United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508W)

EPA 738-R-97-006
February 1998

Reregistration Eligibility Decision (RED)

Metribuzin

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 metribuzin which includes the active ingredients 4-amino-6(1,1-dimethylethyl)-3-(methylthio)-1,2,4-triazin-5(4H)-one. The enclosed Reregistration Eligibility Decision (RED), which was approved on May 20, 1997 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 also includes 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 is due 90 days from the receipt of this letter. The second set of required responses is due 8 months from the date of this letter.** Complete and timely responses will avoid the Agency taking the enforcement action of suspension against your products.

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

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

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Jean Holmes (703) 308-8008. Address any questions on required generic data to the Special Review and Reregistration Division representative Michael Goodis (703) 308-8157.

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

Metribuzin

LIST A

CASE 0181

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

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METRIBUZIN REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Assessment

Jim Saulmon	Biological Analysis Branch
Art Grube	Economic Analysis Branch
Margaret Cogdell	L.U.I.S. Project

Environmental Fate and Effects Risk Assessment

Mary Powell	Science Analysis and Coordination Staff
Kay Montague	Ecological Effects Branch
Jim Breithaupt	Environmental Fate and Groundwater Branch
Estella Waldman	Environmental Fate and Groundwater Branch
Henry Nelson	Environmental Fate and Groundwater Branch

Health Effects Risk Assessment

Kathryn Boyle	Risk Characterization and Analysis
John Leahy	Occupational and Residential Exposure Branch
Sue Hummel	Registration and Support Chemistry Branch
Brian Steinwand	Science Analysis Branch
Stephen C. Dapson	Toxicology Branch II

Registration Support

Vickie Walters	Fungicide-Herbicide Branch
Mark Perry	Registration Support Branch

Risk Management

Jean Holmes	Planning and 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
FAO/WHO	Food and Agriculture Organization/World Health Organization
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection 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_{lo}	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
μg/L	Micrograms per liter
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.

GLOSSARY OF TERMS AND ABBREVIATIONS

N/A	Not Applicable
NOEC	No Observable 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
Pa	pascal, the pressure exerted by a force of one newton acting on an area of one square meter.
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
RUP	Restricted Use Pesticide
SLN	Special Local Need (Registrations Under Section 24 (c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
WP	Wettable Powder
WPS	Worker Protection Standard

ABSTRACT

The U. S. Environmental Protection Agency has completed its reregistration eligibility decision for the pesticide metribuzin. This decision includes a comprehensive reassessment of the required target data and 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.

Metribuzin is a herbicide used on a wide range of sites, including vegetable and field crops, turf grasses (recreational areas), and non-crop areas, to selectively control certain broadleaf weeds and grassy weed species. The Agency has concluded under FIFRA that all uses, as prescribed in this document, will not cause unreasonable risks to humans or the environment and therefore, all products are eligible for reregistration. To mitigate potential health risks to mixer/loader/applicators, the Agency has accepted risk mitigation measures proposed by the technical registrant, Bayer Corporation, requiring the removal of certain application methods from the label and application rate reductions. Also, measures to reduce environmental risks to birds, mammals, and non-target plants include the removal of certain application methods from the label, application rate reductions, and spray drift label requirements. Certain product chemistry and residue chemistry data are being required to be submitted to confirm the Agency's risk assessment and conclusions.

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 does not have at this time, available data to determine whether metribuzin has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, metribuzin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that metribuzin has a common mechanism of toxicity with other substances.

The Agency has reassessed metribuzin food and feed related 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 metribuzin residues. The only type of exposures evaluated were dietary and drinking water routes, since significant non-occupational exposures are unlikely with metribuzin use.

Before reregistering products containing metribuzin, the Agency is requiring that product specific data, revised Confidential Statements of Formula (CSF), and revised labeling be submitted within eight months of the issuance of this document for all products containing metribuzin. The product specific data include product chemistry for each registration and acute toxicity testing. After reviewing all these data and any revised labels and finding them acceptable in accordance with section 3(c)(5) of FIFRA, the Agency will reregister a product. However, those products which bear uses of this or any other active ingredients which have not been determined to be eligible for reregistration will be reregistered only when such uses and active ingredients are determined to be eligible for reregistration.

I. INTRODUCTION

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. 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 metribuzin including the risk to infants and children for any potential dietary, drinking water, dermal, inhalation or other oral exposures, and cumulative effects as stipulated under the FQPA. The document consists of six sections. Section I is the introduction. Section II describes metribuzin, 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 metribuzin. Section V discusses the reregistration requirements for metribuzin. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW

A. Chemical Overview

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

- **Common Name:** Metribuzin

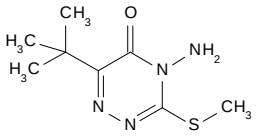
- **Chemical Name:** 4-amino-6-(1,1-dimethylethyl)-3-(methylthio)-1,2,4-triazin-5(4*H*)-one

- **Chemical Family:** Triazinone

- **CAS Registry Number:** 21087-64-9

- **OPP Chemical Code:** 101101

- **Empirical Formula and Structure:** $C_8H_{14}N_4OS$



- **Molecular Weight:** 214.28

- **Trade and Other Names:** Sencor, Lexone, Preview

- **Basic Manufacturer:** Bayer Corporation

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 metribuzin is in Appendix A.

For Metribuzin:

Type of Pesticide: Herbicide

Mode of Action: Inhibits electron transport in photosynthesis

Use Sites:

TERRESTRIAL FOOD CROP

Grain Crops: Wheat

Miscellaneous Vegetables: Asparagus

Root Crop Vegetables: Carrot (including tops)

TERRESTRIAL FOOD+FEED CROP

Agricultural Uncultivated Areas: Agricultural fallow/idleland

Fruiting Vegetables: Tomato

Grain Crops: Barley, Corn (Field), Wheat

Groups of Agricultural Crops Which Cross Established Crop Groupings: Corn, Peas, Soybeans

Root Crop Vegetables: Potato (White/Irish)

Seed and Pod Vegetables: Garbanzos (including chick peas), Lentils, Peas (Dried-Type, Field, Pigeon)

Sugar Crops: Sugarcane

TERRESTRIAL FEED CROP

Forage Grasses: Barley, Bermudagrass, Bluegrass, Grass Forage/Fodder/Hay,

Timothy, Wheat

Forage Legumes and Other Nongrass Forage Crops: Alfalfa, Lentils, Sainfoin

TERRESTRIAL NON-FOOD CROP

Groups of Agricultural Crops Which Cross Established Crop Groupings: Grasses grown for seed

Nonagricultural Uncultivated Areas: Nonagricultural uncultivated areas/soils, recreational areas

TERRESTRIAL NON-FOOD

Ornamental Lawns and Turf: Ornamental Lawns and turf (No residential uses)

Target Pests:

Broadleaves: annual polemonium, ageratum, ameranth, beggarweed, bristly starbur, buffalobur, buttercup, bedstraw, carpetweed, chickweed, clover, cocklebur, coffeeweed, common ragweed, corn cockle, Carolina geranium, cutleaf evening primrose, dandelion, dayflower, dock, dogfennel, falseflax, field bindweed, field pennycress, filaree, fireweed, flixweed, Florida pusley, fumitory, galinsoga, gromwell, haloe koa, henbit, hialoa, hophornbeam copperleaf, horsenettle, horseweed, jacob's ladder, jimsonweed, knotweed, kochia, ladysthumb, lambsquarters, London rocket, mallow, marestail, meadow salsify, mexicanweed, minerslettuce, morningglory, mustard, nettleleaf goosefoot, parsley-piert, pepperweed, pigweed, pineappleweed, prickly lettuce, purple deadnettle, purslane, rattlebox, redweed, red tassel-flower, red sorrel, sand catchfly, sensitiveplant, sesbania, shepherdspurse, sicklepod, spurred anoda, smartweed, snapweed, speedwell, spurge, spurweed, sunflower, thistle, toadflax, velvetleaf, white campion, wild buckwheat, wild poinsettia, yellow rocket;

Grasses: alexandergrass, barnyardgrass, barley, bluegrass, broadleaf panicum, browntop millet, brome, cheat, crabgrass, crowfootgrass, fall panicum, field sandbur, foxtail, guineagrass, Italian ryegrass, johnsongrass, junglerice, littleseed canarygrass, quackgrass, rabbitfoot polypogon, radiate fingergrass, rescuegrass, ricegrass, spring whitlowgrass, signalgrass, volunteer wheat, wild oat, windgrass, wiregrass

Formulation Types Registered:

TECHNICAL GRADE ACTIVE INGREDIENT	
SOLID	90.00%
MANUFACTURING PRODUCT	
WETTABLE POWDER	50.00%
END USE PRODUCT	
EMULSIFIABLE CONCENTRATE	14.00 to 15.00%
FLOWABLE CONCENTRATE	41.00%
WATER DISPERSIBLE GRANULES (DRY FLOWABLE)	64.30% to 75.00%
WETTABLE POWDER	50.00% to 70.00%

Method and Rates of Application:
(Please refer to Appendix A for site/use rate combinations.)

Equipment -

Aircraft (fixed-wing and helicopter); Center pivot irrigation; Ground; Low pressure ground sprayer; Power sprayer; Sprayer; Sprinkler irrigation

Method and Rate -

Band treatment; Broadcast; Chemigation; Conservation tillage; Directed spray; Low volume spray (concentrate); Soil band treatment; Soil broadcast treatment; Soil incorporated treatment; Spot treatment; Spray

Timing -

At planting; Dormant; Early postemergence; Early preplant; Early spring; Established plantings; Fall; Fallow; Foliar; Late spring; Layby; Post-final harvest; Postemergence; Postharvest; Postplant; Preemergence; Preplant; Preplant Spring); Pretransplant (Spring)

C. Estimated Usage of Pesticide

This section summarizes the best estimates available for the pesticide uses of metribuzin. 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. The table below summarizes metrobuzin use on agricultural crops by site.

Table 1

Metribuzin Usage

Site	Acres (000) Planted	Acres Treated (000)		Lb AI Applied (000)		Application Rates			States of Most Usage and % of Usage in These States
		Likely Average	Likely Max	Likely Average	Likely Max	lb ai/# acre/yr	appl lb /year	ai/A appl	
Corn	76,200	180	290	30	80	0.2	1.0	0.2	IA 99%
Barley	8,200	5	10	3	15	0.6	1.0	0.6	WA UT 85%
Wheat	71,500	400	500	65	80	0.2	1.0	0.2	WA OR 92%
Sorghum	11,600	1	4	1	3	0.6	1.0	0.6	LA 90%
Lentils	130	<1	<1						
Peas, Dry	170	60	100	15	25	0.3	1.0	0.3	ID WA 90%
Peas, Green	320	15	30	4	7	0.2	1.0	0.2	WA OR 92%
Alfalfa	24,800	200	340	110	200	0.6	1.0	0.6	WA OR UT ID MT MI 86%
Hay, Other	36,000	10	30	4	12	0.4	1.0	0.4	NJ WA 85%
Potatoes	1,400	830	920	430	550	0.5	1.0	0.5	ID WA WI ME FL OR 77%
Soybeans	59,300	6,540	11,540	1,980	3,690	0.3	1.0	0.3	OH IL IN IA MO MI 66%
Sugarcane	900	90	140	90	180	1.0	1.0	1.0	LA FL 100%
Grasses & Turf		30	60	30	60	1.0	1.0	1.0	
Asparagus	90	25	50	25	51	1.1	1.0	1.1	WA CA 81%
Carrots	100	5	10	1	2	0.2	1.0	0.2	MN WI 81%
Tomatoes	450	110	130	60	80	0.5	1.0	0.5	FL OH MI IN TN PA 78%
Sainfoin	NO DATA								

NOTES
Calculations of the above numbers may not appear to agree because they are displayed as rounded.

% of each crop treated with metribuzin is 1% or less, except for soybeans. The likely average % of soybeans treated is 11% and the likely maximum % of soybeans treated is 20%.

NO DATA = This site is NOT covered by EPA data sources.

Usage data primarily covers 1990 - 1994 for most sites and as early as 1987 for some sites.
Likely averages are based on weighted averages of data with most recent years and more reliable data weighted more. Early years are weighted very low.
Likely maximums are an amount above which the actual usage is unlikely to be.
Application rates are calculated from likely averages or are based on typical rather than maximum rates.
SOURCES: EPA data, USDA, and National Center for Food and Agricultural Policy

D. Data Requirements

Data requested in the July 1985 Registration Standard for metribuzin included studies on product chemistry, residue chemistry, toxicology, ecological effects, and environmental fate. These data were required to support the uses listed in the Registration Standard. Data Call-Ins were issued for metribuzin in 1991 and 1995 requiring additional product chemistry, environmental fate and groundwater, and ecological effects data. The ecological effects, environmental fate and groundwater data have been submitted to the Agency and reviewed. The residue chemistry data have been initiated by the registrant but have not been completed. Appendix B includes all data requirements identified by the Agency for currently registered uses needed to support reregistration.

E. Regulatory History

Metribuzin was registered in the United States in 1973 for use as a herbicide. In July, 1985, a Registration Standard (NTIS # PB86-174216) was issued for metribuzin. The Registration Standard required submission of additional data in the areas of toxicology, product and residue chemistry, ecological effects, and environmental fate and groundwater. The Standard also classified metribuzin as "Restricted Use" based on potential for groundwater contamination and possible carcinogenic effects. This classification was deleted six months after it was instituted, following the evaluation of additional data submitted by the registrant, Miles, now Bayer Corporation, clarifying carcinogenicity effects. This Reregistration Eligibility Decision evaluates data submitted in response to the Registration Standard and subsequent data call-ins.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

IDENTIFICATION OF ACTIVE INGREDIENT

Metribuzin is a white crystalline solid with a melting point of about 126 ^{o}C. Pure metribuzin is soluble in water at 1200 ppm, and soluble in dimethylformamide (178 g/100 g), chloroform (85 g/100 g), acetone (82 g/100 g), ethyl acetate (47 g/100 g), methanol (35 g/100 g), ethanol (19 g/100 g), toluene (12 g/100 g), xylene (9 g/100 g), and n-hexane (0.2 g/100 g).

MANUFACTURING-USE PRODUCTS

As of 7/29/96 there were two metribuzin manufacturing-use products (MPs) registered to Bayer Corporation: a 90% technical (EPA Reg. No. 3125-270) and a 50% formulation intermediate (FI) (EPA Reg. No. 3125-305). The formulation intermediate is a wettable powder end-use product (EP).

