs for all uses of bromacil. The highest RQ was selected for each kind of mammal and application rate.

TABLE 24: Summary of the Range of Acute Mammalian Risk Quotients for All Uses.

Use Sites	Application Rate	Herbivores		Insectivores		Granivores
		High	Low ²	High	Low ²	
Liquid Formulation						
Grapefruit, Oranges	3.2	0.18	0.1	0.1	0.01	0.0
Citrus	4.24	0.24	0.14	0.14	0.02	0.0
Pineapple	6	0.34	0.19	0.19	0.02	0.0
Recreational Areas; Rights-of-Way; Nonagriculture uncultivated; Industrial Outdoors	24	1.37	0.77	0.77	0.09	0.02
Granular Formulations						
Power Stations	8.712	0.36		0.36		0.36
Recreational Areas	16	0.67		0.67		0.67
Citrus, Drainage Systems	24	1.00		1.00		1.00
Rights-of-Way; Nonagriculture uncultivated; Industrial Outdoors	32	1.33		1.33		1.33

¹H indicates the highest value of the range of RQs.

²L indicates the lowest value of the range of RQs.

Summary of Mammalian Acute Effects.

For the liquid formulations, the acute mammalian RQs exceeded the nonendangered species LOCs at 16 lb. a.i./A rate and above, and the endangered species LOCs at all rates. RQs exceeded the restricted use LOCs at the 4.24 and 6 lb. a.i./A use rates.

Mammalian acute LOCs were exceeded for all application rates for the granular formulations except at the 8.7 lb ai/A application rate. That rate exceeded the endangered species and restricted use LOCs.

Summary of Mammalian Chronic Effects.

Chronic effects were observed in a 2 year rat reproduction study at concentrations above 250 ppm (NOEL). The following effects were seen at the 2,500 ppm (LOEC) level: body weight reductions in both sexes of both generations (parental (P) and offspring (F1)), food consumption in male offspring (F1), and body weight reduction in the offspring of the offspring (F2).

Although, all uses exceeded the mammalian chronic LOCs the significance of the exceedances is uncertain due to the nature of the parameters affected.

(a) Insects

The results of the honey bee acute toxicity study show that honey bees are relatively insensitive to bromacil (LD₅₀ 193.3 µg a.i./bee). Based on this low risk, no label warnings are required.

(1) Exposure and Risk to Nontarget Aquatic Animals

Expected Aquatic Concentrations: Two different EECs were calculated: the GENEEC derived EEC, and the direct application EEC. The direct application scenario may be appropriate for several of the use patterns. For example, drainage systems, rights-of-way, recreation areas, and citrus often are in very close association with drainage systems, irrigation ditches and wetlands. The GENeric Expected Environmental Concentration (GENEEC) program is a simple model that uses a chemical's soil/water partition coefficient and degradation half-life values to estimate runoff from a ten hectare field into a one hectare by two meter deep pond. This program calculates both acute and chronic generic expected environmental concentration (EEC) values. It considers reduction in dissolved pesticide concentrations due to adsorption of pesticide to soil or sediment, incorporation, and degradation in soil before washoff to a water body. It also includes direct deposition of spray drift into the water body, and degradation of the pesticide within the water body.

EEC values from GEENEC (TABLE 25) range from 0.264 to 2.63 ppm. EEC values calculated using the direct application scenario (applying the pesticide to the surface of the water at normal application rates) ranged from 2.35 to 23.49 ppm. The direct application scenario may be appropriate for several use patterns, including, drainage systems, rights-of-way, recreation areas, and citrus which are often in very close association with drainage ditches, irrigation ditches and wetlands.

TABLE 25: Aquatic Estimated Environmental Concentrations (EECs) for Bromacil

Use	Application Rate in lbs a.i./A	EEC (ppm)		
		GENEEC ¹		Direct App. 6" ²
		Liquid	Granular	
Grapefruit; Orange	3.2	0.264	---	2.35
Citrus	4.24	0.35	---	3.11
	24	---	1.97	17.62
Pineapple	6	0.495	---	4.40
Drainage Systems	24	1.98	1.97	17.62
Recreational Areas	8.712	---	0.715	6.39
	24	1.98	---	17.62
Rights-of-Ways; Nonagricultural Uncultivated; Industrial Outdoors	24	1.98	---	17.62
	32	---	2.63	23.49
Power Stations	16	---	1.32	11.74

¹Based on a telephone conversation with Andrew Rose, a County Agent in Florida, a typical use of bromacil on citrus is one or two applications approximately 6 months apart. Therefore, two applications per year were assumed with 180 days interval between applications. The methods used in GENEEC assumes that there is minimal drift from applications of granular formulations and one percent drift loss from applications of liquid formulations.

²Direct application to water is possible (i.e., drainage systems, irrigation ditches etc.). Therefore, an EEC was provided for direct application to a 6" deep water body.

(a) Freshwater Fish

TABLES 26 and 27 show the freshwater fish and amphibians RQs for liquid and granular formulations, respectively.

TABLE 26: Liquid Formulation Acute Risk Quotients (RQ) for Freshwater Fish and Amphibians.

Use	Appl. Rate	Surrogate Species	EEC (ppm)		LC ₅₀ (ppm)	Risk Quotients EEC/LC ₅₀	
			GENEEC ¹	Direct App. ²		GENEEC ¹	Direct App. ²
Grapefruits Oranges	3.2	Bluegill	0.264	2.35	36	0.007	0.07
		Rainbow trout	0.264	2.35	127	0.002	0.02
Citrus	4.24	Bluegill	0.35	3.1	36	0.010	0.09
		Rainbow trout	0.35	3.1	127	0.003	0.02
Pineapples	6	Bluegill	0.495	4.4	36	0.014	0.12
		Rainbow trout	0.495	4.4	127	0.004	0.03
Recreational Areas; Rights-of-Way; Nonagricultural uncultivated areas; Industrial Outdoors	24	Bluegill	1.98	17.6	36	0.055	0.49
		Rainbow Trout	1.98	17.6	127	0.016	0.14

¹Based on a telephone conversation with Andrew Rose, a County Agent in Florida, a typical use of bromacil on citrus is one or two applications approximately 6 months apart. Therefore, two applications per year were assumed with 180 days interval between applications. The methods used in GENEEC assumes that there is minimal drift from applications of granular formulations and one percent drift loss from applications of liquid formulations.

²Direct application to water is possible (i.e., drainage systems, irrigation ditches etc.). Therefore, an EEC was provided for direct application to a 6" deep pond.

TABLE 27: Granular Formulation Acute Risk Quotients (RQ) for Freshwater Fish and Amphibians.

Use	Appl. Rate	Surrogate Species	EEC (ppm)		LC ₅₀ (ppm)	Risk Quotient (EEC/LC ₅₀)	
			GENEEC ¹	Direct App. ²		GENEEC ¹	Direct App. ²
Recreational Areas	8.712	Bluegill	0.715	6.4	36	0.02	0.18
		Rainbow trout	0.715	6.4	127	0.01	0.05
Power Stations	16	Bluegill	1.32	11.74	36	0.04	0.33
		Rainbow trout	1.32	11.74	127	0.01	0.09
Citrus; Drainage Systems	24	Bluegill	1.97	17.6	36	0.05	0.49
		Rainbow trout	1.97	17.6	127	0.02	0.14
Rights-of-Way; Nonagricultural uncultivated areas; Industrial Outdoors	32	Bluegill	2.63	23.5	36	0.07	0.65
		Rainbow Trout	2.63	23.5	127	0.02	0.19

¹Based on a telephone conversation with Andrew Rose, a County Agent in Florida, a typical use of bromacil on citrus is one or two applications approximately 6 months apart. Therefore, two applications per year were assumed with 180 days interval between applications. The methods used in GENEEC assumes that there is minimal drift from applications of granular formulations and one percent drift loss from applications of liquid formulations.

²Direct application to water is possible (i.e., drainage systems, irrigation ditches etc.). Therefore, an EEC was provided for direct application to a 6" deep pond.

Based on the RQs calculated using the GENEEC model, use patterns with an application rate of 32 lbs a.i./A for the granular formulation (rights-of-way, non-agricultural uncultivated, and industrial outdoors), and an application rate of 24 lbs a.i./A for both liquid and granular formulations, exceed the acute endangered species LOC for freshwater fish and amphibians. Application rates that were equal to or less than 16 lbs a.i./A, granular or liquid formulations, did not exceed any LOC. The restricted use and the acute nonendangered species LOCs are not exceeded.

Direct application EECs were also used to calculate RQs for citrus, drainage systems, and rights-of-way use patterns. Typical use of bromacil is expected to result in the direct application of the chemical to the surface of water found in irrigation ditches in citrus groves, ditches along right-of-ways, and drainage ditch systems. Both fish and/or amphibians may use these ditches and drainage ways.

Only the granular formulation used at 32 lbs a.i./A exceeded the nonendangered freshwater fish acute LOC. The restricted use freshwater fish acute LOC is exceeded for the 16, 24, and 32 lbs a.i./A rates for both granular and liquid formulations. The endangered freshwater fish acute LOC was exceeded for all use patterns for both liquid and granular formulations.

Chronic risk to fish was not assessed because no relevant chronic studies were available.

(b) Freshwater Invertebrates

Tables 28-29 show the liquid and granular formulation RQs for freshwater invertebrates.

TABLE 28: Liquid Formulation Risk Quotients (RQ) for Freshwater Invertebrates Surrogate Species: *Daphnia Magna*

Use	Appl. Rate (lbs a.i./A)	EEC (ppm)		LC ₅₀ (ppm)	Risk Quotient (EEC/LC ₅₀)	
		GENEEC ¹	Direct App. ²		GENEEC ¹	Direct App. ²
Grapefruit; Orange	3.2	0.264	2.35	121	0.002	0.02
Citrus	4.24	0.35	3.1	121	0.003	0.03
Pineapples	6	0.495	4.4	121	0.004	0.04
Recreational Areas; Nonagricultural uncultivated areas; Industrial Outdoors	24	1.98	17.6	121	0.016	0.15

¹Based on a telephone conversation with Andrew Rose, a County Agent in Florida, a typical use of bromacil on citrus is one or two applications approximately 6 months apart. Therefore, two applications per year were assumed with 180 days interval between applications. The methods used in GENEEC assumes that there is minimal drift from applications of granular formulations and one percent drift loss from applications of liquid formulations.

²Direct application to water is possible (i.e., drainage systems, irrigation ditches etc.). Therefore, an EEC was provided for direct application to a 6" deep pond.

**TABLE 29: Granular Formulation Risk Quotients (RQ) for Freshwater Invertebrates
Surrogate Species: *Daphnia Magna***

Use	Appl. Rate (lbs a.i./A)	EEC (ppm)		LC ₅₀ (ppm)	Risk Quotient (EEC/LC ₅₀)	
		GENEEC ¹	Direct App. ²		GENEEC ¹	Direct App. ²
Recreational Areas	8.712	0.715	6.4	121	0.006	0.05
Power Stations	16	1.32	11.74	121	0.011	0.10
Citrus; Drainage Systems	24	1.97	17.6	121	0.016	0.15
Rights-of-Way; Nonagricultural uncultivated areas; Industrial Outdoors	32	2.63	23.5	121	0.022	0.19

¹Based on a telephone conversation with Andrew Rose, a County Agent in Florida, a typical use of bromacil on citrus is one or two applications approximately 6 months apart. Therefore, two applications per year were assumed with 180 days interval between applications. The methods used in GENEEC assumes that there is minimal drift from applications of granular formulations and one percent drift loss from applications of liquid formulations.

²Direct application to water is possible (i.e., drainage systems, irrigation ditches etc.). Therefore, an EEC was provided for direct application to a 6" deep pond.

Using the GENEEC EECs to calculate RQs, no aquatic invertebrate LOCs were exceeded for any use pattern.

Using the direct application EECs, application rates of 8.715 lbs. a.i./A or greater (citrus, drainage systems, recreational areas, rights-of-ways, industrial outdoors, and nonagricultural uncultivated areas) exceedances of the acute endangered species LOC. The acute restricted use and nonendangered LOCs were not exceeded in any of the use patterns.