Physical Chemistry Assessment

All pertinent data requirements are satisfied for the metribuzin 50% FI. (Some of the 50% FI data requirements are fulfilled by data for the technical source product.) Data remain outstanding for the 90% T for GLNs 62-2 and 62-3 for the three manufacturing process impurities. The Agency has concerns that the three manufacturing impurities, which are structurally related to metribuzin and are present at greater than 0.1% in the product, could be of toxicological concern. The registrant must either demonstrate that these impurities are not toxicologically significant, or provide upper certified limits. In addition, the label claim of 90% is not in agreement with the nominal concentration of the active ingredient. Per PR Notice 91-2, dated 5/2/91, the label claim for the product must reflect the nominal concentration of the active ingredient.

The registrant must submit the outstanding data for the 90% T for GLNs 62-2 and 62-3 concerning the three manufacturing process impurities, and certify that the suppliers of beginning materials and the manufacturing processes for the metribuzin MPs have not changed since the last comprehensive product chemistry review. If changes have occurred, then the registrant must submit complete updated product chemistry data packages.

B. Human Health Assessment

1. Toxicology Assessment

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

a. Acute Toxicity

Table 2 summarizes the acute toxicity and toxicity categories of metribuzin.

Table 2: Acute Toxicity Data

GLN No.	Study	% a.i.	MRID	Results	Category
§81-1	Acute Oral - rat	Technical	00106158	LD_{50} = m = 2.3 g/kg f = 2.2 g/kg	III
§81-2	Acute Dermal - rabbit	Technical	00106149	LD_{50} > 20 g/kg	IV
§81-3	Acute Inhalation - rat	92.6%	00157524	LC_{50} > 0.648 mg/L	III
§81-4	Primary Eye Irritation - rabbit	Technical	00106158	not an eye irritant	IV
§81-5	Primary Skin Irritation - rabbit	Technical	00106158	PIS = 0.33/8.0 not a dermal irritant	IV
§81-6	Dermal Sensitization - guinea pig	93.5%	41555101	Not a dermal sensitizer	NA

* Note: Data pertaining to acute eye irritation, dermal irritation, and dermal sensitization are not required to support the reregistration of the TGAI. These data are presented only for informational purposes.

Acute toxicity studies with metribuzin indicate low toxicity. The LD_{50} in an acute dermal study with rabbits was greater than 20 g/kg, no systemic toxicity and no mortality was noted. An acute inhalation toxicity study in rats, using the maximum obtainable concentration of technical metribuzin as dust, found the LC_{50} was greater than 0.648 mg/L. Metribuzin was not an eye irritant in a primary eye irritation test in rabbits. In a primary dermal irritation study, metribuzin produced very slight irritation on rabbit skin. Metribuzin was found not to produce a dermal sensitization reaction in guinea pigs under conditions of the study.

b. Subchronic Toxicity

In a 21-day dermal toxicity study, New Zealand rabbits of the HC:NZW strain from Interfauna UK Limited, Huntingdon, England were exposed to either 0, 40, 200 or 1000 mg/kg/day of metribuzin (DIC 1468, technical 94.0% a.i.; batch 238603171). The treatment area on the backs and flanks of the rabbits was a shaved area approximately 11 x 12 cm. The solution of metribuzin was applied to 4-ply gauze dressings which were held in place with adhesive strapping tape for 6 hours. At the end of 6 hours, the dressing and strapping were removed and the treatment area washed with soap and water. The rabbits were treated only on working days (i.e., 5 consecutive days each week) for 3 weeks. No dermal irritation was noted. No animals died during the study. High dose males and females had a dose-related increase in cholesterol. T_3 (triiodothyronine) was decreased in all males, but statistically significant only at the high

dose. There was a statistically significant increase in N-demethylase and cytochrome P450 activities in high dose males. Thus, the systemic toxicity NOEL is 200 mg/kg/day. The systemic toxicity LOEL is 1000 mg/kg/day based on increased plasma cholesterol and liver enzyme activities. Due to the lack of dermal irritation, the dermal Noel is equal to or greater than 1000 mg/kg/day and the dermal toxicity LOEL is greater than 1000 mg/kg/day. (GLN 82-2; MRID 43970701).

In a 21-day inhalation toxicity study Wistar TNO/W 74 albino rats from Winkelmann, Borchen were exposed to metribuzin (DIC 1468, 98.2 and 93.1% a.i.) in Ethanol-lutrol 1:1 (polyethylene glycol 400) at analytical doses ranging from 32 to 720 mg metribuzin/m^3 air. A control group of males and females was exposed to the ethanol-lutrol. The animals' conditions of exposure ensured that aerosols could only be inhaled. Groups (10 males and 10 females) were exposed to the aerosols daily for six hours. Systemic toxicity related to treatment with metribuzin was noted in the high exposure level as increased clinical signs of toxicity (*disturbed behavior* which was comprised of animals appearing apathetic and with ungroomed coat), increased N-demethylase, O-demethylase, and cytochrome P-450 activities along with increased liver weights, which indicate increased activity in the liver. Body weight gains were decreased in all treated groups. However, these decreases were not dose related, the decreases were of great variability, and did not appear to be of any toxicological significance. There were increased absolute and relative thyroid weights. For systemic toxicity, the NOEL is 219 mg/m^3 air (0.219 mg/L). The LOEL is 720 mg/m^3 air (0.720 mg/L) based on clinical signs of toxicity, increased liver enzyme activities, and increased organ weights (GLN 82-4; MRID 00153706).

Two subchronic 90 day feeding studies in rats and one in dogs (an unvalidated Industrial Biotest Study) were conducted. However, they were classified as unacceptable due to multiple deficiencies. These studies were not required to be repeated since the chronic toxicity study was acceptable.

c. Chronic toxicity and Carcinogenicity

In a two year chronic toxicity study, Beagle dogs from Appleton Kennels, England received either 0, 25, 100, or 1500 ppm (0, 0.82, 3.44, or 55.65 mg/kg/day for males; 0, 0.84, 3.56, or 55.3 mg/kg/day for females) of metribuzin (BAY 94 337 technical 99.5% a.i., batch 1603/71) in the diet. Toxicity was noted at the high dose in the form of mortality (75% of the 1500 ppm group) along with decreased body weight, increased relative liver weight and changes in liver and kidney function (increased

SGOT and SGPT levels, increased ornithine-carbamyl transferase levels, increased BSP retention, increased alkaline phosphatase, increased total protein in blood and urine, increased urea, decreased creatinine, increased blood sugar and increased cholesterol). For chronic toxicity the NOEL is 100 ppm (3.44 mg/kg/day in males, 3.56 mg/kg/day in females) and the systemic toxicity LOEL is 1500 ppm (55.65 mg/kg/day for males, 55.3 mg/kg/day in females) based on mortality, decreased body weight, increased liver weights and changes in clinical chemistry parameters (GLN 83-1b; MRID 00061260).

In a combined chronic toxicity and carcinogenicity study metribuzin (BAY 94 337 technical 99.5% a.i.; batch 1603/71) was fed to Wistar rats from Winkelmann, Kirchborchem, Kreis Paderborn for two years at doses of 0, 25, 35, 100, or 300 ppm (0, 1.3, 1.87, 5.27, or 14.36 mg/kg/day in males; 0, 1.68, 2.28, 6.53, or 20.38 mg/kg/day in females). Toxicity was noted at the high dose as decreased body weight gain along with pathological changes in the liver, kidneys, uterus, and mammary glands. Pituitary adenomas and carcinomas were observed; however, this was not considered to be statistically significant when compared to the historical control data. For chronic toxicity the NOEL is 100 ppm (5.27 mg/kg/day in males and 6.53 mg/kg/day in females). The LOEL is 300 ppm (14.36 mg/kg/day in males, 20.38 mg/kg/day in females) based on decreased body weight gain and pathological changes in the liver, kidneys, uterus, and mammary glands. There was no evidence of carcinogenicity in either sex (MRID 00061261).

In a repeat combined chronic feeding/carcinogenicity study, metribuzin (93.0% a.i.; Batch 77-297-50) was fed to Fischer 344 rats from Charles River Laboratories, Raleigh, NC at doses of 0, 30, 300, or 900 ppm (0, 1.3, 13.8, or 42.2 mg/kg/day in males; 0, 1.6, 17.7, or 53.6 mg/kg/day in females) for either 52 or 104 weeks. Toxicity was noted at 300 ppm and above based on decreased body weight gain in females; increased thyroid weight and thyroid/body weight ratio in males, increased liver weight and liver/body weight ratio in males and females. At the lowest dose, there were statistically significant changes in thyroxine (T_4) and triiodothyronine (T_3) levels, but no other systemic effects were observed. The OPP/HED RfD Committee determined that the 1.3 mg/kg/day dose level (males) should be considered as the NOEL since the effects at the 1.3 mg/kg/day dose were considered to be of marginal biological significance. This conclusion was based primarily on the knowledge that metribuzin is a liver enzyme inducer and that the rat has no other compensatory mechanism to re-establish normal levels of thyroid hormones other than to increase thyroid production of these hormones, the

effect observed at the lowest dose was considered a compensatory homeostatic response and not a toxic effect. There was no evidence of carcinogenicity and there was no increase in tumor incidence. For chronic toxicity, the NOEL is 30 ppm (1.3 mg/kg/day in males and 1.6 mg/kg/day in females) and the LOEL is 300 ppm (13.8 mg/kg/day in males and 17.7 mg/kg/day in females) based on decreased body weight gains in females, increased thyroid weights in males, and increased liver weights in males and females (GLN 83-5; MRID 42672501).

In a carcinogenicity study, dietary doses of 0, 200, 800, or 3200 ppm (0, 25, 111, or 438 mg/kg/day for males; 0, 35, 139, or 567 mg/kg/day for females) metribuzin (92.9% a.i.) were given to CD1 mice from Charles River Laboratories for two years. Systemic toxicity was noted at the high dose as increased liver weights along with decreased hemoglobin and hematocrit values. This study demonstrated that under these test conditions metribuzin does not increase the incidence of tumors in mice. For chronic toxicity, the NOEL is 800 ppm (111 mg/kg/day in males, 139 mg/kg/day in females) and the LOEL is 3200 ppm (438 mg/kg/day for males, 567 mg/kg/day for females) based on increased liver weights and decreased hematological parameters (GLN 83-2; MRID 00087795).

d. Developmental Toxicity

In a developmental toxicity (teratology) study, metribuzin (92.6% a.i.; Batch No. 77-297-50) was administered in doses of 0, 25, 70, or 200 mg/kg/day by gavage on gestation days 6-18 to pregnant Charles River Crl:CD BR rats from Charles River Breeding Laboratories, Portage, MI. Maternal toxicity was shown at all dose levels as reduced body weight gain, reduced mean gravid uterine weights, and decreased food consumption. The mid (70 mg/kg/day) and high (200 mg/kg/day) doses showed an effect on the thyroid gland as demonstrated by reduced T_4 levels. At the high dose there was also increased thyroid weight. The maternal toxicity NOEL is less than 25 mg/kg/day and the maternal toxicity LOEL is equal to or less than 25 mg/kg/day. For developmental toxicity, the NOEL is 70 mg/kg/day and the LOEL is 200 mg/kg/day based on decreased fetal body weight and reduced ossification or unossified skull bones, ribs, vertebrae, sternebrae, pelvic bones, and appendages (GLN 83-3a; MRID 00163802).

In a developmental toxicity (teratology) study, American Dutch rabbits from Langshaw Farms, Augusta, MI were given 0, 10, 30, or 85 mg/kg/day of metribuzin (92.7% a.i.; Batch 77-297-50) by gavage on gestation days 6-18. Maternal toxicity was noted at 30 mg/kg/day and

above based on decreased maternal body weight gains on gestation days 18-28 at the mid dose level and decreased body weight gains, decreased food consumption and decreased food efficiency on gestation days 7-19 at the high dose level. Developmental toxicity was noted at the high dose in the form of an increased incidence of irregular spinous processes. For maternal toxicity, the NOEL is 10 mg/kg/day and the LOEL is 30 mg/kg/day, based on decreased weight gain on days 18-28. The developmental toxicity NOEL is 30 mg/kg/day and the developmental toxicity LOEL is 85 mg/kg/day based on an increase incidence of irregular spinous processes (GLN 83-3b; MRID 41249201).

In a repeat developmental toxicity (teratology) study, New Zealand white rabbits were given 0, 15, 45, or 135 mg/kg/day of metribuzin by gavage on gestation days 6-18. Maternal systemic toxicity was noted at 45 mg/kg/day, as reduced body weight gain, and reduced food and water intake. Additionally, at 135 mg/kg/day there was an increased incidence of abortions and decreased body weights. For maternal toxicity, the NOEL is 15 mg/kg/day and the LOEL is 45 mg/kg/day based on reduced body weight gains and reduced food and water consumption. The developmental toxicity NOEL is 15 mg/kg/day and the developmental toxicity LOEL is 45 mg/kg/day based on decreased fetal body weights, increased number of runts and increased incidence of extra and partial ribs. (GLN 83-3b; MRID 00087796).

Based on the results of the existing studies, at this time metribuzin is not considered to be a developmental toxin. The developmental toxicity observed in these studies occurred at or above doses that induced maternal toxicity.

e. Reproductive Toxicity

In a two-generation reproduction study, Crl:CD BR rats from Charles River Breeding Laboratories, Portage, MI received in the feed 0, 30, 150, or 750 ppm (approximately 0, 1.5, 7.5, and 37.5 mg/kg/day by standard conversion factors) metribuzin (Sencor® technical 92.6% a.i.; batch 77-297-50) . Systemic toxicity in both the parental animals and the pups was noted at the mid dose as slightly decreased body weights in the F_1 high and the F_2 mid and high dose pups. The F_1 females had decreased body weight gains during the gestation period for mid and high doses; F_0 and F_1 females had increased body weight during lactation and hypertrophy of hepatocytes in high dose males and mid and high dose females. The parental/offspring systemic toxicity NOEL is 1.5 mg/kg/day and the parental/offspring systemic toxicity LOEL is 7.5 mg/kg/day based

on decreased body weights and body weight gains and hypertrophy of the hepatocytes (GLN 83-4; MRID 40838401).

f. Mutagenicity

Metribuzin was non-mutagenic in bacterial mutation assay systems both with and without metabolic activation, using strains of S. typhimurium (TA1535, TA1537, TA98, and TA100), B. subtilus (NIG17 and NIG45), and E. coli (WP2 her) using concentrations of 0.2 to 2000 ug/plate of metribuzin (technical Sencor® 93.7% a.i.). The negative control was DMSO. The positive controls were AAF, AF-2, 9-AA, NTG, 2-NF, and BP. (MRID# 00086770; 00109254).

No evidence of mutagenicity was seen in an in vitro CHO/HGPRT assay when tested at doses ranging from 50-200 ug/mL with S-9 activation and at doses ranging from 600-1000 ug/mL with out activation. The positive control was ethyl methane sulfonate and benzo(a)pyrene. The negative control was acetone (MRID 00157527).

In the preliminary screening cytotoxicity tests for an in vitro Chinese hamster ovary (CHO) cell test severe cytotoxicity was observed at doses equal to or greater than 1750 ug/ml without activation and at doses equal to or greater than 584 ug/ml with S9 activation. For the study the non-activated doses using a 20 hour harvest were 199, 299, 399, 499 or 598 ug/mL. The S9 activated doses using a 10 hour harvest were 37.5 or 50.0 ug/mL; and using a 20 hour harvest were 50.1, 100, 150, or 200 ug/mL. The positive control was mitomycin C and cyclophosphamide. The negative control was ethanol. No statistically significant or dose-related increases in aberration frequency were observed with nonactivated metribuzin. However, in the presence of S9 activation there was an increase in chromosome and chromatid breaks, triradials, and quadriradials which indicates that metribuzin is possibly an in vitro clastogen. There is no evidence of mutagenicity in the in vivo tests; therefore, the increase is not considered to be of concern. The study was not repeated (MRID 42555102).

A series of three in vivo tests for dominant lethal mutations in NMRI mice was performed. Males were given 300 mg of metribuzin (Sencor® 99.5% a.i.) by gavage and then mated with undosed females in two of the tests. Females were given 300 mg/kg metribuzin, and were then mated with untreated males. On gestation day 14 females were sacrificed and examined for the number of corporal lutea, viable implantation sites, and dead implants. No statistically significant differences were noted

(MRID 00086766).

In an in vivo cytogenetic study, metribuzin at doses of 100 mg/kg body weight failed to induce chromosomal aberrations in Chinese hamster spermatogonia (MRID 00086765).

When tested at dose levels of 0.007 to 200 ug/ml, metribuzin did not induce unscheduled DNA synthesis in rat primary hepatocytes. The positive control was DMBA, and the negative control was ethanol or DMSO. (MRID 00157526).

These studies taken together satisfy GLN 84.

g. Metabolism

Metabolism studies in Wistar rats from Charles River Breeding Laboratory, Inc., (Boston, MA.) using a single low dose (5 mg/kg) of ^{14}C-metribuzin (98.4-99.4% a.i.; SA = 20.8 mCi/nmol), a single high dose (500mg/kg) of ^{14}C-metribuzin, and multidoses of 5 mg/kg unlabeled metribuzin (99.0% a.i.; Lot# 51025) for 14 days followed by a single radiolabeled dose of 5 mg/kg were performed. No significant differences were detected in the rates and routes of ^{14}C-elimination between male and female rats in either the low or high dose single administration group. The studies indicated that metribuzin was rapidly excreted in the urine and feces, with a plateau being reached at 48 hours for all single dose groups excepting 72 hours for the high dose female feces. From 27.3 to 43.4% of the radiolabel was found in the urine and from 55.8 to 71.5% in feces at 96 hours. Very small amounts of metribuzin were found in the blood at 96 hours. The high dose group had higher tissue levels, as expected, with the GI tract having higher levels. Sixteen metabolites of which 12 could be identified were found in the urine. Very small amounts of the parent were recovered. Many of the same metabolites were found in the feces. The most prevalent metabolite in both urine and feces was DA-N-Ac-Cys. The metabolism of metribuzin in rats appears to involve deamination, dethioalkylation, hydroxylation of the t-butyl side chain and conjugation. (MRID 40255503).

h. Dose-Response Assessment

The OPP/HED RfD Peer Review Committee comprehensively evaluates the toxicological database for a pesticide chemical and establishes the RfD for the chemical. It also operates as the Agency's quality assurance unit with respect to the acceptance or rejection of

toxicological data for regulatory purposes; and determines whether a chemical has been sufficiently tested to evaluate its carcinogenic potential and its effects on developmental or reproductive parameters. The OPP/HED RfD Peer Review Committee refers chemicals as necessary to the OPP/HED Cancer Peer Review Committee and/or OPP/HED Developmental and Reproductive Effects Peer Review Committee.

The OPP/HED Toxicity Endpoints Selection Committee (TESC) considers the available toxicology data for a pesticide chemical and performs the dose-response assessment by determining which of the toxicological endpoints (if any) should be used in evaluating: 1) an acute dietary risk assessment, 2) a short-term occupational or residential exposure (1 to 7 days) risk assessment, 3) an intermediate-term occupational or residential exposure (1 week to several months) risk assessment, and 4) a chronic (non-cancer) occupational or residential exposure risk assessment.

A NOEL is selected for use in calculating the MOE. TESC selects the best toxicological study that most closely matches the duration of the exposure of interest and the route of exposure. For occupational or residential scenarios, exposure is most likely via the dermal and/or inhalation route. Therefore, the most appropriate toxicological endpoint is provided by a dermal or inhalation toxicity study. If adequate dermal or inhalation studies are not available, then an oral study may be identified for use in risk assessment. The NOEL from the oral study would need to be adjusted by the dermal exposure factor to reflect the dermal exposure that occurs in an occupational scenario. If an appropriate study cannot be identified (i.e., no effect occurs during the duration of exposure), the risk assessment cannot be performed because the hazard that would be used in the equation risk = hazard x exposure does not exist.

1. Reference Dose (Rfd)

The OPP/HED RfD Committee recommended that an RfD be established on the basis of a two-year feeding study in rats (MRID 42672501). Increased absolute and relative weight of thyroid, decreased lung weight in females, statistically significant increases in blood levels of thyroxine (T4) and statistically significant decreases in blood levels of triiodothyronine (T3) were observed at 30 ppm (1.3 mg/kg/day for males and 1.6 mg/kg/day in females). However, as previously stated, the effects observed at the lowest dose tested were considered to be of marginal biological significance. Therefore, the RfD Committee determined that the dose of 30 ppm (1.3 in males) should be considered as a NOEL. An

uncertainty factor (UF) of 100 was applied to account for the inter-species extrapolation and intra-species variability. On this basis, the RfD was calculated to be 0.013 mg/kg/day. It was also recommended to use the reproductive toxicity study (MRID 40838401) with a NOEL of 1.5 mg/kg/day as a co-critical study.

The OPP/HED RfD Peer Review Committee met on January 5, 1995, to discuss the weight of the evidence on metribuzin's carcinogenic potential, and to determine if review to the OPP/HED Cancer Peer Review Committee was appropriate. The Committee determined that referral was not warranted. Metribuzin was classified as Group D, not classifiable as to human carcinogenicity. The Committee based this classification on the lack of evidence for carcinogenicity in the following studies: 1) a mouse study in which there were no increases in tumor incidences at dosing levels up to 438 mg/kg/day for males and 567 mg/kg/day for females (MRID 00087795); 2) a 1974 (MRID 00061261) rat study (SPF Wistar rats) in which the observed pituitary adenomas and carcinomas were not statistically significant at dosing levels up to 14.36 mg/kg/day for males and 20.38 mg/kg/day for females; and 3) a 1993 (MRID 42672501) rat study (Fischer [CDF(F-344)/BR] rats) which indicated no evidence for carcinogenicity at dosing levels up to 42.2 mg/kg/day for males and 53.6 mg/kg/day for females.

2. Toxicological Endpoint Selection for Use in Human Risk Assessment

(a) Dermal Absorption Factor

No acceptable dermal absorption data are available; therefore, a default assumption of 100% is used in this assessment..

(b) Acute Dietary Assessment (one day)

This risk assessment is required. The NOEL to be used for calculating the MOE is 15 mg/kg/day from an oral developmental toxicity study in rabbits (MRID 00087796). (The LOEL was 45 mg/kg/day based on decreased fetal body weight, increased number of runts, and increased incidence of extra and partial ribs.) The NOEL from a developmental toxicity study was selected for this assessment since the possibility exists that the exhibited effects could be caused by a one-day exposure. The

Agency considers an MOE of 100 to be acceptable when the NOEL is taken from an animal study.

(c) Chronic Dietary

The RfD is the traditionally accepted endpoint for calculating a chronic dietary assessment.

(d) Short Term (1 to 7 days) Occupational Dermal Assessment
and
Intermediate Term (1 week to several months) Occupational Dermal Assessment

These risk assessments are not required. In the 21-day dermal toxicity study in rabbits (MRID 43970701) minimal systemic changes were noted at the 1000 mg/kg/day. However, no dermal irritation was noted at any dose level. Since the dermal NOEL is equal to or greater than 1000 mg/kg/day (highest dose tested), the 21-day dermal study does not support performing a short term or intermediate term DERMAL risk assessment.

(e) Short Term (1 to 7 days) Occupational Inhalation Assessment
and
Intermediate Term (1 week to several months) Occupational Inhalation Assessment

These risk assessments are required. The NOEL to be used for calculating the MOE is 219 mg/m^3 from a 21-day inhalation toxicity study (MRID 00153706). (The LOEL is 720 mg/m^3 (0.720 mg/L) based on clinical signs of toxicity, increased liver enzyme activities and increased organ weights).

Route-to-route extrapolation was used to convert the animal inhalation concentration into a mg/kg dose by the following equation:

$$\frac{(\text{mg/L/day})(A)(RV)(D)(AF)}{BW} = \text{mg/kg/day}$$

where:

mg/L/day = 0.219 mg/L/day from the 21-day inhalation toxicity

study

A = absorption of inhaled material = 1(i.e., 100%, which is a default assumption used by the Agency)

RV = 8.46 L/hr = mean liters of air respired per hour by the rat

D = 6 hr = daily duration of exposure during the 21-day study

AF = 1 = default animal activity factor

BW = 0.190 kg = mean rat weight

$$\frac{(0.219)(1)(8.46)(6)(1)}{(0.190)} = 58.5 \text{ mg/kg/day}$$

The Agency considers a MOE equal to or greater than 100 to be sufficiently protective when the NOEL is taken from an animal study.

3. WHO

The Joint FAO/WHO Meeting on Pesticide Residues has not evaluated metribuzin.

2. Exposure Assessment

The residue chemistry data base for metribuzin is now substantially complete for reregistration purposes. A reasonable dietary risk assessment of metribuzin can be performed using the available residue data. The need for additional/revised tolerances or revisions to exposure assessments will be made upon review of any new data.

The Residue Chemistry Chapter of the Reregistration Standard was issued 12/20/84. As previously stated, the Metribuzin Reregistration Standard Guidance Document was issued 6/85 and the Reregistration Standard Update was issued 4/10/90. These documents summarized the regulatory conclusions based on the available residue chemistry data and specified the additional data required for reregistration purposes. Several data submissions have been received and evaluated since the Update; a few submissions are still under review.

The Agency has recently updated the Livestock Feeds Table (Table II of the Pesticide Assessment Guidelines, Subdivision O, Residue Chemistry, issued

September 1995). Any new data requirements as a result of Table II changes are being imposed at the issuance of the RED. The need for additional tolerances and/or revisions to exposure/risk assessments will be made upon receipt of the required data.

New alfalfa and field corn trials, and field rotational crop studies need to be submitted as confirmatory data. These studies have been initiated by the registrant. Tolerances for these commodities will be reassessed once the data have been submitted and reviewed.

The available data for alfalfa forage and hay are insufficient to completely support the established tolerances on these commodities because of inadequate geographic representation of data. The western growing region is not represented, and the states for which residue data are adequate (e.g., states where tests were conducted according to the parameters of registered metribuzin uses on alfalfa) represent less than one-fourth of the 1988 U.S. alfalfa hay production. The tolerances may be revised once confirmatory data, which is in progress, is submitted and reviewed.

a. Dietary Exposure

GLN 171-4 (a): Plant Metabolism

The qualitative nature of the residue in plants is adequately understood based on upgraded soybean and wheat metabolism studies which are supported by supplemental alfalfa, potato, sugarcane, and tomato metabolism data. The residues of concern in plants are metribuzin and its triazinone metabolites.

The metabolism of metribuzin in plants occurs via deamination and/or dethiomethylation to yield triazinone moieties and their conjugates. The requirements for radiovalidation of the current or any proposed enforcement analytical method using samples from soybean and wheat metabolism studies have been waived. The waiver was granted after comparing the methodologies employed in these metabolism studies with the current enforcement method, and because samples from these studies have been depleted.

Soybean Metabolism Study: The total radioactive residues (TRR, expressed as metribuzin equivalents) found following a preemergence soil application of [^{14}C]metribuzin at 0.3 lb ai/A (active ingredient/acre) were 12.1 ppm in soybean plants and 0.48 ppm in mature soybean seeds. The major organosoluble residue identified in soybean plant tissue was 6-(1,1-

dimethylethyl)-3,5-(diketo)-1,2,4-triazin-5-(2H,4H)-dione (DADK), which is 19.2% of the TRR. The minor organosoluble residues include metribuzin, 4-amino-6-(1,1-dimethylethyl)-3,5-(diketo)-1,2,4-triazin-5-(2H,4H)-dione (DK), hydroxy-t-butyl DADK, hydroxy-t-butyl metribuzin, and 3-amino-DA which collectively accounted for ~3.6% of the TRR. In soybean seeds, the major organosoluble residue identified was free or conjugated DADK which is 44.5% of the TRR. There was a supplemental study designed to determine the nature of the residue in the aqueous fraction. The glucose conjugates of DADK (17% of the TRR) were found in soybean plant tissues. The glucose conjugates of DK (10.7% of the TRR) were found in seeds.

Wheat Metabolism Study: Wheat grown to the 3-tiller stage was treated postemergence with [5-^{14}C]metribuzin at 0.15 lb ai/A; the resulting TRRs at the following pre-harvest intervals (PHI) are listed below:

Table 3: Total Radioactive Residues in Wheat

Commodity	PHI (days)	TRR (ppm, expressed as metribuzin equivalents)
Forage	0	5.4
Forage	7	1.2
Straw	33	5.5
Grain	33	0.2

The organosoluble residues identified in wheat forage were metribuzin (42.8% of TRR), DADK (6.8% of TRR), and DK (7.5% of TRR). The organosoluble residues identified in wheat straw were metribuzin (3.9% of TRR), DADK (11.2% of TRR), DK (3.5% of TRR), 6-(1,1-dimethylethyl)-3-(methylthio)-1,2,4-triazin-5-(4H)-one (DA) (0.7% of TRR), 3-amino DA (4.3% of TRR), and hydroxy-*t*-butyl-DADK (0.6% of TRR). A large percentage of the metribuzin residues in wheat straw were bound and shown to be associated with lignin (~25% of TRR) or other biopolymers (10-15% of TRR) such as starch or protein. In grain, residues were found to consist of metribuzin, DADK, DK, DA, hydroxy-*t*-butyl-DADK, and hydroxy-*t*-butyl-DA which collectively accounted for 9.3% of the TRR. In a separate study designed to elucidate the nature of the residue in the aqueous fraction, the only residue identified was tert-leucine (10.7% TRR).