Chronic risk to aquatic invertebrates was not assessed because no relevant chronic studies were available.

(c) Estuarine and Marine Animals

Acute LOCs for estuarine and marine species were not exceeded (Table 30 and 31). Therefore, the use of bromacil is not likely to adversely affect estuarine and marine animals.

Chronic risks to estuarine and marine organisms were not assessed because no relevant chronic studies were available.

TABLE 30: Risk Quotients (RQ) for Estuarine and Marine Organisms - Liquid Formulations.

Use	App. Rate (lbs a.i./A)	Surrogate Species	GENEEC ¹	LC ₅₀ (ppm)	Risk Quotient (EEC/LC ₅₀)
Grapefruit; Orange	3.2	Sheepshead	0.264	162	0.002
		Oyster	0.264	130	0.002
		Mysid	0.264	112	0.002
Citrus	4.24	Sheepshead	0.35	162	0.002
		Oyster	0.35	130	0.003
		Mysid	0.35	112	0.003
Pineapples	6	Sheepshead	0.495	162	0.003
		Oyster	0.495	130	0.004
		Mysid	0.495	112	0.004
Recreational Areas; Rights-of- Way; Nonagricultural Uncultivated Areas; Industrial Outdoor	24	Sheepshead	1.98	162	0.012
		Oyster	1.98	130	0.015
		Mysid	1.98	112	0.018

¹Based on a telephone conversation with Andrew Rose, a County Agent in Florida, a typical use of bromacil on citrus is one or two applications approximately 6 months apart. Therefore, two applications per year were assumed with 180 days interval between applications. The methods used in GENEEC assumes that there is minimal drift from applications of granular formulations and one percent drift loss from applications of liquid formulations.

TABLE 31: Risk Quotients (RQ) for Estuarine and Marine Organisms - Granular Formulations.

Use	App. Rate (lbs a.i./A)	Surrogate Species	GENEEC ¹	LC ₅₀ (ppm)	Risk Quotient (EEC/LC ₅₀)
Recreational Areas	8.715	Sheepshead	0.715	162	0.004
		Oyster	0.715	130	0.006
		Mysid	0.715	112	0.006
Power Station	16	Sheepshead	1.32	162	0.008
		Oyster	1.32	130	0.010
		Mysid	1.32	112	0.012
Citrus; Drainage Systems	24	Sheepshead	1.97	162	0.012
		Oyster	1.97	130	0.015
		Mysid	1.97	112	0.018
Rights-of-Way; Nonagricultural Uncultivated Areas; Industrial Outdoor	32	Sheepshead	2.63	162	0.016
		Oyster	2.63	130	0.020
		Mysid	2.63	112	0.024

¹Based on a telephone conversation with Andrew Rose, a County Agent in Florida, a typical use of bromacil on citrus is one or two applications approximately 6 months apart. Therefore, two applications per year were assumed with 180 days interval between applications. The methods used in GENEEC assumes that there is minimal drift from applications of granular formulations and one percent drift loss from applications of liquid formulations.

(2) Exposure and Risk to Nontarget Plants

(a) Terrestrial and Semi-aquatic

"Semi-aquatic" plants are plants that usually inhabit low-lying wet areas that may or may not be dry 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 two simple formulas. Runoff to an adjacent area receiving sheet runoff from one treated acre, or a channelized runoff from 10 treatment acres to a low lying area some distance away that may expose semi-aquatic and terrestrial plants.

EECs and RQs have been determined for nontarget terrestrial and semi-aquatic plants that may be exposed from the application of bromacil (TABLE 32). The EC₂₅ value of the most sensitive species in the seedling emergence study was used with runoff exposure to determine the RQ.

All RQs exceeded the LOC for both endangered and nonendangered species. The RQ range for the channel runoff scenario was 151 to 1132 for liquid formulations. The RQ range for sheet runoff was 411 to 1368 for granular formulations.

TABLE 32: RQ and EEC Values for Terrestrial and Semi-aquatic Plant Species.

Use Site	Maximum Applic. Rate	Type of EEC	EEC (lbs a.i./A)	RQ (EEC/EC ₂₅) ¹
Liquid Formulation				
Grapefruit; Oranges	3.2	sheet runoff	0	
		channel runoff	2	150
Citrus	4.24	sheet runoff	0	1915
		channel runoff	2	200
Pineapples	6	sheet runoff	0	28
		channel runoff	3	283
Recreational Areas; Rights-of-Way; Nonagricultural Uncultivated Areas; Industrial Outdoors	24	sheet runoff	1	113
		channel runoff	12	1132
Granular Formulation				
Recreational Areas	8.712	sheet runoff	0	42
		channel runoff	4	411
Power Stations	16	sheet runoff	1	75
		channel runoff	8	755
Citrus; Drainage System	24	sheet runoff	1	113
		channel runoff	12	1132
Right-of-Way; Nonagricultural Uncultivated Areas; Industrial Outdoors	32	sheet runoff	2	151
		channel runoff	16	1509

¹The lowest EC₂₅ for shoot length was 0.0106 lbs a.i./A.

All RQs exceeded the LOC for both endangered and nonendangered species. The RQ for the channel runoff scenario ranged from 151 to 1132 for liquid formulations. The RQs for sheet runoff ranged from 411 to 1368 for granular formulations.

(b) Aquatic

Exposure to nontarget aquatic plants may occur through runoff from terrestrial sites. Of course, aquatic plants are directly exposed from aquatic weed control use. However, because they are the "target area" for that use, risk from such exposure is not estimated.

The surrogate duckweed, *Lemna gibba*, is usually used in developing the risk assessment for aquatic vascular plants. Algae and diatom risk assessments are useful surrogates to determining the impact to food sources of aquatic organisms.

As shown in TABLE 33 all of the application rates are expected to produce EECs above the EC₅₀. The RQ will be greater than one, thereby exceeding the endangered and nonendangered LOC.

TABLE 33: RQ and EEC Values for Aquatic Plant Species, Surrogate Plant: Algae

Use Site	Maximum Application Rate (lbs a.i./A)	Type of EEC	GENEEC (ppb)	RQ (EEC/EC ₅₀) ¹
Liquid Formulations				
Grapefruit; Orange	3.20	runoff	264	39
Citrus	4.24	runoff	350	51
Pineapple	6.00	runoff	495	73
Recreational Areas; Right-of-Way; Nonagricultural Uncultivated Areas; Industrial Outdoors	24.00	runoff	1980	291
Granular Formulations				
Recreational Areas	8.71	runoff	715	105
Power Stations	16.00	runoff	1320	194
Citrus; Drainage Systems	24.00	runoff	1970	290
Right-of-Way; Nonagricultural Uncultivated Areas; Industrial Outdoors	32.00	runoff	2630	387

¹Only the test with *Selenastrum capricornutum* provided an EC₅₀, 6.8 ppb.

(3) Endangered Species

Endangered species acute LOCs have been exceeded for birds, mammals, aquatic organisms, and plants. Once the Agency's Endangered Species Protection Program is developed limitations in the use of bromacil and lithium salt of bromacil will be required 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 will

be conducted in accordance with the species-based priority approach described in the Program. After completion of consultation, registrants will be informed if any required label modifications are necessary. Such modifications would most likely consist of the generic label statement referring pesticide users to use limitations contained in county Bulletins.

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 concerning an active ingredient, whether products containing the active ingredients are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing bromacil active ingredients. The Agency has completed its review of these generic data, and has determined that the data are sufficient with certain limitations to support reregistration of all products containing bromacil. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of bromacil, and lists the submitted studies that the Agency found acceptable.

Except for limitations discussed later, the data identified in Appendix B were sufficient to allow the Agency to assess the registered uses of bromacil and to determine that bromacil can be used without resulting in unreasonable adverse effects to humans and the environment when used with the risk mitigation measures required in this decision document. The Agency therefore finds that all products containing bromacil as the active ingredients are eligible for reregistration. The reregistration of particular products is addressed in Section V of this 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, etc. and the data identified in Appendix B. Although the Agency has found that all uses of bromacil are eligible for reregistration, 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 bromacil, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

B. Determination of Eligibility

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredients in this case, the Agency has sufficient information on the health effects of bromacil and its lithium salt, but has certain limitations on their potential for causing adverse effects in fish and wildlife and the environment (see section IVC5 below). The Agency has determined that bromacil products, if labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks of adverse

effects to humans or the environment. Under 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 or to the general population from aggregate exposure to bromacil. Therefore, the Agency concludes that products containing bromacil for all uses are eligible for reregistration.

2. Eligible and Ineligible Uses

The Agency has determined that all uses of bromacil are eligible for reregistration subject to conditions imposed in this RED.

C. Regulatory Position

The following is a summary of the regulatory positions and rationales for bromacil issues. Where labeling revisions are imposed, specific language is set forth in Section V of this document.

To lessen worker risk, and ecological and water quality risks posed by bromacil, EPA is requiring the following mitigation measures from registrants of bromacil-containing products.

- For all risk concerns:
 - Reduce the maximum rate of application from 32 lbs ai/A to 12 lbs ai/A (except for undersurface treatment of toxic-waste holding ponds at 25 lbs ai/A).
- To protect workers:
 - Additional PPE are being required for workers mixing, loading, and applying bromacil. Chemical resistant gloves are required for most of the formulations during mixing and loading. A dust mask is required for the wettable powder formulation.
 - The total number of acres that may be treated in one day by a worker is being restricted to five for the toxic-waste holding pond liner treatment.
- To protect non-target organisms:
 - Continue existing label warnings addressing the potential exposure of very sensitive areas, such as wetlands, to bromacil. Remove label instructions that allow direct application to water (e.g. treating ditchbanks).
- To protect water resources, the Agency is requiring that registrants:
 - Develop training materials to explain management practices that can reduce potential for contamination of water resources and exposure to non-target organisms.
 - Standardize use rates for certain weed control situations (i.e. for use in citrus orchards or to control specific problem weeds).
 - Change labels to specify the time of application.

In addition, the Agency supports risk mitigation measures taken by the states of California and Florida to protect their groundwater resources. These include the ban on use of bromacil on the Central Ridge of Florida and the creation of Pesticide Management Zones for bromacil in California.

The Agency's concerns and risk mitigation measures are discussed in more detail below.

1. Food Quality Protection Act Findings

a. Determination of Safety for US Population

EPA has determined that the established tolerances for bromacil meet the safety standards under the FQPA amendments to section 408(b)(2)(D) for the general population. In reaching this determination, EPA has considered 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 bromacil and other chemicals with a similar mechanism of toxicity.

Since there are no residential or lawn uses of bromacil, no dermal or inhalation exposure is expected in and around the home. No acute toxicity endpoints of concern have been identified for bromacil.

In assessing chronic dietary risk, EPA estimates that bromacil residues in food account for < 2% of the RfD and residues in drinking water account for < 4% of the RfD. Thus the aggregate exposures from all sources of bromacil (in this case, only dietary and drinking water exposures are relevant) account for < 6% of the RfD for the general population. Therefore, the Agency concludes that aggregate risks for the general population resulting from bromacil uses are not of concern.

In evaluating the potential for cumulative effects, EPA compared bromacil with other structurally similar substituted uracil compounds, and then with other compounds producing similar effects. Based on available data, EPA concludes that there is currently no reliable information available to indicate that the toxic effects produced by bromacil would be cumulative with those of any other chemical compounds.

b. Determination of Safety for Infants and Children

EPA has determined that the established tolerances for bromacil meet the safety standard under the FQPA amendment to section 408(b)(2)(C) for infants and children. 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 bromacil residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from bromacil residues, EPA considered the completeness of the data base for developmental and reproductive effects, the nature of the effects observed, and other information.