GLN 171-4 (b): Animal Metabolism

The qualitative nature of the residue in animals is adequately

understood based on acceptable poultry and ruminant metabolism studies reflecting oral exposure. The residues of concern in animal commodities are metribuzin and its triazinone metabolites. The requirements for radiovalidation of the enforcement method using samples from the animal metabolism studies have been waived.

Ruminant Metabolism Study: Two goats were orally dosed with [5-^{14}C]metribuzin at approximately 410 ppm (approximately 59x the calculated dietary burden of metribuzin for ruminants) in the diet for three consecutive days. The TRR were 12.66 ppm in liver, 4.27 ppm in kidney, 0.97 ppm in fat, 0.44 ppm in muscle, and 0.25-2.09 ppm in milk. The major residues identified in muscle, fat, kidney, and liver tissue of goats were metribuzin, its major metabolites (butylthion, DA, the sulfamate conjugate of metribuzin, and the glucuronide conjugate of 2-methyl-DK), and its minor metabolites (DADK, DK, and 2-methyl-DADK).

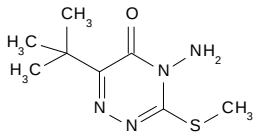
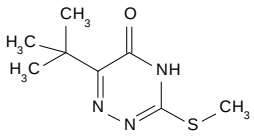
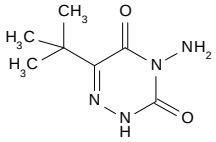
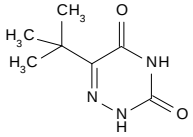
The OPP/HED Metabolism Committee met on October 21, 1993, and concluded that the three metabolites (butylthion, 2-methyl-DADK and the glucuronide conjugate of 2-methyl-DK) which are found only in ruminant tissues need not be specifically included in the tolerance expression (i.e., methodology for the separate determination of these three compounds is not needed).

Poultry Metabolism Study: Laying hens were orally dosed with [5-^{14}C]metribuzin at approximately 400 ppm (approximately 500x the calculated dietary burden of metribuzin for poultry) in the diet for three consecutive days. The TRR were 33.6 ppm in liver, 36.3 ppm in kidney, 1.6 ppm in muscle, 5.3 ppm in gizzard, 4.0 ppm in fat, 4.5 ppm in skin, 5.3 ppm in heart, and 0.2-1.0 ppm in eggs. The study adequately characterized and identified the majority of the total radioactivity including 64.4% of the TRR in liver, 55.9% in kidney, 84.2% in muscle, 92.8% in fat, 75.9% in skin, and 63.2% in eggs. The terminal residues in poultry liver, muscle, and fat tissues; and in eggs were metribuzin and its metabolites DA, DADK, and DK; and their conjugates.

GLN 171-4 (c) and (d): Residue Analytical Methods - Plants and Animals

Adequate methods are available for tolerance enforcement and data collection for residues of metribuzin and three of its triazinone metabolites (DK, DA, and DADK) in/on plant and animal commodities. The chemical structures of these four chemicals are presented in Figure A.

Figure A. The Chemical Structures of Metribuzin and Three of its Triazinone Metabolites.

 **metribuzin**: 4-amino-6-(1,1-dimethylethyl)-3-(methylthio)-1,2,4-triazin-5-(4H)-one	 **DA**: 6-(1,1-dimethylethyl)-3-(methylthio)-1,2,4-triazin-5-(4H)-one
 **DK**: 4-amino-6-(1,1-dimethylethyl)-3,5-(diketo)-1,2,4-triazin-5-(2H,4H)-dione	 **DADK**: 6-(1,1-dimethylethyl)-3,5-(diketo)-1,2,4-triazin-5-(2H,4H)-dione

Tolerance enforcement methods (plant commodities): The Pesticide Analytical Manual (PAM, Vol. II, Section 180.332) lists two gas chromatography (GC) methods, designated as Methods I and II, with electron capture detection (ECD) and a detection limit of 0.01 ppm for determination of metribuzin, DK, DA, and DADK in/on plant commodities. Method I is suitable for determination of residues of metribuzin and DADK only. Method II, the preferred enforcement method, is suitable for determination of residues of metribuzin, DK, DA, and DADK. Method II can detect all four compounds even if they are present as water-soluble conjugates.

Tolerance enforcement methods (animal commodities): Although there are no methods listed in PAM Vol. II for the enforcement of animal commodity tolerances, an adequate method is available. A GC/ECD method, designated as Mobay Method Report No. 42257, is suitable for determination of residues of metribuzin, DK, DA, and DADK in animal tissues, milk, and eggs. In this method, metribuzin *per se* is converted to DK, and DA is converted to DADK. Mobay Method Report No. 42257

had been subjected to successful Agency method tryouts and should be forwarded to FDA for inclusion in PAM Vol. II.

Data collection methods: Field and processing data submitted for tolerance reassessment were collected using the current enforcement methods or modifications thereof. The registrant provided adequate method validation data to verify the suitability of these methods for data collection.

Multiresidue methods: The FDA PESTDATA database dated 1/94 (PAM Vol. I, Appendix I) indicates that metribuzin, DK, DA, and DADK are not recovered using multiresidue method PAM Vol. I Sections 303 (Mills, Onley, Gaither method) and 304 (Mills fatty food method). The database also indicates that when Section 302 (Luke method) is used, DA is completely (>80%) recovered, and metribuzin is variably recovered; however, DK and DADK are not recovered.

GLN 171-4 (e): Storage Stability

Residues of metribuzin *per se* are stable under frozen storage conditions (~-20 ºC) for up to 24 months in/on field corn grain, forage, and fodder; sweet corn; soybeans and soybean hay; tomatoes; and in corn oil. Residues of metribuzin are stable for up to 17 months in tomato catsup and tomato juice; and wheat bran, flour, and shorts. Residues of metribuzin are stable for up to 12 months in/on asparagus, declining approximately 30% after 18 months and approximately 50% after 24 months of storage. Metribuzin residues are stable in/on soybean forage for up to 18 months, declining approximately 50% after 24 months. Residues of metribuzin are stable for up to 18 months in corn meal declining approximately 35% after 24 months. In tomato pomace residues of metribuzin degrade immediately, declining approximately 35% after 1 month of frozen storage and approximately 40% after 3 months of storage. The level then remains constant through 17 months of storage. Since residues of metribuzin *per se* were not consistently stable, all future residue studies must be supported by concurrent storage stability data.

Residues of DADK and DA (metribuzin's metabolites) are stable under frozen storage conditions for up to 24 months in/on asparagus; field corn grain, forage, and fodder; sweet corn; soybeans, forage, and hay; tomatoes; and in corn oil and meal. Residues are also stable for up to 17 months in tomato catsup, juice, and pomace; and wheat bran, flour, and shorts. Residues of DK are relatively stable under frozen storage conditions for up to 24 months in/on sweet corn, soybeans, tomatoes, and

corn meal; and for up to 17 months in wheat flour. However, for asparagus; field corn grain, forage, and fodder; soybean forage and hay; corn oil; tomato catsup, juice, and pomace; and wheat bran and shorts, recoveries of DK from storage stability samples were consistently less than concurrent method recoveries, indicating declines during storage of up to ~60%.

There are additional storage stability data indicating that residues of metribuzin *per se* are stable during frozen storage in/on alfalfa forage and potatoes for up to 1 year, green peas for 2 years, soybeans for 1.5 months, and tomatoes for 3 years, but that residues of metribuzin and DADK are not stable in/on carrots during frozen storage.

Information concerning the storage conditions and intervals of animal commodity samples from the previously evaluated poultry (MRID 00045284, 00045286) and ruminant (MRID 00045283, 00036772) feeding studies are required to confirm that animal commodity samples from these studies were stored at the storage intervals for which residues of metribuzin and its metabolites of concern had been found to be stable in muscle (3 months), milk (17 months), and eggs (3 months). If animal commodity samples were stored for longer intervals, then new animal feeding studies may be required.

GLN 171-4 (k): Magnitude of the Residue in Plants

The reregistration requirements for magnitude of the residue in plants are fulfilled for the following commodities: asparagus; barley grain, forage, hay, and straw; carrots; corn (field) forage and fodder; grass forage and hay; lentils; lentil forage; peas (succulent and dry); pea vines and hay; sainfoin forage and hay; soybeans, forage and hay; sugarcane; tomatoes; and wheat grain, forage, hay, and straw. Adequate residue data, from field trials conducted according to maximum registered use patterns are available for these commodities (or representative commodities).

The registrant has indicated that additional trials on field corn and potatoes have been initiated in lieu of providing storage stability data for the length of time these commodities were stored. Once completed, the results must be submitted to EPA for evaluation.

Aspirated Grain Fractions: The Agency has recently revised its policy on aspirated grain fractions (previously referred to as "grain dust"), and determined that it should be considered a raw agricultural commodity. The Agency has also determined that aspirated grain fraction tolerances should

be established based on the use of the pesticide on corn, wheat, sorghum, and soybeans. Presently, there are registered uses of metribuzin on corn, wheat, and soybeans. The available field corn aspirated grain fraction data indicate that residues of metribuzin and its metabolites DA and DADK were nondetectable (< the level of detection (LOD) of 0.01 ppm) and residues of DK were nondetectable (< LOD of 0.03 ppm) following treatment at 5x. The tolerance for metribuzin residues of concern in/on aspirated grain fractions will be evaluated after the outstanding data for wheat aspirated grain fractions are submitted.

Carrots: The labels for Miles' 75% DF (EPA Reg. Nos. 3125-325 and 3125-402) were amended 9/14/94 to include metribuzin uses on carrots. The presently registered uses of metribuzin on carrots are supported by adequate residue data. The available field residue data, reviewed in conjunction with the establishment of the tolerance petition PP#4E3112, indicate that the combined residues of metribuzin and its triazinone metabolites were below the established tolerance of 0.3 ppm following multiple postemergence applications of the 75% DF at up to 4x the maximum rate in trials conducted in CA, DE, IL, MI, NJ, TX, and WA.

Grass Forage and Hay: There are no registered FIFRA Section 3 metribuzin uses on grass *per se*. The established tolerances of 2 ppm and 7 ppm for grass forage and hay, respectively, were established to cover metribuzin residues on grasses which may be treated incidentally in mixed alfalfa pastures. Adequate data are available to support the established tolerances for these commodities. These data are also sufficient to cover any residues that may arise from metribuzin uses under several recent Section 24(c) registrations on grasses grown for seed (SLNs OR900025, OR900028 and WA930003, MT950007, WY950003).

GLN 171-4 (l): Magnitude of the Residue in Processed Food/Feed

Adequate processing studies have been conducted, to determine the potential for concentration or reduction of the residues of metribuzin and its triazinone metabolites, in processed products of the following raw agricultural commodities: field corn, potatoes and soybeans. Additional processing studies on sugarcane, tomatoes, and wheat have been initiated and the results, once completed, must be submitted to EPA for evaluation. The wheat processing data will be translated to fulfill the reregistration requirements for a barley processing study.

GLN 171-4 (j): Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

The reregistration requirements for magnitude of the residue in animals are tentatively fulfilled pending submission of acceptable confirmatory data on storage stability of animal commodity samples. There are no registered direct animal treatments for metribuzin on cattle, goats, hogs, horses, sheep, or poultry.

The maximum dietary burdens for beef and dairy cattle were previously calculated in the Metribuzin Registration Standard to be 7 ppm. (See Table 4)

Table 4: Ruminant Dietary Burden

Commodity	Tolerance (ppm)	% Dry Matter	Beef Cattle		Dairy Cattle	
			% of Diet	Burden (ppm)	% of Diet	Burden (ppm)
Barley or wheat grain	0.75	--	40	0.3	40	0.3
Alfalfa or sainfoin forage	2	21	35	3.3	35	3.3
Soybean forage	4	24	20	3.3	20	3.3
Dehydrated tomato pomace	2	--	5	0.1	5	0.1
Total			100	7.0	100	7.0

It will be necessary to recalculate the dietary burden for ruminants after the outstanding field and processing data for ruminant feed commodities have been submitted and evaluated.

Beef Cattle Feeding Study: An unspecified breed of cattle was fed unlabeled metribuzin at 3 or 10 ppm in the diet (approximately 0.4x and 1.4x the calculated dietary burden, respectively) for approximately 30 days. The detected residues are given in Table 5. As previously stated in the discussion on Residue Analytical Methods, in animal tissues, metribuzin *per se* is converted to DK, thus being detected as a single peak, (level of detection (LOD) meat = 0.01 ppm). Similarly, DA is converted to DADK and is also detected as a single peak, (LOD meat = 0.02 ppm).

Dairy Cattle Feeding Study: An unspecified breed of dairy cattle was fed unlabeled metribuzin at 3 or 10 ppm in the diet (approximately 0.4x and 1.4x the calculated dietary burden, respectively) for approximately 30 days. The residues detected in milk are also given in Table 5. This procedure also converts metribuzin *per se* to DK (LOD milk = 0.002 ppm), and DA to DADK (LOD milk = 0.002 ppm).

Table 5: Results of Beef and Dairy Cattle Feeding Studies

TISSUE	Total Residues (Metribuzin, DK, DA, and DADK) (ppm)
Diet of 10 ppm Metribuzin	
muscle	Non-Detectable (< 0.03)
liver	0.55 - 1.01
kidney	0.08 - 0.17
fat	0.06 - 1.13
milk	<0.004 - 0.007
Diet of 3 ppm Metribuzin	
muscle	Non-Detectable (< 0.03)
liver	0.27 - 0.40
kidney	<0.03 - 0.10
fat	<0.05 - 0.07
milk	<0.004 - 0.006

The maximum expected dietary intake of metribuzin residues by poultry was previously calculated to be approximately 0.8 ppm from a diet consisting of 50% barley or wheat grain, 30% soybeans, 10% wheat milled by-products, 7% potato waste, and 3% sugarcane molasses. It will be necessary to recalculate the dietary burden for poultry after the outstanding field and processing data for poultry feed commodities have been submitted and evaluated.

Poultry Feeding Study: Laying hens were fed unlabeled metribuzin at 5 ppm, 15 ppm, or 50 ppm in the diet (approximately 6.3x, 19x, and 63x the calculated dietary burden, respectively) for 28 consecutive days. The resulting combined residues of metribuzin *per se*, DK, DA, and DADK, expressed as metribuzin equivalents, in eggs and poultry tissues are given in Table 6.