Based on the current data requirements, bromacil has a complete data base for developmental and reproductive toxicity. In the developmental studies effects were seen in the

fetuses only at the same or higher dose levels than effects on the mothers. In the reproduction study, no effects on reproductive performance were seen. EPA concludes that it is unlikely that there is additional risk concern for immature or developing organisms. Finally, that Agency has no epidemiological information suggesting special sensitivity of infants and children to bromacil. Therefore, EPA finds that an additional uncertainty factor is not warranted for assessing the risks of bromacil.

EPA estimates that bromacil residues in the diet of infants and children account for 1% of the RfD and residues in drinking water account for 10% of the RfD. Thus the aggregate exposure from all sources of bromacil account for only 11% of the RfD for infants and children. Therefore, the Agency concludes that aggregate risks for infants and children resulting from bromacil uses are not of concern.

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 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 consider itself free to pursue whatever action may be appropriate, including but not limited to reconsideration of any portion of this RED.

2. Tolerance Reassessment

The available data support the current tolerances for bromacil *per se* at 0.1 ppm in/on citrus and pineapples (40 CFR §180.210). The available data support these tolerances. No tolerances in animal commodities (milk, eggs, animal fat, meat, and meat byproducts) or tolerances for food/feed additives have been established, nor do they need to be based on the reviewed data base. However, the commodity definitions for citrus and pineapple need to be changed to agree with current definitions.

A summary of the bromacil tolerance reassessment and modifications in commodity definitions is presented in Table 34.

Table 34. Tolerance Reassessment Summary for Bromacil.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ <i>Correct Commodity Definition</i>
Tolerances listed under 40 CFR 180.210:			
Citrus fruits	0.1	0.1	<i>Citrus fruits group</i>
Pineapple	0.1	0.1	<i>Pineapples</i>

CODEX HARMONIZATION

No maximum residue limits (MRLs) for bromacil have been established by Codex for any agricultural commodity. Therefore, no compatibility questions exist with respect to U.S. tolerances.

3. Cancer Risk Assessment

The Office of Pesticide Programs has classified bromacil as a Group C (possible human) carcinogen and believes that the RfD approach should be used for quantification of human dietary risk of cancer. This decision was based on the increased incidence of liver tumors in male mice, and positive trends in thyroid tumors in male rats, and on limited support from SAR compounds.

In the dietary risk assessment above, the Agency concluded the potential chronic risk from dietary exposure is not of toxicological concern. Even with very conservative assumptions (e.g. dietary residues at tolerance levels and 100% of citrus and pineapple treated), chronic dietary exposures occupy no more than 1% of the RfD for the general population or any subgroup.

Since the Agency does not expect workers to be exposed to bromacil for a substantial portion of their lives and since there are no residential uses of bromacil, the Agency is not estimating the risk of cancer from this type of exposure. Therefore chronic occupational and residential exposure and risk estimates were not calculated for bromacil.

4. Benefits from Use of Bromacil

Bromacil has benefits in vegetation management on agricultural and industrial sites. Industrial benefits include reduced cost of road and railway repair and reconstruction. Use of bromacil also enhances visibility on these sites. In addition, its use should also reduce the hazard from fire or electric shock in oil wells, refineries, electric substations, as well as roads and tracks.

5. Ecological Effects Risk Mitigation

The risk assessment shows that various levels of concern (LOCs) have been exceeded for acute toxicity to both plants and animals. For plants, LOCs are exceeded by very large margins in virtually all use situations. Mitigation measures, including reduction in rates and requirements to reduce spray drift reduce the risk.

For animals, LOCs based on conservative screening models, have been exceeded for acute toxicity to birds, reptiles, and mammals at the higher rates (e.g. in table 37 the risk quotient is 1.37 for herbivores exposed to foodstuffs treated with 24 lb a.i./A of the liquid formulation). In addition, the concentration of bromacil that is expected in puddles or shallow irrigation ditches due to direct application exceeds the fish and amphibian LOCs at almost all application rates (e.g. in table 39 the risk quotients range from 0.07 to 0.48 for 3.2 and 24 lb ai/acre).

Several factors reduce the Agency's concern regarding these LOC exceedances. The very highest rates (e.g. 24 and 32 lb ai/A) where the greatest exceedance occurs are no longer allowed for all but one very limited use (up to 25 lb ai/A is allowed for undersurface treatment for toxic waste holding ponds). Risk quotients at the typically applied rates (around 4 lbs a.i./A) are not as high (in table 39 at 4.24 lb ai/A the RQ is 0.09, exceeding the acute level of concern for endangered species). Secondly, the screening model is weighted in uncertainty towards conservatism. And finally, the hazard studies show that bromacil is practically nontoxic to these animals and, for birds and reptiles, the LOC exceedance is likely an artifact of the extrapolations more than an indication of actual risk.

Potential chronic risks are considered very relevant in predicting ecological risk from bromacil, more so than acute risk. Potential for chronic exposure to bromacil for non-target terrestrial and aquatic animals is considered to be high as a result of bromacil's persistent nature in soil and water, and the label's allowance of repeat applications.

The Agency was unable to complete its assessment of the chronic and reproductive effects from exposure to bromacil since it lacked the necessary studies to assess risk. These data are needed because bromacil's use and chemical characteristics meet the Agency's criteria for requiring chronic and reproductive testing for birds, freshwater and estuarine and marine fish and invertebrates. In addition, other ecological fate and effects data are required to complete the generic data requirements. The studies necessary for this assessment are being called in through a Data Call-in Notice and are due in 1998.

Although the ecological effects risk assessment cannot be completed until chronic data are submitted and reviewed, the Agency is taking certain measures to mitigate potential ecological risks from bromacil, such as the reduction of maximum application rates of 32 to 12 lbs ai/A and the elimination of the use on ditch banks. Label warnings address the potential exposure of very sensitive areas, such as wetlands, to bromacil. The registrant has proposed to remove direct application to aquatic sites from labels.

In making a reregistration decision the Agency weighs the risk against the benefits from using a chemical. The risk reduction measures required in this RED, namely reduction in application rates and restrictions on aquatic use, are consistent with those imposed for other chemicals for which acute, chronic or reproductive risk to nontarget species in the environment have been proven. Because of this reduction in risk, coupled with the benefits of vegetation management from using bromacil, the Agency does not believe the remaining risk of chronic and reproductive effects to non-target species to be unreasonable during the interim period until data on the chronic effects of bromacil are submitted and evaluated.

6. Spray Drift

The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation to develop the spray drift best management practices. The Spray Drift Task Force has completed their studies, and have submitted their data, and now the Agency is evaluating it, to determine whether further refinements in spray drift management practices are needed. The Agency has put in place interim measures to reduce spray drift while waiting for the data to be reviewed. Products which can be aerially applied will have new requirements and advisories directed at the applicator to reduce off-target spray-drift.

7. Endangered Species Program

Currently, the Agency is developing a program ("The Endangered Species Protection Program") to identify all pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation measures that may eliminate the adverse impacts. The program would require use restrictions to protect endangered and threatened species at the county level. Consultations with the Fish and Wildlife Service may be necessary to assess risks to newly listed species or from proposed new uses. In the future, the Agency plans to publish a description of the Endangered Species Program in the Federal Register and have available voluntary county-specific bulletins. Because the Agency is taking this approach for protecting endangered and threatened species, it is not imposing label modifications at this time through the RED. Rather, any requirements for product use modifications may occur in the future under the Endangered Species Protection Program.

8. Groundwater Protection Requirements

Overall

The Agency's strategy for reducing risk to groundwater from bromacil use is two-pronged and based on its pattern of use. For all use patterns the Agency is pursuing risk reduction through education of applicators about practices that can reduce potential for groundwater contamination. In citrus, the Agency has focused risk reduction measures on increasing the monitoring of levels of bromacil in groundwater. In non-crop areas, the majority of risk reduction is achieved by reduction of maximum rates by more than half (from 32 lb ai/A to 12 lb ai/A) for all but the undersurface treatment for toxic waste pond liners (25 lb ai/acre).

In addition, the Agency supports risk mitigation measures taken by the State governments of California and Florida, namely a ban on the use of bromacil in the most vulnerable area of Florida and the restrictions on the use of bromacil in Pesticide Management Zones in California. To further mitigate risk, DuPont has agreed to provide training materials to be used in Certification and Training Programs.

Bromacil is also used in citrus-growing areas in Arizona and Texas but there is inadequate monitoring information for these areas. The Agency is requiring DuPont to conduct additional groundwater monitoring through a Data Call-in Notice to determine to what extent bromacil has moved to groundwater. Details of this monitoring must be developed by the Agency and DuPont.

In pineapple production

Although bromacil is one of the principal herbicides used for postemergence weed control for pineapple grown in Hawaii, the Agency does not believe there is unreasonable risk to the quality of groundwater from its use. The average use on pineapples in Hawaii is relatively low (4.8 lb ai/A over four years) and is declining. It appears that the state is monitoring ground water resources in pineapple areas, and bromacil has not been found in the groundwater. Therefore, ground water risk mitigation is not needed for this use at this time.

Bromacil is also used in the U.S. territory of Puerto Rico for weed control in pineapple. The Agency does not have information about the risk to groundwater for this use. Therefore, the Agency has required an assessment of the vulnerability of the groundwater from DuPont.

In non-crop areas

Non-crop uses allow the highest rate of application of bromacil. However, bromacil use comprises only 2-3 % of the area treated. Typical uses are to control vegetation on railroad tracks, in and around electric power substations, and on roadsides. Application is usually made in bands or confined to discrete areas. The historic use on ditch banks is no longer permitted. As noted earlier, the maximum allowable rate has been reduced from 32 to 12 lb ai/A for all uses of bromacil, except for the use of bromacil as an undersurface treatment for toxic-waste holding ponds, which will be allowed at up to the rate of 25 lb ai/A.

9. Occupational Labeling Rationale/Risk Mitigation

The Agency examined results from the risk assessment and identified several scenarios for which there currently are inadequate margins of exposure (MOEs < 100). Each of these scenarios and the Agency's respective regulatory position is discussed below.

1. Mixing and loading wettable powder for groundboom application while wearing chemical resistant gloves at the typical and maximum rates of application resulted in MOEs of 40 and 15, respectively [scenario 1(b) in Table 8].
2. Mixing and loading the dry flowable for groundboom application at the maximum rate using gloves demonstrated an MOE of 83 [scenario 1c in Table 8].

3. Mixing and loading the dry flowable for aerial application at the typical and the maximum rates of application while wearing gloves resulted in MOEs of 19 and 51, respectively [scenario 1(d) in Table 8].
4. Applying bromacil using the rights-of-way sprayer at the maximum rate without gloves resulted in an MOE of 41 [scenario 2(a) in Table 8].
5. Applying bromacil to the toxic-waste holding pond liner site at the maximum rate of 25 lb a.i./acre to the maximum area of 48 acres resulted in an MOE of 11.8 [scenario 2(b)].
6. Applying using a low pressure handwand at both the typical and maximum application rates without gloves yielded MOEs of 13.3 and 4.9 respectively [scenario 6 in Table 8].
7. Mixing, loading and applying using the whirly bird spreader at the maximum rate without gloves resulted in an MOE of 91 [scenario 8 in Table 8].

The worker risk assessment was made using the best available data and according to the Agency's current policies, however, the Agency believes this assessment may be overly conservative for several reasons. First, a study conducted by the oral route of exposure was used to estimate risk from all routes of exposure including dermal and inhalation, as well as oral. Second, the NOEL selected from this oral study was based on a minimal effect demonstrated during only the first two days of dosing, suggesting that the actual NOEL level is likely to be considerably higher than the 20 mg/kg/day selected. Third, a preliminary report from a 28-day dermal study being conducted voluntarily by DuPont suggests that the NOEL may actually be an order of magnitude greater than the 20 mg/kg/day selected. And lastly, dermal absorption was estimated to be 20 percent based on a study that suggested much lower dermal absorption.

Because of this uncertainty in estimating risk to workers, DuPont voluntarily initiated a 28 day toxicity study by the dermal route of exposure. This study more closely characterizes the main worker exposure to bromacil than data now available. Once this study is submitted, the Agency will determine whether additional mitigation is required. Because preliminary reports from this study indicate the MOE will likely be an order of magnitude greater than the current NOEL of 20 mg/kg/day, the Agency expects most MOEs to no longer be of concern.

For scenario 1(b) a significant portion (about half) of the exposure from this use is from inhalation of the powder. Chemical resistant gloves reduce dermal but not inhalation exposure. To further mitigate risk the Agency considered requiring water soluble packaging to reduce exposure from both routes of exposure. However, this would require reformulation of bromacil-containing products. Because of the uncertainty in the risk assessment, the Agency will consider the results of the 28-day dermal toxicity study before imposing this requirement. During the interim, to reduce exposure from the inhalation route, the Agency is requiring that a dust mask be worn during the mixing and loading of wettable powder formulations of bromacil. Chemical-resistant gloves remain as a requirement.

For scenarios 2(a), 6, and 8, MOEs are acceptable with gloves even under this current conservative risk assessment. In addition, MOEs for scenarios 1(a) and 3 from Table 8, which were not of concern, were calculated assuming that gloves were worn since current labels require chemical resistant gloves be worn. Therefore, this requirement will remain in effect.

For scenario 2(b), the MOE is acceptable for the typical size of treated area (5 acres). Therefore, unless the 28 day dermal study relieves concern for application beyond 5 acres, the Agency will require the restriction that only 5 acres be treated per day.

Although scenario 1(c) has an inadequate MOE of 83, the Agency believes that this is an overly conservative estimate and that the true risk is likely to be at acceptable levels. No additional protection is being required.

Scenario 1(d) is mixing and loading for aerial application. This is confined to one use, the control of brush on firing ranges in the Department of Defense Yakima Firing Center. The MOE of concern at the maximum rate is 19. This MOE may change to an acceptable level with new dermal toxicity information. However, because this use is very limited, applicators are trained, and the benefits are high since it is used to control fires, the Agency believes the estimated risk to be not unreasonable.

In conclusion, these above measures reduce risk to applicators to levels considered acceptable by the Agency. However, these requirements may be revisited following submission and review of the 28-day dermal study.

10. Worker Protection Standard

a. Scope of the 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, ornamental, and seedlings).

At this time, some of the uses of bromacil are within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS). Uses of bromacil that are outside the scope of the WPS are those that are not directly related to the production of agricultural plants, including, control of vegetation along rights-of-way, in industrial areas, around power stations, in drainage systems, under toxic-waste holding-ponds, in recreation areas, and in other noncrop areas.

b. Personal Protective Equipment/Engineering Controls for Handlers

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 to certain other adverse effects, such as allergic effects or delayed 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. If the requirement is for two layers of body protection (coveralls over a long- or short-sleeve shirt and long or short pants), the minimum must also include (for all handlers) chemical-resistant footwear and chemical-resistant headgear for overhead exposures and (for mixers, loaders, and persons cleaning equipment) chemical-resistant aprons.

Occupational-Use Products

EPA has determined that regulatory action regarding the establishment of active-ingredient-based minimum PPE requirements for some occupational handlers must be taken for bromacil based on the outcome of the occupational exposure/risk assessment discussed in Chapter IIIB2. In all scenarios, the MOE's for dermal exposure are a problem for occupational mixers and loaders involved in applications where groundboom, aerial, or power (rights-of-way) sprayers are used unless chemical-resistant gloves are worn. Even with chemical resistant gloves, three of these scenarios, the mixing and loading of wettable powders and dry flowables for groundboom application, and dry flowables for aerial application resulted in MOEs of concern (15 to 83). To mitigate this risk, the Agency considered requiring repackaging of this formulation into water soluble bags. Instead, the Agency decided to require the use of a chemical resistant gloves, and in the case of the wettable powder, a dust mask, until new information on toxicity is submitted

(a 28 day dermal toxicity study). The Agency will reassess the risk once the 28-day dermal toxicity study can be evaluated. This decision is partly based on the uncertainty about the actual maternal NOEL in the rat developmental study, a key variable in the calculation of the MOE. In summary, EPA is requiring active-ingredient based protection for handlers of bromacil in all these exposure situations.

WPS and NonWPS Uses:

Since potential handler exposure is similar for uses in the scope of and outside the scope of WPS, there is only one set of active-ingredient-based minimum (baseline) PPE or engineering controls requirements for occupational uses of bromacil (specified in Section V). These requirements must be followed in the labeling of all bromacil end-use products intended primarily for occupational use.

Homeowner-Use Products

There are no homeowner uses of bromacil.

c. Occupational-Use Products (uses in the scope of WPS)

Post-Application/Entry Restrictions

Restricted-Entry Interval:

Under the Worker Protection Standard (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. 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.

The historic WPS REI in effect is 24 hours for the lithium salt of bromacil and 12 hours for bromacil. This was an interim REI placed on bromacil products by PR Notice 93-7. EPA notes that the 24-hour interim WPS REI was established on the lithium salt because data indicated that the lithium salt was in toxicity category II for eye irritation potential. The 12-hour interim

WPS REI was established for bromacil because data indicated that bromacil was in toxicity category III/IV for acute dermal toxicity, skin irritation potential, and eye irritation potential.

Since bromacil is generally directed at the target weeds, contact with treated surfaces is likely to be limited mostly to feet, lower legs, and, in some circumstances, hands. In considering the risk from post-application exposures, EPA notes that the toxicological endpoint is based upon a developmental toxicity study in rats in which the maternal NOEL was established at 20 mg/kg/day and the maternal LOEL at 75 mg/kg/day. The maternal effect noted was a minimal effect involving decreases in body weight gain and food consumption during only the first two days of dosing. Thus, the actual maternal NOEL level is likely to be considerably higher than 20 mg/kg/day. It is further noted that both the maternal and developmental NOELs in the rabbit study were established at a higher dose level, 100 mg/kg/day. Consideration of the minimal, transitory effects noted at the rat maternal LOEL (75 mg/kg/day), the much higher dose (200 mg/kg/day) required to elicit pronounced developmental effects, and the likelihood of relatively low post-application exposures, leads to a conclusion that the risks from post-application exposures are likely to be acceptable as long as entry does not occur immediately following application. Therefore, the REI remains at 24-hours or 12-hours for all occupational-use products that contain the lithium salt of bromacil or bromacil respectively and are within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS).

Non-WPS scope Uses

The 12- or 24-hour post-application entry restriction for bromacil does not apply to uses outside the scope of the WPS. The predicted frequency, duration, and degree of exposure related to such uses do not warrant the same risk mitigation measures as are required for users covered by the WPS. The Agency has determined that such post-application exposures do not appear to pose an unreasonable risk to persons entering treated areas, as long as entry is not permitted immediately after application.

For nonWPS occupational uses, the Agency is requiring:

- **for liquid applications -- a prohibition on entry until sprays have dried,**
- **for granular, dust, and other dry applications -- a prohibition on entry until dusts have settled.**

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.

EPA is establishing early-entry PPE for dermal protection on the basis of the acute toxicity of the active ingredient. Since bromacil is classified as toxicity category IV for acute dermal toxicity and toxicity category IV for skin irritation potential, PPE for dermal protection required for early entry is the minimum early-entry PPE permitted under the WPS. Since bromacil is classified as toxicity category III for eye irritation potential, no protective eyewear is required. However, since the lithium salt of bromacil is classified as toxicity II for eye irritation potential, protective eyewear is required for the lithium salt of bromacil.

WPS Notification Statement:

Under the WPS, the labels of some pesticide products require employers to notify workers about pesticide-treated areas orally as well as by posting of the treated areas. The reregistration process also may decide that a product requires this type of "double notification." EPA has determined that double notification is not required for bromacil end-use products.

Occupational-Use Products (NonWPS Uses)

EPA is establishing entry restrictions for all nonWPS occupational uses of bromacil end-use products. For specific requirements, refer to Section V of this document.

Homeowner-Use Products

At this time there are no end-use products intended primarily for homeowner use.

Other Labeling Requirements

The Agency is also requiring other use and safety information to be placed on the labeling of all end-use products containing bromacil. For the specific labeling statements, refer to Section V of this document.

11. Aerial Application

The Special Local Need registration for the state of Washington, WA93000200, allows aerial application to control weeds on the Yakima Firing Center to prevent fires. Aerial application is being allowed for this specific use because ground application is dangerous and slow.

V. ACTIONS REQUIRED BY REGISTRANTS

This section specifies the data requirements and responses necessary for the reregistration of both manufacturing-use and end-use products.

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of bromacil for the above eligible uses has been reviewed and determined to be substantially complete. The following studies are required to be conducted on the generic active ingredient.

- Avian Reproduction Quail [71-4 (a)].
- Avian Reproduction Duck [71-4 (b)].
- Early Life-Stage Fish [72-4(a)].
- Life-Cycle Aquatic Invertebrate [72-4(b)].
- Dermal toxicity study[82-2].
- Groundwater monitoring studies [166-1]

2. Additional Monitoring of Groundwater

The Agency is requiring monitoring of groundwater in citrus growing areas to establish to what extent groundwater quality is being impacted. The Agency will work with DuPont to establish a monitoring program.

Normal agricultural use of bromacil has led to ground-water contamination in the Central Ridge of Florida and in certain areas of California as demonstrated by monitoring data. For these areas, certain mitigation measures have been taken to reduce risk to water resources. The Agency is also concerned with risk to groundwater in other citrus-growing areas where bromacil is used.

The Agency believes that it is appropriate to take additional precautions to ensure that the quality of ground-water resources is not degraded. The Agency recommends that benchmarks (or triggers), that are based on monitoring data, be established before widespread groundwater contamination occurs. These benchmarks should clarify the kinds of actions that a registrant will take to mitigate and better manage the use of the pesticide, as well as to define the circumstances under which the use of the pesticide would require additional regulatory action .

B. Applicator Training Material

DuPont has agreed to provide material to be used in the Certification and Training Program.

C. Vulnerability assessment for Groundwater in pineapple production areas of Puerto Rico

DuPont is required to provide an assessment of the vulnerability of the groundwater to bromacil contamination in pineapple production areas in Puerto Rico.

D. End-Use Products

1. 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 G, the Product Specific Data Call-In Notice.

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria (Appendix F; 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.

2. 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.

PPE/Engineering Control Requirements for Pesticide Handlers

For **sole-active-ingredient** end-use products that contain bromacil, the product labeling must be revised to adopt the handler personal protective equipment/engineering control requirements set forth in this section. Any conflicting PPE requirements on the current labeling must be removed.

For **multiple-active-ingredient** end-use products that contain bromacil, the handler personal protective equipment/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.

Products Intended Primarily for Occupational Use (WPS and nonWPS)

Minimum (Baseline) PPE Control Requirements

The Agency generally sets the minimum baseline PPE control requirements for pesticides based on results from the risk assessment (Chapter 4).

EPA is establishing minimum (baseline) personal protective equipment (PPE) requirements for some occupational uses of bromacil end-use products. The following is the minimum (baseline) PPE for all occupational uses of bromacil end-use products formulated as a liquid, wettable powder, or dry flowable:

"Applicators and other handlers must wear:
-- long-sleeved shirt and long pants,
-- chemical-resistant gloves*, and
-- shoes plus socks."

In addition, while mixing and loading the wettable powder formulation, pesticide handlers are required to wear a dust mask.

* For the glove statement, use the statement established for bromacil through the instructions in Supplement Three of PR Notice 93-7.

EPA is not establishing minimum (baseline) personal protective equipment (PPE) requirements for bromacil end-use products formulated as granules and pellets.

Determining PPE Requirements for End-use Product Labels

The PPE that would be established on the basis of the acute toxicity category of the end-use product must be compared to the active-ingredient-based minimum (baseline) personal protective equipment specified above. 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.

Placement in Labeling

The personal protective equipment requirements must be placed on the end-use product labeling in the location specified in PR Notice 93-7, and the format and language of the PPE requirements must be the same as is specified in PR Notice 93-7.

Entry Restrictions

For **sole-active-ingredient** end-use products that contain bromacil the product labeling must be revised to adopt the entry restrictions set forth in this section. Any conflicting entry restrictions on the current labeling must be removed.