Table 6: Combined Residues of Metribuzin (ppm) in Eggs and Poultry Tissues

Tissues	Feeding level		
	5 ppm	15 ppm	50 ppm
28-Day Eggs	0.011-0.020	0.032-0.053	Not reported
Giblet	0.12-0.17	0.23-0.27	1.13-1.80
Muscle	<0.02-0.02	0.06-0.07	Not reported
Fat	0.04-0.05	0.04-0.08	Not reported
Skin	0.04-0.07	0.03-0.08	Not reported

GLNs 165-1 and 165-2: Confined/Field Rotational Crops

A confined rotational study (MRID 40838402) had been submitted, evaluated, and classified as supplemental, not upgradable since (1) the test substance was applied at 0.5x the maximum rate for crops which can be rotated and (2) no storage stability data were provided. (A new confined rotational study is required.)

Although the above study was classified as supplemental, it indicates that metribuzin residues accumulated in confined rotational crops (kale, red beets, and wheat) planted in sandy loam soil 32, 122, or 270 days following treatment of the soil with [^{14}C]metribuzin at 0.19 lb ai/A. The major residue identified in the crops and soil was DADK; minor residues that were identified were DA, DK, OH-t-butyl-DADK, and 3-amino-DA.

b. Drinking Water Exposure

Acute (1 day) Exposure

A metribuzin concentration appropriate for use in an acute drinking water assessment is 21 ppb. This concentration was the highest value detected in drinking water wells in the Central Sands area of Wisconsin.

Exposure was calculated using the equation:

Exposure (mg/kg/day) = (ppb (ug/L) metribuzin in the water consumed) (10^{-3} ug/mg) (2L/day) divided by 60kg.

in which 60 kg is the default assumption for female body weight and 2L is the default assumption for the amount of water consumed by an adult in a day.

Exposure = 0.0007 mg/kg/day

Chronic Drinking Water Exposure

Water consumption is defined as all water obtained from the household tap that is consumed either directly as a beverage or is used to prepare foods (mixing water with a can of soup) and beverages (diluting frozen juice concentrate). Two generally accepted default values for water consumption are 2 liters (28.6 g/kg-body wt/day) or 1.5 liters (21.4 g/kg-body wt/day). The 22.6 g/kg-body wt/day used in this calculation was derived using water consumption values and self reported body weights obtained from USDA's 1977-1978 Nationwide Food Consumption Survey.

The other assumption used is assuming that water from the same source containing the same contaminant level is consumed throughout a 70 year lifetime. Most of the US population moves at some time during their life and does not live in the same area, drinking from the same water source for a 70 year lifetime. It could be considered as either an over-estimation or an under-estimation of risk depending on the contaminant levels in the other sources of drinking water.

The chronic drinking water exposure assessment is based on a small scale retrospective study conducted in Portage County, Wisconsin, in which metribuzin and its DK, and DADK metabolites were detected in groundwater (six wells). All analyses of the DA metabolites were reported as BQL (Below Quantitation Limit). The information supplied indicated that sampling occurred from June 1988 through September 1989 with no samples taken January through April 1989, (i.e. 12 samples for each well). Analysis was by GC/MS (gas chromatography with a mass-selective detector) with a specified LOQ (Limit of Quantitation) of 1 ppb. A monthly concentration for each well was calculated by adding the detections of metribuzin, DK, and DADK. Concentrations reported as BQL were averaged in as 0.5 ppb, which is one-half of the LOQ. Then, the concentrations from the 12 samples for each well were averaged to obtain a yearly concentration.

The yearly average values calculated for the six wells are:

AW1 4.275 ppb
AW2 5.3667 ppb
AW3 3.7 ppb
AW4 5.25 ppb

AW5 3.925 ppb
AW6 5.2 ppb

Exposure was calculated using the equation:

Exposure (mg/kg/day) = (ppb metribuzin + DA + DK + DADK)(10^{-6})(22.6)

For the general population, the exposure values in mg/kg/day calculated for the 6 wells are:

AW1 0.0000966
AW2 0.0001212
AW3 0.0000836
AW4 0.0001186
AW5 0.0000887
AW6 0.0001175

For children (1-6), the exposure values in mg/kg/day calculated for the 6 wells are:

AW1 0.0004275
AW2 0.0005366
AW3 0.00037
AW4 0.000525
AW5 0.0003925
AW6 0.00052

Metribuzin and its degradates are persistent and mobile. Thus, it is expected that metribuzin and its degradates would be available for runoff. Metribuzin has been detected in surface water samples with concentrations ranging from below the detection limit of 0.05 ppb to 7.6 ppb. No information on detections of metribuzin degradates in surface water are available. A USGS stream reconnaissance survey of numerous midwestern streams in 1989, 1994, and 1995 collected samples during the first major runoff event after application. Thus, these samples could be considered to represent peak concentrations, not time-weighted averages. The 90th percentile concentrations for 1989, 1994, and 1995 respectively were 1.4, 1.2, and 0.5 ppb.

These concentrations are less than the estimated yearly averages for groundwater, although of the same order of magnitude. Thus, the exposures would be comparable. Annual means in surface water, unlike sometimes for groundwater, are typically substantially less than peak concentrations.

c. Occupational Exposure

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

All products containing metribuzin are intended primarily for occupational use; no products containing metribuzin are intended primarily for homeowner use. Therefore, a handler assessment for a residential scenario will not be conducted.

Handler (Mixer/Loader/Applicator) Exposure Scenarios

The Agency has determined that there is a potential for exposures to mixers, loaders, applicators, or other handlers during usual use-patterns associated with metribuzin. There are potential exposures to: mixer/loaders supporting ground, aerial, and chemigation applications of liquid, wettable powder, and dry-flowable formulations; mixers/loaders impregnating fertilizer with metribuzin and supporting impregnated fertilizer applications; applicators using ground and aerial equipment to apply as a spray; applicators using granular equipment to apply the impregnated dry-bulk fertilizer; applicators using high-volume hand equipment to apply liquid formulations (commercial turfgrass); flaggers participating in aerial application of sprays; and persons mixing, loading, and applying using low-pressure handwand equipment.

Based on the use patterns and potential exposures described above, ten exposure scenarios for handlers were identified for metribuzin: (1) mixing/loading the liquid formulation, (2) mixing/loading the dry-flowable formulation, (3) mixing/loading the wettable powder formulation, (4) mixing/loading the impregnated dry-bulk fertilizer (5) applying as a spray with aerial equipment, (6) applying as a spray with groundboom sprayer, (7) applying the impregnated dry-bulk fertilizer, (8) applying liquid formulation with high-volume hand equipment, (9) flagging during aerial spray application, and (10) mixing/loading/applying liquid formulations with low-pressure handwand equipment. The mixing/loading to support ground-boom applications scenario is considered worse-case (i.e. highest exposure) for mixers/loaders supporting ground applications (other than chemigation) using other types of equipment. Therefore, a separate assessment for mixer/loaders supporting high volume turfgrass sprayer applications is not necessary. The assumptions used in defining the

exposure scenarios are described in Table 7.

As previously explained, a NOEL for calculating a MOE for dermal exposure was not identified. Therefore, a dermal exposure occupational assessment will not be performed. Only a NOEL for calculating an inhalation exposure was identified. Therefore, only inhalation exposures for agricultural workers have been assessed. Baseline inhalation exposure values for uses of metribuzin are presented in Table 8. Note that the description of the calculations is in the footnotes.

Table 7. Metribuzin Exposure Scenario Descriptions

Exposure Scenario (Number)	Data Source	Standard Assumptions[a]	Comments[b]
Mixer/Loader Exposure			
Mixing All Liquids (1a,b)	PHED V1.1	350 acres aerial; 80 acres groundboom.	**Baseline:** Inhalation acceptable grades. Inhalation = 85 replicates; High confidence for inhalation data.
Mixing Dry Flowables (2a,b)	PHED V1.1	350 acres aerial; 80 acres groundboom	**Baseline:** Inhalation acceptable grades. Inhalation = 23 replicates; High confidence for inhalation data.
Mixing Wettable Powder (3a,b)	PHED V1.1	350 acres aerial; 80 acres groundboom	**Baseline and PPE:** Inhalation grades A,B,C Inhalation = 44 replicates; Medium confidence for inhalation data. An 80 percent protection factor was used for the addition of a dust/mist respirator in the PPE scenario.
Mixing/Loading Dry Bulk Fertilizer (4)	Registrant[c]	720 acres[c]	**Baseline:** Inhalation grades A,B,C[c] Inhaltion = 44 replicates
Applicator Exposure			
Aerial equipment (liquids)--Enclosed Cockpit (5)	PHED V1.1	350 acres	**Baseline:** Inhalation grades A,B,C; Inhalation = 23 replicates; Medium confidence for inhalation data.
Groundboom (6)	PHED V1.1	80 acres	**Baseline:** Inhalation acceptable grades; Inhalation = 22 replicates; High confidence for inhalation data.
Granular Drop-Type Spreader (Fertilizer Application) (7)	PHED V1.1	80 acres	**Baseline:** Inhalation acceptable grades; Inhalation = 5 replicates; Low confidence for inhalation data.
Spreader Truck (Metribuzin Impregnated Fertilizer Application) (7)	Registrant[c]	1,200 acres[c]	**Baseline:** Inhalation acceptable grades;[c] Inhalation = 5 replicates;
High Volume Hand Sprayer--Turf Grass Applications (8)	PHED V1.1	8 acres	**Baseline:** Inhalation acceptable grades; Inhalation = 14 replicates; Low to medium confidence for inhalation data.
Flagger			

Exposure Scenario (Number)	Data Source	Standard Assumptions[a]	Comments[b]
Flagging (Liquids) (9)	PHED V1.1	350 acres	**Baseline:** Inhalation grades acceptable. Inhalation = 18 replicates High confidence for inhalation data.
Mixer/Loader/Applicator			
Low Pressure Hand Wand (10)	PHED V1.1	1 acre	**Baseline:** Inhalation all grades. Inhalation = 96 replicates Low confidence for inhalation data.

a Daily acres treated are from the Agency's estimates of acreage that could be treated in a single day for each exposure scenario of concern.

b These grades are based on Quality Assurance/Quality Control data provided as part of the exposure studies. A replicate refers to data acquired during one complete work cycle. "Best Available" grades are defined by the Agency's SOP for meeting Subdivision U Guidelines. Best available grades are assigned as follows: matrices with grades A and B data and a minimum of 15 replicates; if not available, then grades A, B, and C data and a minimum of 15 replicates; if not available, then all data regardless of the quality and number of replicates. Data confidence are assigned as follows:
High confidence = grades A and B and 15 or more replicates per body part
Medium confidence = grades A, B, and C and 15 or more replicates per body part
Low confidence = grades A, B, C, D, and E or any combination of grades with less than 15 replicates

c Registrant supplied data was used because no data was in Pesticide Handlers Exposure Database (PHED). Discussion to follow in risk assessment section.

Table 8. Baseline Inhalation Exposure Values for Uses of Metribuzin

Exposure Scenario (Scen. #)	Baseline Inhalation Unit Exposure[a] (ug/lb ai)	Crop	Maximum Label Application Rate[b] (lb ai/acre)	Daily Max. Treated[c] (acres)	Daily Inhalation Exposure[d] (mg/day)
Mixer/Loader Exposure					
Mixing All Liquids for Aerial\Chemigation Application (1a)	1.2	Sugar Cane/Noncrop	5	350	2.10
		Asparagus	2		0.84
		Other Crops	1		0.42
		Carrots	0.25		0.11
Mixing All Liquids for Groundboom Application (1b)		Sugar Cane/Noncrop	5	80	0.48
		Asparagus	2		0.19
		Other Crops	1		0.10
		Carrots	0.25		0.02
Mixing Dry Flowables for Aerial/Chemigation Application (2a)	0.77	Sugar Cane/Noncrop	6	350	1.62
		Asparagus	2		0.54
		Other Crops	1		0.27
		Carrots	0.25		0.07
Mixing Dry Flowables for Groundboom Application (2b)		Sugar Cane/Noncrop	6	80	0.37
		Asparagus	2		0.12
		Other Crops	1		0.06
		Carrots	0.25		0.02
Mixing Wettable Powder for Aerial\Chemigation Application (3a)	43.4	Sugar Cane/Noncrop	6	350	91.14
		Asparagus	2		30.4
		Other Crops	1		15.19
		Carrots	0.25		3.80
Mixing Wettable Powder for Groundboom Application (3b)		Sugar Cane/Noncrop	6	80	20.83
		Asparagus	2		6.94

Exposure Scenario (Scen. #)	Baseline Inhalation Unit Exposure[a] (ug/lb ai)	Crop	Maximum Label Application Rate[b] (lb ai/acre)	Daily Max. Treated[c] (acres)	Daily Inhalation Exposure[d] (mg/day)
		Other Crops	1		3.47
		Carrots	0.25		0.87
Mixing/Loading Dry Bulk Fertilizer (4)	43.4[e]	Soybeans[e] Alfalfa	1[e]	720[e]	31.3[e]
Applicator Exposure					
Aerial (Liquid Application)--Enclosed Cockpit (5)	0.068	Sugar Cane/Noncrop	6	350	0.14
		Asparagus	2		0.05
		Other Crops	1		0.02
		Carrots	0.25		0.006
Groundboom Tractor (6)	0.7	Sugar Cane/Noncrop	6	80	0.34
		Asparagus	2		0.11
		Other Crops	1		0.06
		Carrots	0.25		0.01
Granular Drop-Type Spreader (Fertilizer Application) (7)	1.24	Soybeans Alfalfa	1	80	0.10
Spreader Truck (Metribuzin Impregnated Fertilizer Application) (7)	1.24[e]	Soybeans[e] Alfalfa	1[e]	1,200[e]	1.49[e]
High Volume Hand Sprayer - Turf Grass Applications (8)	1.4	Turf	0.5	8	0.006
Flagger					
Flagging (liquid applications) (9)	0.28	Sugar Cane/Noncrop	6	350	0.59
		Asparagus	2		0.20
		Other Crops	1		0.10
		Carrots	0.25		0.02
Mixer/Loader/Applicator					
Low Pressure Hand Wand (10)	31	Sugar Cane/Noncrop	5	1	0.16
		Asparagus	2		0.06
		Other Crops	1		0.03
		Carrots	0.25		0.008

[a] The baseline inhalation unit exposure values are for workers wearing no respirators while using open pour for mixing/loaders, enclosed cockpit for aerial applications (open cockpit data are not available), and open cab for tractor drawn applications.