For **multiple-active-ingredient** end-use products that contain bromacil 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."

Products Intended Primarily for Occupational Use

WPS Uses

Restricted-entry interval:

A 24-hour restricted-entry interval (REI) is required for uses within the scope of the WPS on all lithium-salt bromacil end-use products.

A 12-hour restricted-entry interval (REI) is required for uses within the scope of the WPS on all other (non-lithium-salt) bromacil end-use products.

Early-entry personal protective equipment (PPE):

The PPE required for early entry is:

- coveralls,
- chemical-resistant gloves, and
- shoes plus socks.

For the lithium salt of bromacil, protective eyewear also is required.

Placement in labeling:

The REI must be inserted into the standardized REI statement required by Supplement Three of PR Notice 93-7. The PPE required for early entry must be inserted into the standardized early-entry PPE statement required by Supplement Three of PR Notice 93-7.

NonWPS uses

Entry restrictions:

The Agency is establishing the following entry restrictions for nonWPS occupational uses of bromacil end-use products:

For liquid applications:

"Do not enter or allow others to enter the treated area until sprays have dried."

For dry applications:

"Do not enter or allow others to enter the treated area until dusts have settled."

Placement in labeling:

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 nonWPS entry restrictions in that box.

If no WPS uses are on the label -- Place the appropriate nonWPS entry restrictions in the Directions for Use, under the heading "Entry Restrictions."

Other Labeling Requirements

Products Intended Primarily for Occupational Use

The Agency is requiring the following labeling statements to be located on all end-use products containing bromacil that are intended primarily for occupational use.

Application Restrictions

"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."

Engineering Controls

"When handlers use closed systems (including water-soluble packets), enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS."

User Safety Requirements

1. Registrants: place the following statement on the labeling if coveralls are required for pesticide handlers on the end-use product label:

"Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."

2. Registrants always place the following statement on the end-use product labeling:

"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."

User Safety Recommendations

- "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."
- "Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."
- "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."

Skin Sensitizer Statement

"This product may cause skin sensitization reactions in some people."

Reduction in Maximum Label Rates

All registrants are required to reduce maximum allowed rates to 12 lb ai/A. If the State of Florida lifts the current ban of bromacil on the central ridge of Florida, the Agency will not allow application of bromacil above the rate of 1.6 lb ai/acre per year at that location to minimize risk to groundwater.

E. Restriction of total acres allowed to be treated for the Toxic-Waste Holding-Pond Liner Treatment

DuPont is required to change labels for this use to restrict the daily acres allowed to be treated to a maximum of five acres per day.

F. Reduction of maximum application rate to no more than 12 lb ai/A for all uses except the undersurface treatment for toxic-waste holding ponds.

All registrants are required to submit labels restricting the maximum application rate to no more than 12 lb ai/A per year except for the undersurface treatment for toxic-waste holding ponds. In addition, registrants are required to drop rates on citrus in Texas from 6.4 to 2.4 lb ai/acre.

G. Specify timing of application.

Registrants must submit labels that specify the timing of the application.

H. Removal of Recreational Areas from labels.

Registrants must remove language that permits application to recreational areas. Registrants must also include the statement "Not to be used in any recreational areas or in or around homes." on their labels.

I. Maximum seasonal application rate.

Registrants must submit labels where the maximum seasonal rate on citrus has been standardized between labels.

J. Removal of the Ditch-bank treatment

Registrants must remove the statement "It is permissible to treat the berm of ditches, seasonally dry flood plains, deltas, marshes, swamps, bogs and transitional areas between upland and lowland sites" from labels.

K. Appropriate Use Rate for Russian thistle and kochia

Registrants must specify appropriate rate of application for control of Russian thistle and kochia so that applicators can target their application rates to adequately control these noxious weeds and minimize risks from over-application.

L. 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 bromacil and bromacil lithium salt containing 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

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case bromacil covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to bromacil 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) 487-4650.

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 Bromacil

REQUIREMENT	USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY		
61-1	Chemical Identity	42648401
61-2A	Start. Mat. & Mnfg. Process	42648401
61-2B	Formation of Impurities	42648401
62-2	Certification of limits	Outstanding
62-3	Analytical Method	00013314
63-2	Color	00057519, 42516101
63-3	Physical State	00057519, 42516101
63-4	Odor	00057519, 42516101
63-5	Melting Point	00057519, 42516101
63-6	Boiling Point	00057519, 42516101
63-7	Density	00057519, 42516101
63-8	Solubility	42516101, 02, 03
63-9	Vapor Pressure	00057519, 42516101, 42516104
63-10	Dissociation Constant	42516105
63-11	Octanol/Water Partition	00141631, 42516101, 42516106
63-12	pH	42516101
63-13	Stability	00057519, 42516101, 42516107

Data Supporting Guideline Requirements for the Reregistration of Bromacil

REQUIREMENT	USE PATTERN	CITATION(S)
<u>ECOLOGICAL EFFECTS</u>		
71-1A	Acute Avian Oral - Quail/Duck	ALL 40951501
71-2A	Avian Dietary - Quail	ALL 00013295
71-2B	Avian Dietary - Duck	ALL 00013295
71-3	Wild Mammal Toxicity	ALL 00022077
71-4A	Avian Reproduction - Quail	ABC DATAGAP
71-4B	Avian Reproduction - Duck	ABC DATAGAP
72-3A	Estuarine/Marine Toxicity-Fish	ABC 41588702, 40098001
72-3C	Estuarine/Marine Toxicity-Shrimp	ABC 41588701,40098001
72-4A	Early Life Stage Fish	ABCF DATAGAP
72-4B	Life Cycle Invertebrate	ABCF DATAGAP
122-2	Aquatic Plant Growth	ABCF 42516401
123-1A	Seed Germination/Seedling Emergence	ABCF 42491101
123-1B	Vegetative Vigor	ABCF 42491101
123-2	Aquatic Plant Growth	ABCF OUTSTANDING
<u>TOXICOLOGY</u>		
81-1	Acute Oral Toxicity - Rat	ALL 00022077
81-2	Acute Dermal Toxicity - Rabbit/Rat	ALL 00013272
81-3	Acute Inhalation Toxicity - Rat	ALL 00022080

Data Supporting Guideline Requirements for the Reregistration of Bromacil

REQUIREMENT	USE PATTERN	CITATION(S)
81-4	Primary Eye Irritation - Rabbit	ALL 00022079
81-5	Primary Dermal Irritation - Rabbit	ALL 00022081
81-6	Dermal Sensitization - Guinea Pig	ALL 41304107
82-1A	90-Day Feeding - Rodent	ALL 41261701
82-1B	90-Day Feeding - Non-rodent	ALL 41869701
82-2	21-Day Dermal - Rabbit/Rat	ALL DATAGAP
83-1A	Chronic Feeding Toxicity - Rodent	AB 412641701
83-1B	Chronic Feeding Toxicity - Non-Rodent	AB 41869701, 47869701
83-2A	Oncogenicity - Rat	AB 41261701
83-2B	Oncogenicity - Mouse	AB 00072782
83-3A	Developmental Toxicity - Rat	ALL 40984802
83-3B	Developmental Toxicity - Rabbit	ALL 40984801
83-4	2-Generation Reproduction - Rat	ALL 41804601
84-2A	Gene Mutation (Ames Test)	ALL 42465701
84-2B	Structural Chromosomal Aberration	ALL 42465801
84-4	Other Genotoxic Effects	ALL 42465901
85-1	General Metabolism	AB 42825201
<u>OCCUPATIONAL/RESIDENTIAL EXPOSURE</u>		
132-1A	Foliar Residue Dissipation	waived
132-1B	Soil Residue Dissipation	waived

Data Supporting Guideline Requirements for the Reregistration of Bromacil

REQUIREMENT	USE PATTERN	CITATION(S)
133-3	Dermal Passive Dosimetry Exposure	waived
133-4	Inhalation Passive Dosimetry Exposure	waived
<u>ENVIRONMENTAL FATE</u>		
161-1	Hydrolysis	ALL 4095105
161-2	Photodegradation - Water	ALL 40951507, 40951508
161-3	Photodegradation - Soil	ABC 40951509
162-1	Aerobic Soil Metabolism	ABC 40951510
162-3	Anaerobic Aquatic Metabolism	F 40951511
164-1	Terrestrial Field Dissipation	ABC 41677101
165-4	Bioaccumulation in Fish	ALL 40951513
<u>RESIDUE CHEMISTRY</u>		
171-4A	Nature of Residue - Plants	AB 013202, 42967501, 43460601
171-4B	Nature of Residue - Livestock	AB 42998901
171-4CD	Residue Analytical Method - Plants and Animals	AB 42967301, 43078801
171-4E	Storage Stability	AB 42967401, 43461601
171-4J	Magnitude of Residues - Meat/Milk/Poultry/Egg	AB 05002192
171-4K	Crop Field Trials	
	- <u>Citrus Fruits Group</u>	AB 0013203, 0013206, 0013321, 0030632, 050468, 137865,

Data Supporting Guideline Requirements for the Reregistration of Bromacil

REQUIREMENT	USE PATTERN	CITATION(S)
171-4L	- <u>Pineapple</u>	0013205, 0013293, 43461601
	Processed Food	
	- <u>Citrus Fruits Group</u>	0013203, 0013206, 0013321, 0030632, 137865
	- <u>Pineapple</u>	43461601

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of the lithium salt of bromacil

REQUIREMENT	USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY		
61-1	Chemical Identity	ALL Outstanding
61-2A	Start. Mat. & Mnfg. Process	ALL 43076201, outstanding for 7.5% FI
61-2B	Formation of Impurities	ALL 43076201, 43375001, outstanding for 7.5% FI
62-1	Preliminary Analysis	ALL Outstanding
62-2	Certification of limits	ALL Outstanding
62-3	Analytical Method	ALL 43076301, datagap for 7.5% FI
63-2	Color	ALL Outstanding
63-3	Physical State	ALL Outstanding
63-4	Odor	ALL Outstanding
63-5	Melting Point	ALL Outstanding
63-6	Boiling Point	ALL Outstanding
63-7	Density	ALL Outstanding
63-8	Solubility	ALL Outstanding
63-9	Vapor Pressure	ALL Outstanding
63-10	Dissociation Constant	ALL Outstanding
63-11	Octanol/Water Partition	ALL Outstanding
63-12	pH	ALL Outstanding
63-13	Stability	ALL Outstanding

Data Supporting Guideline Requirements for the Reregistration of the lithium salt of bromacil

REQUIREMENT	USE PATTERN	CITATION(S)
ECOLOGICAL EFFECTS Except for acute toxicity to the eyes, the reregistration decision for the lithium salt of bromacil relies upon data using bromacil, per se. Therefore, all ecological effects and environmental effects data requirements are waived.		
TOXICOLOGY - waived except:		
81-4	Primary Eye Irritation - Rabbit	ALL
		00129182, 00129183

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.

BIBLIOGRAPHY

MRID

CITATION

- 00013202 Gardiner, J.A.; Barrier, G.E. (1964?) Uptake and Metabolism of 2-¹⁴C-Labeled Bromacil by Young Orange Trees. (Unpublished study received Mar 10, 1966 under 6F0499; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:090394-N)
- 00013203 E.I. du Pont de Nemours & Company, Incorporated (1966) [Results of Tests on the Amount of Residue in Crops Grown on Treated Soil: Bromacil]. (Unpublished study received Dec. 2, 1966, under 6F0499; CDL:090253-C).
- 00013205 E.I. du Pont de Nemours and Company (1966) [Results of Tests on the Amount of Residue in Crops Grown on Treated Soil: Bromacil]. Summary of studies 090253-G through 090253-I. (Unpublished study received Nov. 15, 1966, under 6F0499; CDL:090253-F).
- 00013206 Day, B.E.; Russell, R.C. (1965) Progress Report on Bromacil Studies in California Citrus Orchards. (Unpublished study received Nov. 15, 1966, under 6F0499; prepared by Univ. of California--Riverside, Citrus Research Center, submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, DE; CDL:090253-H).
- 00013251 E.I. du Pont de Nemours & Company (1964) Analytical and Recovery Data: Bromacil-Pineapple. (Unpublished study received Mar. 2, 1965, under 352-287; CDL:002909-F).
- 00013272 Colburn, CW and Frank, KM. 1969. Skin Absorption LD₅₀. Study HLR 276-69. Unpublished study conducted at DuPont Haskell Laboratory for Toxicology and Industrial Medicine.
- 00013293 E.I. du Pont de Nemours & Company (1972) Data Supporting Use of Hyvar X Bromacil Weed Killer in Pineapple in Hawaii. (Unpublished study received Apr. 24, 1974, under 352-287; CDL:023287-A).
- 00013295 Dieterich, W.H. (1965) Acute Oral Toxicity--Mallard Ducks, BobwhiteQuail: Project No. 201-154. (Unpublished study received Nov 22, 1965 under 352-287; prepared by Hazleton Laboratories, Inc., submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:100405-A)
- 00013314 E.I. du Pont de Nemours and Company (1976) Trade Secret Data on Bromacil Technical: Manufacturing Process; Composition; Determination of Impurities. (Unpublished study received Nov. 5, 1976, under 352-325; CDL:226812-B).

BIBLIOGRAPHY

MRID

CITATION

-
- 00013321 E.I. du Pont de Nemours & Company (1963) Residue Data Uracil Herbicides-Citrus Fruits. (Unpublished study received Feb. 25, 1964, under 352-EX-67; CDL:123347-E).
- 00022077 Raltech Scientific Services, Inc.. 1979. Oral Defined LD₅₀. Study 34704-52. Unpublished study conducted at Raltech Scientific Services Laboratory.
- 00022078 Raltech Scientific Services, Inc. 1979. Defined Dermal LD₅₀. Study 34704-52. Unpublished study conducted at Raltech Scientific Services Laboratory.
- 00022079 Raltech Scientific Services, Inc. 1979. Eye Irritation. Study 34704-52. Unpublished study conducted at Raltech Scientific Services Laboratory. Document # 003380-81.
- 00022080 Biesemeier, JA and Argevine, DM. 1979. Inhalation--EPA. Study 34704-52. Unpublished study conducted at Raltech Scientific Services Inc.
- 00022081 Raltech Scientific Services, Incorporated. 1979. Primary Skin Irritation. Study 34704-52. Unpublished study conducted at Raltech Scientific Services Laboratory.
- 00030632 Anon. (1970) Residue Data: Diuron Plus Sub. Uracils-Citrus. (Unpublished report).
- 00050468 E.I. du Pont de Nemours & Company (1980) Results of Tests on the Amount of Residue Remaining on Treated Crops: Krovar I. (Unpublished study received Oct. 22, 1980, under 352-352; CDL:243548-A).
- 00057519 E.I. du Pont de Nemours & Company, Incorporated (1979) Bromacil Technical Data Sheet. (Unpublished study received Jan. 23, 1981, under 34913-14; submitted by SSI Industries, Inc., Huntington, W.Va.; CDL:244378-B).
- 00072782 Kaplan, AM, Schneider, PM, Jr., Wood, CK, et al.. 1980. Long-Term Feeding Study in Mice With 5-Bromo-3-sec-butyl-6-methyluracil (INN-976; Bromacil). Study HLR-893-80. Unpublished study conducted at DuPont Haskell Laboratory.
- 00129181 E.I. du Pont de Nemours & Co., Inc. (19??) Product Chemistry: [Bromacil]. (Unpublished study received Jul. 7, 1983, under 352-425; CDL:250676-A).
- 00132778 E.I. Du Pont de Nemours & Co., Inc. (1978) Product Chemistry: [Bromacil and Hyvar Weed Killers]. (Compilation; unpublished study received Nov. 18, 1983, under 352-287; CDL:251801-A).

BIBLIOGRAPHY

MRID

CITATION

-
- 00137865 E.I. du Pont de Nemours & Co., Inc. (1983) Introduction and Summary: [Krovar I Herbicide]. (Compilation; unpublished study received Apr. 12, 1984, under 352-352; CDL:252942-A).
- 00141631 Rhodes, R. (1984) Determination of N-Octanol-Water Partition Coefficients. Unpublished study prepared by E.I. du Pont de Nemours and Co., Inc. 4 p.
- 05002192 Gutenmann, W.H.; Lisk, D.J. (1970) Metabolism and excretion of bromacil in milk of dairy cows. Journal of Agricultural and Food Chemistry 18(1):128-129.
- 05002415 Gardiner, J.A.; Rhodes, R.C.; Adams, J.B., Jr.; Soboczenski, E.J. (1969) Synthesis and studies with 2-C14-labeled bromacil and terbacil. Journal of Agricultural and Food Chemistry 17(5):980-986.
- 05013999 Pease, H.L. (1966) Determination of bromacil residues. Journal of Agricultural and Food Chemistry 14(1):94-96.
- 05014217 Jolliffe, V.A.; Day, B.E.; Jordan, L.S.; Mann, J.D. (1967) Method of determining bromacil in soils and plant tissues. Journal of Agricultural and Food Chemistry 15(1):174-177.
- 05014750 Shriver, J.W.; Bingham, S.W. (1973) Physiological effects of bromacil on Kentucky bluegrass and orchardgrass. Weed Science 21(3):212-217.
- 05019944 Ting, K.C.; Root, G.A.; Tichelaar, G.R. (1980) Gas-liquid chromatographic determination of bromacil residues. Journal of the Association of Official Analytical Chemists 63(1):43-46.
- 40098001 Mayer, F.; Ellersieck, M. (1986) Manual of Acute Toxicity: Interpretation and Data Base 410 Chemicals and 66 Species of Freshwater Animals. US Fish & Wildlife Service; Resource Publication (160): 579 p.
- 40951501 Grimes, J. (1986) H-16287: An Acute Oral Toxicity Study with the Bobwhite: Final Report: Wildlife International Ltd., Project No. 112-173. Unpublished study prepared by Wildlife International Ltd. 18 p.
- 40951505 Das, Y. (1988) Hydrolysis of [2-[carbon 14]]Bromacil in Aqueous Solutions Buffered at pH 5,7, and 9: Project No. 86001-02; DuPont Document No. AMR-522-86. Unpublished study prepared by Biospherics Inc. 33 p.

BIBLIOGRAPHY

MRID

CITATION

-
- 40951507 Das, Y. (1986) Photodegradation of [2-[carbon 14]]Bromacil in Aqueous Solutions Buffered at pH 5, 7, and 9: Project No. 86001 01; Study No. AMR-523-86. Unpublished study prepared by Biospherics Inc. 65 p.
- 40951508 Dulka, J.; Ryan, T. (1988) Photodegradation of [2-[carbon 14]]Bromacil in Water at pH 9: Project ID: AMR-901-87. Unpublished study prepared by E.I. du Pont de Nemours and Co., Inc. 28 p.
- 40951509 Das, Y. (1988) Photodegradation of [2-[carbon 14]]Bromacil on Soil Under Artificial Sunlight: Project No. 86001-03; Du Pont Document No. AMR-558-86. Unpublished study prepared by Biospheric Inc. 46 p.
- 40951510 Vigon, B.; Arthur, M. (1988) Aerobic Soil Metabolism of [2-[carbon 14]]Bromacil in Stine Farm, DE, Silty Clay Loam: Project ID: N0766-7300; Du Pont Report No. AMR-500-86. Unpublished study prepared by Battelle Columbus Div. 50 p.
- 40951511 Vigon, B.; Arthur, M. (1988) Anaerobic Aquatic Metabolism of [2- [carbon 14]]Bromacil in West Jefferson, OH Pond Sediment and Water: Project ID: N0766-7300. Unpublished study prepared by Battelle Columbus Div. 57 p.
- 40951513 Hutton, D. (1986) [2-[carbon 14]] Bromacil Bioconcentration in Bluegill Sunfish: Du Pont HLR 378-86; AMR-494-86. Unpublished study prepared by E.I. du Pont de Nemours and Co., Inc. 49 p.
- 40984801 Zellers, JE. 1987. Teratogenicity Study of INN-976 in Rabbits. Study Medical Research # 8187-001; HLR-527-87. Unpublished study conducted at DuPont Haskell Laboratory for Toxicology and Industrial Medicine.
- 40984802 Alvarez, I. 1988. Teratogenicity Study of INN-976 in Rats. Study 16473; MR-7977-001. Unpublished study conducted at Haskell Laboratory for Toxicology and Industrial Medicine.
- 41261701 Bogdanffy, MS. 1989. Combined Chronic Toxicity/ Oncogenicity Study With Bromacil (IN N976): Two Year Feeding Study in Rats. Study HLR 186-89. Unpublished study conducted at Agricultural Products Division, Experimental Station, DuPont.
- 41304107 Brock, W. (1988) Closed-Patch Repeated Insult Dermal Sensitization Study (Buehler Mehtod) with IN N976-134 in Guinea Pigs: Lab Project Number: HLR 390-88: 4581-626. Unpublished study prepared by E. I. Du Pont de Nemours & Co., Inc. 25 p.

BIBLIOGRAPHY

MRID

CITATION

-
- 41588701 Boeri, R. (1989) Static Acute Toxicity of Bromacil to the Mysid, *Mysidopsis bahia*: Lab Project Number: DP2788. Unpublished study prepared by Enseco Inc. 21p.
- 41588702 Boeri, R. (1989) Static Acute Toxicity of Bromacil to the Sheepshead Minnow, *Cyprinodon variegatus*: Lab Project Number: DP2888. Unpublished study prepared by Enseco Inc. 21p.
- 41677101 Schneiders, G. (1990) Field Soil Dissipation of Hyvar X Herbicide: Lab Project Number: AMR/1146/88. Unpublished study prepared by E. I. du Pont de Nemours and Co. 64 p.
- 41804601 Miller, LMA. 1991. Reproductive and Fertility Effects With Bromacil: Multigeneration Reproduction Study in Rats. Study HLR-724-90; Medical Research Project # 8767-001. Unpublished study conducted at Haskell Laboratory for Toxicology and Industrial Medicine.
- 41869701 Bogdanffy, MS. 1991. Chronic Toxicity Study With Bromacil (DPX-N 976-136) -One Year Feeding Study in Dogs. Study HLR 1-91; Medical Research Project # 8676-001. Unpublished study conducted at Haskell Laboratory for Toxicology and Industrial Medicine.
- 42465601 Bentley, K. (1988) Mutagenicity Evaluation of Bromacil in the CHO/HPRT Assay: Lab Project Number: 739-88: 8452-001. Unpublished study prepared by E. I. du Pont de Nemours and Co., Inc., Haskell Lab. 22 p.
- 42465701 Reynolds, V. 1988. Mutagenicity Testing of Bromacil in the *Salmonella typhimurium* Plate Incorporation Assay. Study 551-88: 8452-001. Unpublished study conducted at Haskell Laboratory for Toxicology and Industrial Medicine.
- 42465801 Vlachos, D. 1988. Mouse Bone Marrow Micronucleus Assay of Bromacil (in N976). Study 783-88: 8452-001. Unpublished study conducted at Haskell Laboratory for Toxicology and Industrial Medicine.
- 42465901 Bentley, K. 1988. Assessment of Bromacil in the *In Vitro* Unscheduled DNA Synthesis Assay in Rat Primary Hepatocytes. Study 518-88: 8452-001. Unpublished study conducted at DuPont Haskell Laboratory for Toxicology and Industrial Medicine.
- 42491101 Carski, T. (1992) Influence of Bromacil on Seed Germination, Seedling Emergence, and Vegetative Vigor of Several Terrestrial Plants: Lab Project Number: AMR 2304-92. Unpublished study prepared by Dupont Haskell Labs. 237 p.