[b] Label Reg No. 3125-314, 3125-325 and 3125-402

[c] Values represent the maximum area or the maximum volume of spray solution which is likely to be used in a single day to complete treatments for each exposure scenario of concern.

[d] Daily inhalation exposure (mg/day) = Exposure (ug/lb ai) * (1mg/1000ug) conversion * Max. Appl. Rate (lb ai/A) * Max. Treated (acres/day)

[e] Registrant supplied data was used because no data was in PHED. Discussion to follow in risk assessment section.

Post-Application Exposures

The Agency has determined that there is potential inhalation exposure to persons entering treated sites after application is complete. These post-application exposures may occur (1) to agricultural workers following applications to vegetables and agronomic crops and to turfgrass being grown for sod, and (2) to employees and the public following applications to turfgrass in recreational areas.

No active-ingredient-specific data are available for post-application inhalation exposures to metribuzin. Although these exposures cannot be estimated, the Agency is not requiring this data at this time.

3. Risk Assessment

a. Dietary Risk

Acute (1 day) Dietary Risk

As previously stated, the endpoint for acute dietary risk characterization is the NOEL from the rabbit developmental toxicity study, 15 mg/kg/day (MRID 00087796). Since this endpoint is from a developmental toxicity study, the population subgroup females (13+ years) was used to represent women of child-bearing age. It was assumed that one hundred percent of each commodity was treated with metribuzin (100% CT), that all residues were at the current or reassessed tolerance level as specified in Table 46, and that metribuzin is uniformly distributed in the commodity supply.

The Margin of Exposure (MOE) is a measure of how closely the estimated high end exposure comes to the NOEL. The MOE for acute dietary exposure for metribuzin was calculated using the following formula:

$$\text{MOE} = \frac{15 \text{ mg/kg/day}}{\text{Exposure}}$$

The calculated exposure of those individuals most highly exposed is 0.012 mg/kg/day. Thus:

$$\text{MOE} = \frac{15 \text{ mg/kg/day}}{0.012 \text{ mg/kg/day}} = 1{,}250$$

The MOE is not less than 100; therefore, the Agency considers the MOE

to be sufficiently protective.

Chronic Dietary Risk

The RfD (0.013 mg/kg bwt/day) is used for assessing chronic dietary risk. It was assumed that one hundred percent of each commodity was treated with metribuzin (100% CT), that all residues were at the current or reassessed tolerance level as specified in Table 11, and that metribuzin is uniformly distributed in the commodity supply.

The Theoretical Maximum Residue Contribution (TMRC) was calculated for the U.S. population and 22 subgroups. The TMRC for the U.S. population is 0.0046 which is 36% of the RfD. The commodity with the largest contribution to the %RfD is wheat flour which is 7% of the RfD. The two subgroups with the highest %RfDs are non-nursing infants (less than 1 year) with the TMRC equal to 0.0081 and %RfD equal to 62%, and children (1 - 6 years) with the TMRC equal to 0.0097 and %RfD equal to 75%. For children (1 - 6 years) the commodity with the largest contribution to the %RfD is wheat flour which is 16% of the RfD. The second largest is boneless beef (lean without removable fat) which is 11% of the RfD.

These calculations represent a "worst case" estimate of dietary exposure for metribuzin since tolerance level residues and 100 %CT were assumed. The RfD was not exceeded; therefore, the Agency's chronic dietary risk concerns are not exceeded.

b. Drinking Water Risk

Acute Drinking Water Risk

The acute MOE for drinking water is calculated in the same manner as the acute dietary (food source).

$$\text{MOE} = \frac{15 \text{ (mg/kg/day)}}{\text{exposure (mg/kg/day)}}$$

Chronic Drinking Water Risk

Metribuzin chronic dietary risk from drinking water is calculated using the RfD, which is 0.013 mg/kg/day, and exposure is based on a groundwater study. Thus, risk can be estimated using the equation

% RfD = [exposure/RfD](100)

The % RfD for the general population from drinking water are as follows:

AW1 0.7%
AW2 0.9%
AW3 0.6%
AW4 0.9%
AW5 0.7%
AW6 0.9%

The % RfD for children (1-6) are:

AW1 3%
AW2 4%
AW3 3%
AW4 4%
AW5 3%
AW6 4%

All values are less than 1% of the RfD for the general population and no more than 4% for the children (1-6). Metribuzin has been detected in surface water at concentrations less than the estimated yearly averages for groundwater, although of the same order of magnitude. Thus, the % RfDs would be comparable. The RfD was not exceeded; therefore, the Agency's chronic dietary consumption of metribuzin in drinking water (groundwater and surface water) is not exceeded.

c. Occupational Risk

A NOEL of 58.5 mg/kg/day, based on a 21-day inhaltion toxicity study, is used for calculating MOEs for the short-term and intermediate term inhalation scenarios.

$$\text{MOE} = \frac{\text{NOEL (58.5 mg/kg/day)}}{\text{inhalation exposure}}$$

The inhalation MOEs are in Table 9.

Table 9. Baseline Short-Term and Intermediate-Term Inhalation Risk

Exposure Scenario (Scen. #)	Crop	Baseline Daily Inhalation Dose[a] (mg/kg/day)	Baseline Inhalation MOE[b]
Mixer/Loader Risk			
Mixing All Liquids For Aerial\Chemigation Application (1a)	Sugar Cane/Noncrop	0.03	1,950
	Asparagus	0.01	5,850
	Other Crops	0.006	9,750
	Carrots	0.002	29,250
Mixing All Liquids for Groundboom Application (1b)	Sugar Cane/Noncrop	0.007	8,357
	Asparagus	0.003	19,500
	Other Crops	0.001	58,500
	Carrots	0.0003	195,000
Mixing Dry Flowables for Aerial\Chemigation Application (2a)	Sugar Cane/Noncrop	0.02	2,925
	Asparagus	0.008	7,313
	Other Crops	0.004	14,625
	Carrots	0.001	58,500
Mixing Dry Flowables for Groundboom Application (2b)	Sugar Cane/Noncrop	0.005	11,700
	Asparagus	0.002	29,250
	Other Crops	0.0009	65,000
	Carrots	0.0003	195,000
Mixing Wettable Powder for Aerial\Chemigation Application (3a)	Sugar Cane/Noncrop	1.30	45
	Asparagus	0.43	136
	Other Crops	0.22	266
	Carrots	0.05	1170
Mixing Wettable Powder for Groundboom Application (3b)	Sugar Cane/Noncrop	0.30	195
	Asparagus	0.10	585
	Other Crops	0.05	1,170
	Carrots	0.01	5,850

Exposure Scenario (Scen. #)	Crop	Baseline Daily Inhalation Dose[a] (mg/kg/day)	Baseline Inhalation MOE[b]
Mixing/Loading Dry Bulk Fertilizer (4)	Soybeans Alfalfa	0.45[c]	130[c]
Applicator Risk			
Aerial (Liquid Application)--Enclosed Cockpit (5)	Sugar Cane/Noncrop	0.002	29,250
	Asparagus	0.0007	83,571
	Other Crops	0.0003	195,000
	Carrots	0.00009	650,000
Groundboom Tractor (6)	Sugar Cane/Noncrop	0.005	11,700
	Asparagus	0.002	29,250
	Other Crops	0.0009	65,000
	Carrots	0.0001	585,000
Granular Drop-Type Spreader (Fertilizer Application) (7)	Soybeans Alfalfa	0.001	58,500
Spreader Truck (Metribuzin Impregnated Fertilizer Application) (7)	Soybeans[c] Alfalfa	0.021[c]	2,786[c]
High Volume Hand Sprayer--Turf Grass Applications (8)	Turf	0.00009	650,000
Flagger Risk			
Flagging (liquid applications) (9)	Sugar Cane/Noncrop	0.008	7,313
	Asparagus	0.003	19,500
	Other Crops	0.001	58,500
	Carrots	0.0003	195,000
Mixer/Loader/Applicator Risk			
Low Pressure Hand Wand (10)	Sugar Cane/Noncrop	0.002	29,250
	Asparagus	0.0009	65,000
	Other Crops	0.0004	146,250
	Carrots	0.0001	585,000

[a] The baseline inhalation unit exposure assumes no respirator. Daily Inhalation Dose (mg/kg/day;) = Daily Inhalation Exposure (mg/day; see Table 8)/70 kg. Note that 70kg is the Agency's default male body weight

[b] MOE = NOEL (mg/kg/day)/Daily Inhalation Dose (mg/kg/day). The inhalation NOEL (rat) = 58.5 mg/kg/day.

[c] Registrant supplied data was used because no data was in PHED. Discussion to follow.

All of the MOEs were calculated using the 70 kg default male body weight. If these MOEs were to be re-calculated using the 60 kg default female body weight, the MOEs would be slightly smaller. The calculated MOEs were greater than 100 except for scenario 3a, mixing loading wettable powders for aerial and chemigation applications, although only at the highest label rate of 6 lbs ai/acre. A dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C) would provide an 80% protection factor. Thus, exposure would be considered to be 20% of the baseline inhalation exposure. (See Tables 8 and 9 for an explanation of the calculations.)

Daily Inhalation Exposure = (43.4)(.2)(0.001) (6) (350) = 18.228

Where: 43.4 is the unit inhalation exposure value for open mixing/loading of wettable powders (mg/lb/ai) protection factor.
.2 is the 20% from the protection factor of 80%.
0.001 is the conversion factor from ug to mg.
6 is the application rate (lbs ai/acre).
350 is the area treated (acres).

Daily Inhalation Dose = 18.228/70 = 0.26

MOE = 58.5/0.26 = 225

A possible alternative to the use of a respirator would be the use of water soluble packets. Another possible alternative to the use of a respirator would be to lower the label rate of 6 lbs ai/acre since label rates of 2, 1, and 0.25 lbs ai/acre had MOEs greater than 100.

The Agency has determined that no additional risk mitigation measures are required at this time for mixers/loaders impregnating dry bulk fertilizer, or for applicators applying fertilizer impregnated with metribuzin. This determination is based on information provided to the Agency by Bayer Corporation in a letter dated August 21, 1996, in which the processes involved in treating fertilizer with metribuzin and applying the treated fertilizer were described. The Agency has used surrogate data from the Pesticide Handlers Exposure Database (PHED, Version 1.1) to estimate risks to these workers. A more detailed explanation follows.

Mixers/Loaders Impregnating Dry Bulk Fertilizer

At the Agency's request information was provided by Bayer describing the process for impregnating dry bulk fertilizer with metribuzin and for applying

metribuzin impregnated fertilizer. Bayer stated in their letter, dated August 21, 1996, that the inhalation exposure to the mixer at the dealer site (where the impregnation takes place) is very similar to that of a worker who performs open system mixing under typical field use conditions. Therefore, open mixing/loading of wettable powders was used as the most appropriate scenario for surrogate data. The unit inhalation exposure value for open mixing/loading wettable powders is 43.4 μg/lb ai (PHED V1.1, inhalation grades A, B, and C, 44 replicates; medium confidence).

The amount of fertilizer and metribuzin handled (at the dealer location) depends on the number of acres to be treated. According to metribuzin labels, impregnated fertilizer is applied to alfalfa and soybeans at a maximum rate of 1 lb active ingredient metribuzin per acre. From 200 to 450 lbs of treated fertilizer may be applied per acre.

Bayer stated that mixers/loaders can treat 2 - 3 tons of fertilizer per batch, and that it takes 15 to 20 minutes to treat one batch. At 1 lb active ingredient per 200 lbs fertilizer, each ton of fertilizer would require 10 lbs of metribuzin active ingredient.

If mixers/loaders prepare 3 batches per hour (an average of 20 minutes per batch), 24 batches could be prepared during an 8-hour work period. At 3 tons per batch and 10 lbs ai per ton, mixers/loaders would prepare 72 tons in a day and would handle 720 lbs of metribuzin. This would equal 144,000 lbs treated fertilizer (72 x 2,000 = 144,000) which would be sufficient to treat 720 acres at the rate of 200 lbs fertilizer per acre (144,000/200 = 720). This appears to be a reasonable estimate since Bayer estimates that dealers apply fertilizer to an average of 700 to 800 acres per day. Bayer indicates that in most cases dealers make the application because in February and March, when most applications are made, growers often do not have the appropriate equipment up and running. Additionally, dealers use spreader trucks which, according to Bayer, provides a more uniform application. Bayer indicates that dealers can treat from 400 - 1,200 acres per day using spreader trucks, with 700 - 800 being the average.

Risk for mixers/loaders impregnating dry bulk fertilizer was estimated as follows:

Daily inhalation exposure (mg/day) is calculated using the following equation:

unit exposure (µg/lb ai) x lbs ai handled per day x 1/1,000 (µg to mg conversion)

Given, inhalation unit exposure value = 43.4 µg/lb ai, and
720 lb ai handled per day.

Therefore,

43.4 µg x 720 lbs handled/day x 1/1,000 (conversion to mg) = 31.3 mg/day.

Daily inhalation dose (mg/kg/day) is calculated by dividing the daily exposure (mg/day) by the body weight (bw) of the worker:

Given,

Daily exposure = 31.3 mg/day, and
bw = 70 kg.

Therefore,

31.3 mg/day ÷ 70 kg = 0.45 mg/kg/day.

Risk, in terms of margins of exposure, is calculated by using the following equation:

NOEL (mg/kg/day) / daily dose (mg/kg/day) = MOE.

Given,

NOEL = 58.5 mg/kg/day, and
Daily inhalation dose = 0.45 mg/kg/day.

Therefore, the MOE for handlers mixing/loading to impregnate fertilizer with metribuzin is

58.5 mg/kg/day / 0.45 mg/kg/day = 130.

Because the MOE for mixers/loaders impregnating fertilizer exceeds 100, the Agency does not recommend that any additional measures to mitigate risk to these workers be required.

Applicators Applying Dry Bulk Fertilizer Impregnated with Metribuzin

Bayer also stated, in the August 21, 1996 letter, that a grower using conventional fertilizer-spreading equipment can treat from 100 to 300 acres per day; however, a dealer using a spreader truck can treat 400 to 1,200 acres per day. It was noted that spreader trucks are equipped with an activated charcoal filtering system.

Because the Agency has no data for spreader trucks applying treated fertilizer, "applying using a granular drop-type spreader" was determined to be the most appropriate

surrogate data scenario from PHED for use estimating impregnated dry bulk fertilizer applicator exposure to metribuzin. The unit exposure value for granular drop-type spreader applicator is 1.24 µg/lb ai (PHED V1.1, inhalation acceptable grades, 5 replicates; low confidence). Since spreader trucks may have functioning air filtering devices, this should be considered a worst case scenario for fertilizer application.