BIBLIOGRAPHY

MRID

CITATION

- 42516101 Schmuckler, M.; Cooke, L. (1992) Physical and Chemical Characteristics of Bromacil: Lab Project Number: AMR 2369-92. Unpublished study prepared by E.I. du Pont de Nemours and Co. 24 p.
- 42516102 Schmuckler, M. (1992) Determination of the Water Solubility of Bromacil, N976: Lab Project Number: N976.A. Unpublished study prepared by E.I. du Pont de Nemours and Co. 27 p.
- 42516103 Schmuckler, M.; Cooke, L. (1992) Solubility of Bromacil in Organic Solvents Using Continuous Sample Agitation: Lab Project Number: AMR 2373-92. Unpublished study prepared by E.I. du Pont de Nemours and Co. 20 p.
- 42516104 Schmuckler, M. (1992) Vapor Pressure of Bromacil: Lab Project Number: AMR 896-87. Unpublished study prepared by E.I. du Pont de Nemours and Co. 14 p.
- 42516105 Schmuckler, M.; Cooke, L. (1992) Dissociation Constant of Bromacil: Lab Project Number: AMR 2368-92. Unpublished study prepared by E.I. du Pont de Nemours and Co. 23 p.
- 42516106 Schmuckler, M. (1992) N-Octanol/Water Partition Coefficient Determination of Bromacil at pH 5, pH 7, and pH 9: Lab Project Number: DUP-23-88: AMR 1178-88. Unpublished study prepared by E.I. du Pont de Nemours and Co. 23 p.
- 42516107 Schmuckler, M.; Cooke, L. (1992) Stability of Bromacil in the Presence of Metal and Metal Ions, in Sunlight and at Normal and Elevated Temperatures: Lab Project Number: AMR 2371-92. Unpublished study prepared by E.I. du Pont de Nemours and Co. 29 p.
- 42648401 Douglass, D. (1992) Technical Bromacil: Description of Beginning Materials and Manufacturing Process Discussion of Formation of Impurities: Lab Project Number: AMR 2463-92. Unpublished study prepared by E.I. du Pont de Nemours and Co. 29 p.
- 42825201 M^c Cooley, KT. 1989. Metabolism of [Carbonyl-2-¹⁴C] Bromacil by the Laboratory Rat. Study HLR # 104-89; DuPont AMR # 834-87. Unpublished study conducted at Haskell Laboratory for Toxicology and Industrial Medicine.

BIBLIOGRAPHY

MRID

CITATION

-
- 42967301 Amoo, J.; Walker, D.; Irelan, P. (1993) Analytical Method for the Quantitation of Bromacil in Citrus Crops (Oranges) and Pineapples by Gas Chromatography/Electron-Capture Detection: Lab Project Number: AMR 2465-92. Unpublished study prepared by E. I. du Pont de Nemours and Co., 39 pp.
- 42967401 Schneiders, G.; Irelan, M. (1993) Stability of Bromacil in Stored Analytical Samples: Lab Project Number: AMR 2282-92: EBT-208.01. Unpublished study prepared by E.I. du Pont de Nemours and Co., 53 pp.
- 42967501 Schneiders, G.; Irelan, M. (1993) Uptake and Metabolism of 2-(carbon 14)-Bromacil by Orange Trees: Lab Project Number: AMR 2322-92. Unpublished study prepared by E.I. du Pont de Nemours and Co., 105 pp.
- 42979801 Lakoski, J., Au, W., and Legator, M. 1992. Open-Field Behavioral Assessment of Locomotor Effects of Acute and Repeated Bromacil Administration in the Rat. Unpublished study conducted at the University of Texas Medical Branch at Galveston.
- 42998901 McEuen, S.; Stringer, D. (1993) Metabolism of (Carbon 14)-bromacil by Lactating Goats: Lab Project Nos. 2283/92; 40112. Unpublished study prepared by ABC Laboratories, Inc., 93 pp.
- 43078801 Fomenko, J. (1992) Testing of Bromacil Through FDA Multi-Residue Protocols A through E. Unpublished study prepared by Spectralytix, Inc., 97 pp.
- 43076201 Kern, R. (1993) Bromacil Lithium Salt: Description of Beginning Materials and Synthesis: Discussion of Impurities: Lab Project Number: AMR 2886-93. Unpublished study prepared by E.I. du Pont de Nemours & Co., Inc., Du Pont Agricultural Products. 7 p.
- 43076301 Schmuckler, M.; Kern, R.; O'Donnell, T. et al. (1993) Physical and Chemical Characteristics of the Lithium Salt of Bromacil: Lab Project Number: AMR 2853-93. Unpublished study prepared by E.I. du Pont de Nemours & Co. and Du Pont Explosion Hazards Lab. 27 p.
- 43375001 Kern, R. (1994) Product Identity, Description of Formulation Process, Formation of Impurities, and Certification of Limits for the End-Use Product DuPont HYVAR® X-L. Unpublished compilation submitted by E. I. du Pont de Nemours and Company. 51 p.

BIBLIOGRAPHY

MRID

CITATION

- 43460601 Schneiders, G.; Irelan, M. (1994) Uptake and Metabolism of [2-¹⁴C]Bromacil in Pineapple. Laboratory Project ID: AMR 2395-92. Unpublished study prepared by E. I. du Pont de Nemours & Company. 105 p.
- 43461601 Amoo, J.S. (1994) Magnitude of Residue of Bromacil in Pineapple Fruit and its Processed Fractions Following Application of Hyvar X Herbicide: DuPont Lab Project Number: AMR 2227-92. Unpublished study prepared by E.I. du Pont de Nemours and Company and the Hawaiian Sugar Planters' Association. 123 p.



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 6; 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 6).

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
- 3 - Requirements Status and Registrant's Response Form
- 4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
- 5 - List of Registrants Receiving This Notice
- 6 - Cost Share and Data Compensation Forms

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. 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 Attachment 3, Requirements Status and Registrant's Response Form, 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: 703-487-4650).

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, and the Requirements Status and Registrant's Response Form, Attachment 2 and Attachment 3. 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 must be submitted for each product listed on the Data Call-In Response Form 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 in Attachment 2). Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form and Requirements Status and Registrant's Response Form (if this form is required) 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(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, indicating your election of this option. Voluntary cancellation is item number 5 on the Data Call-In Response Form. 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 6 on the Requirements Status and Registrant's Response Form and item numbers 7a and 7b on the Data Call-In Response Form. 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. 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 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 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. 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.

The time frames in the Requirements Status and Registrant's Response Form 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 and a Requirements Status and Registrant's Response Form 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 8570-31, Certification with Respect to Data Compensation Requirements.

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 and the Requirements Status and Registrant's Response Form, 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 and a Requirements Status and Registrant's Response Form;
 - 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 CANCELLED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or cancelled 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 cancelled 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 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(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 and a completed Requirements Status and Registrant's Response Form (Attachment 2 and Attachment 3 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 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 and Instructions
- 3 - Requirements Status and Registrant's Response Form and Instructions
- 4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
- 5 - List of Registrants Receiving This Notice
- 6 - Cost Share and Data Compensation Forms and the Confidential Statement of Formula Form

BROMACIL DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing bromacil.

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 bromacil. 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 bromacil 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 bromacil are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on bromacil 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 bromacil products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding these product specific data requirements and procedures established by this Notice, please contact Jane Mitchell at (703) 308-8061.

All responses to this Notice for the Product Specific data requirements should be submitted to:

Jane Mitchell
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: bromacil

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.

Page 1 of Part A for the PDCI is inserted here

**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 only one of the following response codes for each data requirement 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 Data Compensation Requirements**" form (**EPA Form 8570-29**) 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 Data Compensation Requirements**" form (EPA Form 8570-29) 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 Offer to Cost Share in the Development Data**" form. 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 8570-29) 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 8570-29) 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 8570-29) 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 8570-29) 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 8570-29)** 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 8570-29)** 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.

Page 1 of Part B for the PDCI is inserted here

Page 2 of Part B for the PDCI is inserted here

Page 3 of Part B for the PDCI is inserted here

Page 4 of Part B for the PDCI is inserted here

EPA'S BATCHING OF BROMACIL 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 Bromacil and Lithium Salt of Bromacil as the active ingredients, 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 sixteen products were found which contain Bromacil or Lithium Salt of Bromacil as the active ingredient. Ninety of these products contain Bromacil, and twenty six contain Lithium salt of Bromacil. The products have been placed into 12 batches for Bromacil and in 6 batches for Lithium salt of Bromacil in accordance with the active and inert ingredients, type of formulation and current labeling. Table I identifies the products containing Bromacil, Table II identifies products containing Lithium Salt of Bromacil, table III identifies products that cannot be batched, and table 4 identifies products containing bromacil or the lithium salt that have either been suspended or voluntarily withdrawn.

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
1	352-287	Bromacil 84.0	Powder
	352-409	" " " "	Powder
2	352-332	Bromacil 10.6	Pelleted
	10107-103	Bromacil 10.7	Granular
3A	228-232	Bromacil 4.211	Granular
	10088-76	Bromacil 4.32	Granular
	49428-4 Alternate	Bromacil 4.20	Granular
3B	769-639	Bromacil 4.00	Granular
	49428-4 Basic	Bromacil 4.20	Granular
3C	228-231	Bromacil 2.106	Granular
	228-230	Bromacil 1.00	Granular
4	352-412	Bromacil 4.0	Granular
	10107-104	Bromacil 4.0	Granular
5A	1769-159	Bromacil 3.32	Emulsifiable Concentrate
	3837-28	Bromacil 2.3	Emulcifiable concentrate
	44446-21	Bromacil 2.3	Emulcifiable Concentrate
5B	491-221	Bromacil 1.52	Emulcifiable Concentrate
	1270-113	" " " "	" " "
6	10088-88	Bromacil 1.03	Ready to use solution
	1029-29	Bromacil 1.13	" " "

Table I

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
7	352-352	Bromacil 42.7, Diuron 42.7	Wettable Powder
	352-411	" " " "	" " "
8A	228-236	Bromacil 4.22, Diuron 5.27	Granular
	228-235	Bromacil 4.22, Diuron 4.22	Granular
	228-234	Bromacil 4.211, Diuron 2.106	Granular
8B	228-227	Bromacil 2.00, Diuron 2.00	Granular
	228-233	Bromacil 0.500, Diuron 0.500	Granular
	228-202	Bromacil 0.211, Diuron 0.211	Granular
8C	9603-1	Bromacil 4.21, Diuron 5.26	Granular
	34913-20	Bromacil 4.21, Diuron 4.09	Granular
8D	13283-9	Bromacil 2.00, Diuron 2.00	Granular
	33560-44 Alternate	Bromacil 2.00, Diuron 2.10	Granular
	34193-19	Bromacil 2.00, Diuron 2.00	Granular
	10807-149	Bromacil 2.00, Diuron 2.00	Granular
9A	10107-107	Bromacil 4.0, Diuron 4.0	Granular
	352-410	" " " "	Granular
9B	10107-106	Bromacil 2.06, Diuron 2.06	Granular
	33560-44 Basic	Bromacil 2.00, Diuron 2.00	Granular
	49428-1	Bromacil 2.00, Diuron 2.00	Granular
10	10088-68	Bromacil 0.980, Acetic Acid(2,4-Dichlorophenoxy-2-ethyl hexyl ether 1.09	Ready to use solution
	3862-92	" " " "	" " "
	11694-43	" " " "	" " "
	402-98	Bromacil 0.7672, Acetic Acid (2,4-Dichlorophenoxy-2-ethyl hexyl ether 1.6389	" " "
	334-245	Bromacil 0.642, Acetic Acid (2,4-dichlorophenoxy-2-ethyl hexyl ether 1.160 2-ethyl-1 hexanol[2,4 D isooctyl esters 0.07	" " "
	9250-15	Bromacil 0.610, Acetic Acid (2,4-Dichlorophenoxy-2-ethyl hexyl ether 1.100	" " "
	34892-4	" " " "	" " "
	10088-2	" " " "	" " "
	9367-13	Bromacil 0.610, Acetic Acid (2,4-Dichlorophenoxy-2-ethyl hexyl ether 1.090	" " "
11	2155-52	Bromacil 0.980, Isooctyl(2 ethyl-4 methylpentyl) Dichlorophenoxy acetate 1.0900	Ready to use solution
	2155-51	" " " "	" " "
	8123-29	" " " "	" " "
	48211-7	" " " "	" " "
	3837-24	Bromacil 0.610, Isooctyl(2 ethyl-4 methylpentyl) Dichlorophenoxy acetate 1.0900	" " "
	8123-28	" " " "	" " "
	48211-9	" " " "	" " "
12	9754-1	Bromacil 0.30, Sodium Metaborate 18.00 Sodium Chlorate 7.10	Soluble Concentrate
	7001-345	Bromacil 0.43, Sodium Metaborate 8.75 Sodium Chlorate 10.43	Soluble Concentrate

Table II

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
1	352-346	5 bromo-3-sec-butyl-6-methyl uracil lithium salt 21.90, Lithium hydroxide 3.90	Soluble concentrate
	352-413	" " " "	" " "
2	10370-251	5 bromo-3-sec-butyl-6- methyl uracil lithium salt 12.5	" " "
	769-458	5 bromo-3-sec-butyl-6- Methyl uracil lithium salt 11.5	" " "
3	34704-52	5 bromo-3-sec-butyl-6- Methyl uracil lithium salt 8.7	Liquid Concentrate
	7401-426	5 bromo-3-sec-butyl-6- Methyl uracil lithium salt 7.5	" " "
	352-414	" " " "	" " "
	10088-82	" " " "	" " "
	10107-105	" " " "	" " "
	2155-99	Bromacil 6.1, Lithium Hydroxide 1.75	" " "
4	10827-63	5 bromo-3-sec-butyl-6- Methyl uracil lithium salt 4.6	Emulsifiable Concentrate
	42050-9	5 bromo-3-sec-butyl-6- Methyl uracil lithium salt 5.0	Ready to use solution
5	48211-8	Bromacil 3.16, Lithium Hydroxide 0.54	Soluble Concentrate
	8123-96	5 bromo-3-sec-butyl-6- Methyl uracil lithium salt 2.75	" " "
	12310-33	5 bromo-3-sec-butyl-6- Methyl uracil lithium salt 2.50	Ready to use solution
	352-415	" " " "	" " "
	7401-427	" " " "	" " "
	228-241	" " " "	" " "
	2155-97	Bromacil 2.44 Lithium Hydroxide 0.70	Soluble Concentrate
6A	10370-308	5 bromo-3-sec-butyl-6- Methyl uracil lithium salt 2.3	" " "
	11515-36	5 bromo-3-sec-butyl-6- Methyl uracil lithium salt 2.19	Ready to use solution
	3862-65	5 bromo-3-sec-butyl-6- Methyl uracil lithium salt 2.00	" " "
	352-416	" " " "	Soluble Concentrate
6B	2155-100	Bromacil 1.22, Lithium Hydroxide 0.35	" " "
	11474-24	5 bromo-3-sec-butyl-6- Methyl uracil lithium salt 1.22	" " "

Table III No Batch

No Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
	352-325	Bromacil 96.2, Impurities 4.0	Granular
	352-546	Bromacil 80.0, Impurities 0.4	Granular
	352-440	Bromacil 57.5, Diuron 28.0	Granular
	352-351	Bromacil 55.94, Diuron 28.63	Wettable Powder
	2393-298	Bromacil 44.63	Liquid
	5905-490	Bromacil 42.10, Simazene 52.63	Wettable Powder
	34704-588	Bromacil 10.64	Pelleted
	8123-74	Bromacil 5.00	Granular
	34704-573	Bromacil 4.30	Granular
	34704-576	Bromacil 4.30, Diuron 4.30	Granular
	10807-144	Bromacil 3.84	Emulsifiable concentrate
	5905-108	Bromacil 3.19, Sodium Chlorate 40.0	Granular
	19713-206	Bromacil 2.64, Sodium Chlorate 58.58	Pelleted
	33560-43	Bromacil 2.00, Diuron 2.00, Sodium Chlorate 40.0, Borax 43.7	Pelleted
	1022-271	Bromacil 1.84, Diuron 1.46	Granular
	7001-339	Bromacil 1.50, Sodium Chlorate 30.00, Borax 52.7	Granular
	7313-3	Bromacil 1.50, Sodium Chlorate 30.00	Granular
	48211-73	Bromacil 1.50	Granular
	10807-99	Bromacil 1.22	Soluble Concentrate
	1203-60	Bromacil 1.053	Ready to use Solution
	1203-68	Bromacil 1.053	" " "
	2155-53	Bromacil 1.03	" " "
	8123-13	Bromacil 1.00	Granular
	1769-188	Bromacil 0.63	Ready to use Solution
	10807-97	Bromacil 1.000	" " "
	11694-10	Bromacil 0.4900, 2,4-Dichlorophenoxy acetic acid isooctyl ester 0.550, Inerts from 2,4 DIsooctyl ester 0.296	Pressurized Liquid
	44446-24	Bromacil 0.4900, 2,4-dichlorophenoxy acid isooctyl ester 0.613	" " "
	7001-345	Bromacil 0.43, Sodium metaborate 8.75, Sodium Chlorate 10.43	Soluble concentrate
	9754-1	Bromacil 0.30, Sodium Metaborate 18.0, Sodium Chlorate 7.10	Soluble concentrate
	1553-101*	5 bromo-3-sec-butyl-6-methyl uracil lithium salt 5.0	Soluble concentrate
	42050-9 Alternate	5 bromo-3-sec-butyl-6-methyl uracil lithium salt 5.0	Ready to use solution

* Product listed as active. File room does not have Jacket for this registration.

Table IV: Suspended or voluntarily cancelled products containing Bromacil

No Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
No batch	2749-143	Bromacil 53.0, Diuron 27.0	Powder
	19713-204	Bromacil 10.0, Sodium Chlorate 40.0	Granular
	19713-200	Bromacil 5.0	Granular
	19713-201	Bromacil 5.0	Granular
	19713-202	Bromacil 4.21, Sodium Chlorate 40.40	Granular
	303-150*	Bromacil 1.25, 2,4,D LV ester 1.31	Ready to use solution

*This product has been voluntarily cancelled as per jacket. The stock will be allowed to deplete

RECOMMENDATIONS

Table I

Batch 1 may be registered based on data from Technical Bromacil plus eye, skin, and sensitization studies specific to Batch 1. There is no sensitization data on the technical.

Batch 2 Registration may be based on technical Bromacil (95 % AI), or Batch 1 (84 % AI) with additional eye study for Batch 2

Batch 3A, 3B and 3C may be registered based on Bromacil Technical and eye data from Batch 3 A.

Batch 4 may be registered based on Bromacil technical and additional eye and skin data specific to batch 4.

Data from Bromacil Technical may be bridged to all of batch 5 A and 5 B listings with the exception of eye studies. Eye study conducted with 1769-159 may be used for all Batch 5 A. Individual eye studies need to be submitted for products in 5B.

Batch 6 Registration may be based on Bromacil technical with an additional skin study conducted with Batch 6.

Full set of data necessary for Batch 7.

Batch 8 may be registered based on data generated for Batch 7 with the exception of eye irritation. Eye data generated using EPA 9603-1 may be used for batches 8A and 8B, and registrations 34913-20, 13283-9 and 34913-19. Individual eye studies must be submitted for 33560-44 and 10807-149.

Data from Batch 7 or 8 may be bridged to 9 A and 9 B, with the exception of eye data. Eye study for Batch 9 A may be used for 9B.

Batch 10 EPA 402-98 is estimated to have the greatest hazard potential in batch 10. Data generated from Registration 402-98 with the exception of eye data for registrations 11694-43, 334-245, and 9250-15, can be used for all of batch 10 . Specific eye study is needed for both EPA 334-245 and 9250-15. Eye data from registration 9250-15 may be used for 11694-43.

Batch 11 Data from Batch 10 may be used with the exception of eye studies for EPA 48211-7 and 48211-9. Eye study conducted with 48211-7 may be used for 48211-9

Batch 12 Data generated with 9754-1 may be used to register 7002-345.

Table II

Batch 1 needs a full set of data.

Batch 2 may be registered based on batch 1

Batch 3 may be registered based on batch 1 with an eye study specific for the batch, and one specific for EPA 2155-99

Batch 4 may be registered based on batch 1.

Batch 5 may be registered based on batch 1 with individual eye studies for EPA 48211-8 and 2155-97.

Batch 6 may be registered based on batch 1 with an individual eye study for 2155-100 that will also serve 11474-24.

Table III

352-325 data is incomplete, a complete set of data is necessary.

352-546 can use data from 352-325 with additional eye and skin studies.

Product specific eye data needed for 352-440. Skin and sensitization data from this registration may be bridged to 352-251.

Individual eye and skin studies are necessary for 2393-298. Other data may be bridged from the technical.

Data from technical may be bridged to 34704-588, 8123-74, 34704-573, 10807-1444 with the exception of eye data. Individual eye studies are needed. Data from Batch 8(table I) may be bridged to 34704-576 with an additional eye study.

Data from Batch 7 (Table I) may be bridged down to 1022-271 with a product specific eye study.

Data from 19713-206 may be bridged down to 7313-3.

Technical Bromacil data with product specific eye data may also be used for 48211-73 and 10807-99.

2155-53, 8123-13 and 1769-188 may be based on technical Bromacil with individual eye studies.

**Attachment 5. List of Registrant(s) sent this DCI
(Insert)**



United States Environmental Protection Agency
Washington, D.C. 20460
**Certification of Offer to Cost
Share in the Development of Data**

Form Approved
OMB No. 2070-0106,
2070-0057
Approval Expires
3-31-99

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 suggestions for reducing this burden to, Chief Information Policy Branch, PM-233, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below:

Company Name	Company Number
--------------	----------------

Product Name	EPA Reg. No.
--------------	--------------

I Certify that:

My company is willing to develop and submit the data required by EPA under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), if necessary. However my company would prefer to enter into an agreement with one or more registrants to develop jointly or share in the cost of developing data.

My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an offer to be bound by arbitration decision under section 3(c)(2)(B)(iii) of FIFRA if final agreement on all terms could not be reached otherwise. This offer was made to the following firms on the following date(s):

Name of Firm(s)	Date of Offer
-----------------	---------------

Certification:

I certify that I am duly authorized to represent the company named above, and that the statements that I have made on this form and all attachments therein are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature of Company's Authorized Representative	Date
--	------

Name and Title (Please Type or Print)



**CERTIFICATION WITH RESPECT TO
DATA COMPENSATION REQUIREMENTS**

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 suggestions for reducing this burden to, Chief Information Policy Branch, PM-233, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name

Company Number

Product Name

EPA Reg. No.

I Certify that:

1. For each study cited in support of registration or reregistration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter to cite that study.
2. That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with sections 3(c)(1)(F) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and the amount of compensation due, if any. The companies I have notified are. (check one)

 The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form,"
3. That I have previously complied with section 3(c)(1)(F) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

Signature

Date

Name and Title (Please Type or Print)

GENERAL OFFER TO PAY: I hereby offer and agree to pay compensation to other persons, with regard to the registration or reregistration of my products, to the extent required by FIFRA section 3(c)(1)(F) and 3(c)(2)(D).

Signature

Date

Name and Title (Please Type or Print)

The following is a list of available documents for bromacil that may further assist you 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 can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet using ftp on FTP.EPA.GOV, or using WWW (World Wide Web) on WWW.EPA.GOV., or contact Dee Henderson at (703)-308-8167.

1. PR Notice 86-5.
2. PR Notice 91-2 (pertains to the Label Ingredient Statement).
3. A full copy of this RED document.
4. A copy of the fact sheet for bromacil.

The following documents are part of the Administrative Record for bromacil and may be 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 Chemical Status Sheet.

1. Health and Environmental Effects Science Chapters.
2. Detailed Label Usage Information System (LUIS) Report.

The following Agency reference documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet of this RED document.

1. The Label Review Manual.
2. EPA Acceptance Criteria