Daily inhalation exposure (mg/day) is calculated using the following equation:

unit exposure (µg/lb ai) x application rate (lbs ai/acre) x number of acres treated x 1/1,000 (µg to mg conversion)

Given,

inhalation unit exposure value = 1.24 µg/lb ai,
maximum application rate is 1 lb ai per acre, and
maximum number of acres treated is 1,200

Therefore,

1.24 µg x 1 lbs ai/acre x 1,200 acres x 1/1,000 (conversion to mg) = 1.49 mg/day.

Daily inhalation dose (mg/kg/day) is calculated by dividing the daily exposure (mg/day) by the body weight (bw) of the worker:

Given,

Daily exposure = 1.49 mg/day, and
bw = 70 kg.

Therefore,

1.49 mg/day ÷ 70 kg = 0.021 mg/kg/day.

Risk is calculated by using the following equation:

NOEL (mg/kg/day) / daily dose (mg/kg/day) = MOE.

Given,

NOEL = 58.5 mg/kg/day, and
Daily inhalation dose = 0.021 mg/kg/day.

Therefore, the MOE for applicators applying fertilizer impregnated with metribuzin is

58.5 mg/kg/day / 0.021 mg/kg/day = 2,786.

Because the MOE for applicators applying fertilizer impregnated with metribuzin exceeds 100, the Agency does not recommend that any additional measures to mitigate risk to these workers be required.

Risk From Post-Application Exposures

There are no data available to address post-application exposure for persons reentering areas treated with metribuzin. However, because no dermal endpoints of concern have been identified for metribuzin, the Agency has no special occupational post-application dermal exposure concerns. Also, because metribuzin has a low vapor pressure and because the potential level of inhalation exposure following applications is low, the Agency has no special inhalation exposure concerns for workers or others reentering areas following metribuzin applications as long as the entry is delayed at least until sprays and dusts have settled out of the air.

Additional Occupational Exposure Studies

No additional occupational exposure studies are required for reregistration at this time.

d. Food Quality Protection Act (FQPA) Considerations

The FQPA of 1996 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) 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 metribuzin has food uses, specific consideration of the risks to infants and children, as well as aggregate exposures and potential cumulative effects is warranted.

1) Potential Risks to Infants and Children

In determining whether a safety factor different than the additional 10-fold factor 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 database, the nature and severity of the effects observed in pre- and post-natal studies, and other information such as epidemiological data.

For the purpose of assessing pre-and post-natal toxicity of metribuzin, the Agency has evaluated three developmental studies and one reproductive study. Based on the current data requirements, these studies, when considered with other required guideline toxicity studies, constitute a complete database for evaluating pre- and post-natal effects for food-use chemicals. However, as the Agency fully implements the requirements of FQPA, additional data related to the special sensitivity of infants and children may be required.

Developmental and Reproductive Effects

The effects observed in the metribuzin developmental and reproductive studies can be summarized as follows:

In a developmental toxicity study, metribuzin was administered by gavage on gestation days 6-18 to pregnant Charles River Crl:CD BR rats. Maternal toxicity was shown at all dose levels as reduced body weight gain, reduced mean gravid uterine weights, and decreased food consumption. The maternal toxicity NOEL is less than 25 mg/kg/day and the maternal toxicity LOEL

is equal to or less than 25 mg/kg/day. For developmental toxicity, the NOEL is 70 mg/kg/day and the LOEL is 200 mg/kg/day based on decreased fetal body weight and reduced ossification or unossified skull bones, ribs, vertebrae, sternebrae, pelvic bones, and appendages.

In a developmental toxicity study, American Dutch rabbits were given metribuzin by gavage on gestation days 6-18. Maternal toxicity was noted at 30 mg/kg/day and above based on decreased maternal body weight gains on gestation days 18-28 at the mid dose level and decreased body weight gains, decreased food consumption and decreased food efficiency on gestation days 7-19 at the high dose level. Developmental toxicity was noted at the high dose in the form of an increased incidence of irregular spinous processes. The maternal toxicity NOEL is 10 mg/kg/day and the maternal toxicity LOEL is 30 mg/kg/day, based on decreased weight gain on days 18-28. For developmental toxicity, the NOEL is 30 mg/kg/day and the LOEL is 85 mg/kg/day based on an increase incidence of irregular spinous processes.

In a repeat developmental toxicity study, New Zealand white rabbits were given metribuzin by gavage on gestation days 6-18. Maternal systemic toxicity was noted at 45 mg/kg/day, as reduced body weight gain, and reduced food and water intake. Additionally, at the highest dose tested (135 mg/kg/day) there was an increased incidence of abortions and decreased body weights. The maternal toxicity NOEL is 15 mg/kg/day and the maternal toxicity LOEL is 45 mg/kg/day based on reduced body weight gains and reduced food and water consumption. For developmental toxicity, the NOEL is 15 mg/kg/day and the LOEL is 45 mg/kg/day based on decreased fetal body weights, increased number of runts and increased incidence of extra and partial ribs.

In a two-generation reproduction study, Crl:CD BR rats received feed containing metribuzin. Systemic toxicity in both the parental animals and the pups was noted at the mid dose as slightly decreased body weights in the F_1 high and the F_2 mid and high dose pups. The F_1 females had decreased body weight gains during the gestation period for mid and high doses; F_0 and F_1 females had increased body weight during lactation and hypertrophy of hepatocytes in high dose males and mid and high dose females. The parental/offspring systemic toxicity NOEL is 1.5 mg/kg/day and the parental/offspring systemic toxicity LOEL is 7.5 mg/kg/day

based on decreased body weights and body weight gains and hypertrophy of the hepatocytes.

Uncertainty Factor

In the three metribuzin developmental studies discussed above, the NOELs for developmental effects are equal to or greater than the NOELs for maternal effects. Generally, the Agency would be concerned when developmental effects are seen at doses lower than those which would cause maternal effects. Thus, for metribuzin there is no unique sensitivity from pre-natal exposure based on the current toxicological data requirements. The Agency concludes that an additional uncertainty factor to account for any special sensitivity to infants and children is not warranted for the metribuzin risk assessment.

2) Aggregate (Multipathway) Exposure and Resultant Risk

In examining aggregate exposure, FQPA directs EPA to take into account available information concerning exposures from pesticide residues in food and all other non-occupational exposures. The primary non-food sources of exposure the Agency looks at include drinking water (whether from groundwater or surface water), and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Risk assessments for aggregate exposure consider both short-term and long-term (chronic) exposure scenarios, considering the toxic effects which would likely be seen for each exposure duration.

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

Similarly, long-term aggregate exposure considers average exposure to a population over a lifetime. This average exposure is then compared to pesticide levels at which toxic effects were seen in long-term (usually chronic) toxicity studies to estimate risk.

Acute Risk:

Acute (1 day) Dietary (food source): The endpoint for acute dietary risk characterization is the NOEL from the previously described rabbit developmental toxicity study, 15 mg/kg/day. Since this endpoint is from a developmental toxicity study, the population subgroup females (13+ years) was used to represent women of child-bearing age. It was assumed that one hundred percent of each commodity was treated with metribuzin (100% CT), that all residues were at the current or reassessed tolerance level and that metribuzin is uniformly distributed in the commodity supply.

The Margin of Exposure (MOE) is a measure of how closely the estimated high end acute dietary exposure (0.012 mg/kg/day) comes to the NOEL (15 mg/kg/day). Thus, the MOE for acute dietary exposure for the population subgroup females (13+ years) for metribuzin is 1,250 (15 mg/kg/day/ 0.012 mg/kg/day). The MOE is not less than 100; therefore, the Agency considers the MOE to be sufficiently protective for acute dietary (food source) risk.

Acute Drinking Water: For the population sub-group females 13+, the estimated exposure for acute drinking water is 0.0007 mg/kg/day. The MOE is a measure of how closely the estimated high end acute drinking water exposure (0.0007 mg/kg/day) comes to the NOEL (15 mg/kg/day). Thus, the MOE for acute drinking water exposure for the population subgroup females (13+ years) for metribuzin is 21,000 (rounded to two significant figures) (15 mg/kg/day/0.0007 mg/kg/day). The MOE is not less than 100; therefore, the Agency considers the MOE to be sufficiently protective for acute dietary (drinking water source) risk.

For the population sub-group females 13+, the estimated exposure for acute dietary (food source) is 0.012 mg/kg/day. The estimated exposure for acute drinking water is 0.0007 mg/kg/day. Thus, the total acute dietary exposure (food source + drinking water) is 0.0127 mg/kg/day. Using this total exposure, the aggregate MOE for acute exposure for the population sub-group females 13+ is 1200 (rounded to two significant digits). The MOE is not less than 100; therefore, the Agency considers the MOE to be sufficiently protective for total acute dietary exposure.

Chronic Risk:

Chronic Dietary (food source): The RfD (0.013 mg/kg bwt/day) is used for assessing chronic dietary risk. The Reference Dose for metribuzin was established at 0.013 mg/kg/day based upon a two-year feeding study in rats with a NOEL of 1.3 mg/kg/day and an uncertainty factor of 100. The effect observed at the LOEL (13.8 mg/kg/day) was decreased body weight gains, increased thyroid and liver weights. The reproductive study with a NOEL of 1.5 mg/kg/day was considered to be a co-critical study.

It was assumed that one hundred percent of each commodity was treated with metribuzin (100% CT), that all residues were at the current or reassessed tolerance level, and that metribuzin is uniformly distributed in the commodity supply.

The Theoretical Maximum Residue Contribution (TMRC) was calculated for the U.S. population and 22 subgroups. The TMRC is 36% of the RfD for the U.S. population; 62% of the RfD for non-nursing infants (less than 1 year); and 75% of the RfD for children (1 - 6 years). These later groups represent the two subgroups with the highest %RfDs. These calculations represent an over-estimate of chronic dietary exposure for metribuzin since tolerance level residues and 100 %CT were assumed. Actual risks will be much lower. The RfD was not exceeded; therefore, the Agency's chronic dietary (food source) risk is not exceeded.

Chronic Drinking Water: As stated previously, the drinking water exposure assessment is based on a small scale retrospective study conducted in Portage County, Wisconsin, in which metribuzin and its DK, and DADK metabolites were detected in groundwater (six wells). (For more details see the drinking water exposure and risk assessments sections.)

For the general population the yearly average concentrations in well water ranged from 3.7 ppb to 5.3667 ppb, calculated exposures based on consumption ranged from 0.0000887 mg/kg/day to 0.0001212 mg/kg/day. All values were less than 1% of the RfD.

For the chronic dietary risk (food source), the highest % RfD for a population sub-group was 75% for children (1-6). For this population sub-group the yearly average concentrations in well

water ranged from 3.7 ppb to 5.3667 ppb, calculated exposures based on consumption ranged from 0.00037 mg/kg/day to 0.0005366 mg/kg/day. All values were less than 4% of the RfD.

Metribuzin has been detected in surface water at approximate peak concentrations less than the estimated yearly averages for groundwater, although of the same order of magnitude. Peaks in surface water generally are much greater than means. Thus, the %RfDs would be comparable. Therefore, the Agency has no concerns for chronic dietary consumption of metribuzin in groundwater or surface water, but believes that reserving 1% of the RfD for the general population and 4% of the RfD for children (1-6) for drinking water to be appropriate assumptions.

When total chronic dietary risk is assessed for the population sub-group with the highest %RfDs (children 1-6), the Agency has concluded that 4 % of the RfD will be reserved for exposure to residues of metribuzin in drinking water and 75 % of the RfD will be utilized by exposure to residues of metribuzin in food commodities. The total chronic dietary risk is 79 % of the RfD, thus, not exceeding the Agency's risk concern level.

Non-occupational risk

Metribuzin is not labeled for use by homeowners or certified applicators in the residential setting. However, metribuzin can be used on turf in public areas such as parks, athletic fields, or golf courses. Therefore, non-occupational exposure would be limited to postapplication exposure to persons such as employees and the public following applications to turfgrass in treated recreational areas. No active-ingredient-specific data are available to estimate post-application exposures for persons exposed to metribuzin-treated turf in recreational areas. However, because no dermal endpoints of concern have been identified for metribuzin, the Agency has no special post-application dermal exposure concerns. The Agency has no inhalation concerns for persons exposed to metribuzin-treated turf as long as entry is delayed at least until sprays and dusts have settled out of the air.

Additionally, given the nature of activities and therefore the exposure in an outdoor public setting, the Agency believes that such a short-time exposure is very unlikely to contribute any

significant amount to an aggregate risk.

3) Cumulative Effects

Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The Agency believes that "available information" in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. For example, pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

In the case of metribuzin, EPA does not have at this time,

available data to determine whether metribuzin has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, metribuzin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that metribuzin has a common mechanism of toxicity with other substances.

C. Environmental Assessment

1. Ecological Toxicity Data

a. Toxicity to Terrestrial Animals

(1) Birds, Acute and Subacute

An acute oral toxicity study using the technical grade of the active ingredient is required to establish the toxicity of a pesticide to birds. The preferred test species is either mallard duck (a waterfowl) or bobwhite quail (an upland gamebird). Results of this test are tabulated below.

Table 10. Avian Acute Oral Toxicity

Species	% ai	LD50 (mg/kg)	Toxicity Category	MRID No. Author/Year	Study Classification
Northern bobwhite quail *(Colinus virginianus)*	97	169.2	moderately toxic	255025 Lamb/1992	core

These results indicate that metribuzin is moderately toxic to avian species on an acute oral basis. The guideline requirement (71-1) is fulfilled (ACC # 255025).

Two subacute dietary studies using the technical grade of the active ingredient are required to establish the toxicity of a pesticide to birds. The preferred test species are mallard duck and bobwhite quail. Results of these tests are tabulated below.

Table 11. Avian Subacute Dietary Toxicity

Species	% ai	LC50 (ppm)	Toxicity Category	MRID No. Author/Year	Study Classification
Northern bobwhite quail *(Colinus virginianus)*	92.6	>4000	practically non-toxic	262228 1986	core
Mallard duck *(Anas platyrhynchos)*	99	>5000	practically non-toxic	065507 Burke & Lamb/1977	core

These results indicate that metribuzin is practically non-toxic to avian species on a subacute dietary basis. The guideline requirement (71-2) is fulfilled (ACC # 262228, and 065507).

(2) Birds, Chronic

Avian reproduction studies using the technical grade of the active ingredient are required for metribuzin because the following conditions are met: (1) birds may be subject to repeated or continuous exposure to the pesticide, especially preceding or during the breeding season, (2) the pesticide is stable in the environment to the extent that potentially toxic amounts may persist in animal feed, (3) the pesticide is stored or accumulated in plant or animal tissues, and/or, (4) information derived from mammalian reproduction studies indicates reproduction in terrestrial vertebrates may be adversely affected by the anticipated use of the product. The preferred test species are mallard duck and bobwhite quail. Results of these tests are tabulated below.

Table 12. Avian Reproduction

Species	% ai	NOEC/LOEC (ppm)	Endpoints Affected	MRID No. Author/Year	Study Classification
Northern bobwhite quail *(Colinus virginianus)*	93.5	growth: < 62/62 other: 385/>385	14-day hatchling body weight No other effects reported	43926601 Hancock/1996	Core
Mallard duck *(Anas platyrhynchos)*	93.5	368/>368	None	43860501 Hancock/1996	Core

There was a statistically significant reduction in body weight at 14-days post-hatch at all levels tested in the bobwhite quail study. No other effects were observed in this study. No effects were observed at any level tested in the mallard study. Since there was some doubt as to whether the 14-day body weight effect was treatment-related in the bobwhite study, and since no reproductive parameters were affected in either study, the mallard NOEC of 368 ppm will be used in the risk quotients. The guideline requirement (71-4) is fulfilled (MRID # 43926601, and 43860501).

(3) Mammals

Wild mammal testing is required on a case-by-case basis, depending on the results of lower tier laboratory mammalian studies, intended use pattern and pertinent environmental fate characteristics. In most cases, rat or mouse toxicity values obtained from the Agency's Health Effects Division substitute for wild mammal testing. These toxicity values are reported in the table below.

Table 13. Mammalian Toxicity

Species	% ai	Test Type	Toxicity Values	MRID No.
laboratory rat *(Rattus norvegicus)*		acute oral	2200 mg/kg (female) 2300 mg/kg (male)	00106158
Laboratory mouse *(Mus musculus)*		acute oral	711 mg/kg (female) 698 mg/kg (male)	00106158

The results indicate that metribuzin is slightly toxic (Category III) to small mammals on an acute oral basis.

(4) Insects

A honey bee acute contact study using the technical grade of the active ingredient is required for metribuzin because its use (foliar, postemergent, and on established plants for several terrestrial food crops) may result in honey bee exposure. Results of this test are tabulated below.

Table 14. Nontarget Insect Acute Contact Toxicity

Species	% ai	LD50 (μg/bee)	Toxicity Category	MRID No. Author/Year	Study Classification
Honey bee *(Apis mellifera)*	tech	60.4	practically non-toxic	028772 1973	core

The results indicate that metribuzin is practically non-toxic to bees on an acute contact basis. The guideline requirement (141-1) is fulfilled (MRID 028772).

b. Toxicity to Aquatic Animals

(1) Freshwater Fish

a. Freshwater Fish, Acute

Two freshwater fish toxicity studies using the

technical grade of the active ingredient are required to establish the toxicity of a pesticide to fish. The preferred test species are rainbow trout (a coldwater fish) and bluegill sunfish (a warmwater fish). Results of these tests are tabulated below.

Table 15. Freshwater Fish Acute Toxicity

Species	% ai	LC50 (ppm)	Toxicity Category	MRID No. Author/Year	Study Classification
Rainbow trout *(Oncorhynchus mykiss)*	90	42	slightly toxic	40098001 F.L. Mayer/1986	core
	70	99	slightly toxic	090427 McCann/1984	core
	97	76.77	slightly toxic	255025 Lamb/1972	core
	50	147	practically non-toxic	255025 Lamb/1972	core
Bluegill sunfish *(Lepomis macrochirus)*	90	92	slightly toxic	40098001 F.L. Mayer/1986	core
	97	75.96	slightly toxic	255025 Lamb/1972	core
	50	131.1	practically non-toxic	255025 Lamb/1972	core

These results indicate that metribuzin is slightly toxic to practically non-toxic to freshwater fish on an acute basis. The guideline requirement (72-1) is fulfilled (ACC # 255025, 40098001, and 090427).

b. Freshwater Fish, Chronic

A freshwater fish early life-stage test using the technical grade of the active ingredient is required for metribuzin because the end-use product may be applied directly to water or is expected to be transported to water from the intended use site, and the following conditions are met: (1) the pesticide is intended for use such that its presence in water is likely to be continuous or recurrent regardless of toxicity, (2) any aquatic acute LC50 or EC50 is less than 1 mg/l, (3) the EEC in water is equal to or greater than 0.01 of any acute LC50 or EC50 value, or, (4) the actual or estimated environmental concentration in water resulting from use is less than 0.01 of any acute LC50 or EC50 value and any one of the following conditions exist: studies of other organisms indicate the reproductive physiology of fish may be affected, physicochemical properties indicate cumulative effects, or the pesticide is persistent in water (e.g., half-life greater than 4 days). The

preferred test species is rainbow trout. Results of this test are tabulated below.

Table 16. Freshwater Fish Early Life-Stage Toxicity

Species	% ai	NOEC/LOEC (ppm)	MATC (ppm)	Endpoints Affected	MRID No. Author/Year	Study Classification
Rainbow trout *(Oncorhynchus mykiss)*	94	no NOEC LOEC=3.0	not determined	growth	42447801 Gagliano & Roney/1992	core

No NOEC was achieved in this study due to effects on growth at all levels tested. However, since the LOEC was above exposure estimates calculated at the time of the study, it was classified as core. The guideline requirement (72-4a) is fulfilled (MRID 42447801).

A freshwater fish life-cycle test using the technical grade of the active ingredient is not required for metribuzin.

(2) Freshwater Invertebrates

a. Freshwater Invertebrates, Acute

A freshwater aquatic invertebrate toxicity test using the technical grade of the active ingredient is required to establish the toxicity of a pesticide to invertebrates. The preferred test species is *Daphnia magna*. Results of this test are tabulated below.

Table 17. Freshwater Invertebrate Toxicity

Species	% ai	LC50/ EC50 (ppm)	Toxicity Category	MRID No. Author/Year	Study Classification
Waterflea *(Daphnia magna)*	93	4.2	moderately toxic	72083 Roney/1979	core
	84	98.5	slightly toxic	34016 1978	supplemental

The results indicate that metribuzin is moderately to slightly toxic to aquatic invertebrates on an acute basis. The guideline requirement (72-2) is fulfilled (ACC # 72083).

b. Freshwater Invertebrate, Chronic

A freshwater aquatic invertebrate life-cycle test

using the technical grade of the active ingredient is required for metribuzin since the end-use product may be applied directly to water or expected to be transported to water from the intended use site, and the following conditions are met: (1) the pesticide is intended for use such that its presence in water is likely to be continuous or recurrent regardless of toxicity, (2) any aquatic acute LC50 or EC50 is less than 1 mg/l, or, (3) the EEC in water is equal to or greater than 0.01 of any acute EC50 or LC50 value, or, (4) the actual or estimated environmental concentration in water resulting from use is less than 0.01 of any aquatic acute EC50 or LC50 value and any of the following conditions exist: studies of other organisms indicate the reproductive physiology of invertebrates may be affected, physicochemical properties indicate cumulative effects, or the pesticide is persistent in water (e.g., half-life greater than 4 days). The preferred test species is *Daphnia magna*. Results of this test are tabulated below.

Table 18. Freshwater Aquatic Invertebrate Life-Cycle Toxicity

Species	% ai	NOEC/LOEC (ppm)	MATC (ppm)	Endpoints Affected	MRID No. Author/Year	Study Classification
Waterflea *(Daphnia magna)*	93	NOEC=1.29 LOEC = 2.62	1.84	# offspring length	42447802 Gagliano & Bowers/1992	core

A NOEC was achieved for number of offspring and length; however, there were effects on weight at all levels tested, so a NOEC for weight was not achieved. The guideline requirement (72-4) is fulfilled (MRID # 42447802).

(3) Toxicity to Estuarine and Marine Animals

a. Estuarine and Marine Fish, Acute

Acute toxicity testing with estuarine/marine fish using the technical grade of the active ingredient is required for metribuzin because the end-use product is intended for direct application to the marine/estuarine environment or the active ingredient is expected to reach this environment because of its use in coastal counties. The preferred test species is sheepshead minnow. Results of these tests are tabulated below.

Table 19. Estuarine/Marine Fish Acute Toxicity

Species	% ai	LC50 (ppm)	Toxicity Category	MRID No. Author/Year	Study Classification
Sheepshead minnow *(Cyprinodon variegatus)*	92.6	85	slightly toxic	42094502 Nicholson & Suprenanat/1986	core

The results indicate that metribuzin is slightly toxic to estuarine/marine fish on an acute basis. The guideline requirement (72-3a) is fulfilled (MRID # 42094502).

b. Estuarine and Marine Fish, Chronic

An estuarine/marine fish early life-stage toxicity test using the technical grade of the active ingredient is not required for metribuzin.

c. Estuarine and Marine Invertebrates, Acute

Acute toxicity testing with estuarine/marine invertebrates using the technical grade of the active ingredient is required for metribuzin because the end-use product is intended for direct application to the marine/estuarine environment or the active ingredient is expected to reach this environment because of its use in coastal counties. The preferred test species are mysid shrimp and eastern oyster. Results of these tests are tabulated below.

Table 20. Estuarine/Marine Invertebrate Acute Toxicity

Species	% ai.	LC50/EC50 (ppm)	Toxicity Category	MRID No. Author/Year	Study Classification
Eastern oyster (shell deposition or embryo-larvae) *(Crassostrea virginica)*	92	42	slightly toxic	43851 1975	supplemental
	92	40.7	slightly toxic	106197 Heitmuller/1975	core
	92.6	49.8	slightly toxic	42094501 1986	core
	92.6	52 (shell dep.)	slightly toxic	47023411 Dionne & Suprenant/1986	supplemental
Pink shrimp *(Penaeus duorarum)*	92	48.3	slightly toxic	106197 Heitmuller/1975	core

The results indicate that metribuzin is slightly toxic to estuarine/marine invertebrates on an acute basis. The guideline requirements (72-3b and 72-3c) are fulfilled

(MRID # 106197 and 42094501).

c. Toxicity to Plants

(1) Terrestrial

Terrestrial plant testing (seedling emergence and vegetative vigor) is required for herbicides that have terrestrial non-residential outdoor use patterns and that may move off the application site through volatilization (vapor pressure $\geq 1.0 \times 10^{-5}$mm Hg at 25^{o}C) or drift (aerial, ground, or chemigation) and/or that may have endangered or threatened plant species associated with the application site.

Currently, terrestrial plant testing is not required for pesticides other than herbicides except on a case-by-case basis (e.g., labeling bears phytotoxicity warnings, incident data, or literature that demonstrate phytotoxicity).

For seedling emergence and vegetative vigor testing the following plant species and groups should be tested: (1) six species of at least four dicotyledonous families, one species of which is soybean (*Glycine max*), and the second of which is a root crop, and (2) four species of at least two monocotyledonous families, one of which is corn (*Zea mays*).

Terrestrial Tier II studies are required for all low dose herbicides (those with the maximum use rate of 0.5 lbs ai/A or less). Terrestrial plant testing is required for metribuzin because it is an herbicide with the majority of use rates at 0.5 lbs ai/A or less.

Tier II tests measure the response of plants, relative to a control, at five or more test concentrations. Results of Tier II toxicity testing on the technical material are tabulated below.

Table 21. Nontarget Terrestrial Plant Seedling Emergence Toxicity (Tier II)

Species	% ai	EC25 (lbs ai/A) Endpoint Affected	NOEC or EC05 (lbs ai/A) Endpoint Affected	MRID No. Author/Year	Study Classification
Monocot- corn	91.3	0.059 weight	0.056 weight	42447803 Burge/1992	core
Monocot- onion	91.3	0.020 survival	0.014 survival	42447803 Burge/1992	core
Monocot- wheat	91.3	0.024 % emer. & weight	0.014 weight	42447803 Burge/1992	core
Monocot- pea	91.3	not determined	0.113 weight	42447803 Burge/1992	core
Dicot- turnip	91.3	0.008 % emer.	0.007 %emer.	42447803 Burge/1992	core
Dicot- soybean	91.3	not determined	0.225 all	42447803 Burge/1992	core
Dicot- cotton	94.1	0.0423 weight	0.0281 weight	43208301 Johns/1994	core
Dicot- cucumber	91.3	0.029 height	0.014 height	42447803 Burge/1992	core
Dicot- tomato	91.3	not determined	0.113 survival	42447803 Burge/1992	core
Dicot- sorghum	91.3	0.043 weight	0.028 weight	42447803 Burge/1992	core

For Tier II seedling emergence, turnip is the most sensitive dicot, and onion and wheat are the most sensitive monocots. The guideline requirement (123-1) is fulfilled (MRID#43208301 and 42447803).

Table 22. Nontarget Terrestrial Plant Vegetative Vigor Toxicity (Tier II)

Species	% ai	EC25[1] (lbs ai/A) Endpoint Affected	NOEC or EC05 (lbs ai/A) Endpoint Affected	MRID No. Author/Year	Study Classification
Monocot- corn	91.3	not determined	0.090 none	42447803 Burge/1992	core
Monocot- onion	91.3	0.017 weight	0.0112 height/weight	42447803 Burge/1992	core
Monocot- wheat	91.3	0.041 weight	0.0225 weight	42447803 Burge/1992	core
Monocot- pea	91.3	not determined	0.0900 none	42447803 Burge/1992	core
Dicot- turnip	91.3	0.005 weight	0.0028 weight	42447803 Burge/1992	core
Dicot- soybean	91.3	not determined	0.0450 weight	42447803 Burge/1992	core
Dicot- cotton	91.3	0.016 weight	0.0028 weight	42447803 Burge/1992	core
Dicot- cucumber	91.3	0.024 weight	0.0112 weight	42447803 Burge/1992	core
Dicot- tomato	91.3	not determined	0.0900 none	424478703 Burge/1992	core
Dicot- sorghum	91.3	not determined	0.0450 weight	42447803 Burge/1992	core

[1] EC is the effective concentration. EC25 is 25% detrimental effect on plant growth (mass or rate).

For Tier II vegetative vigor, turnip is the most sensitive dicot and onion is the most sensitive monocot. The guideline requirement (123-1) is fulfilled (MRID#42447803).

(2) Aquatic

Aquatic plant testing is required for any herbicide that has outdoor non-residential terrestrial uses that may move off-site by runoff (solubility >10 ppm in water), by drift (aerial, ground, or chemigation), or that is applied directly to aquatic use sites (except residential). Terrestrial Tier II studies are required for all low dose herbicides (those with the maximum use rate of 0.5 lbs ai/A or less). The following species should be tested at Tier I: *Kirchneria subcapitata* and *Lemna gibba.* The following species should be tested at Tier II: *Kirchneria subcapitata, Lemna gibba, Skeletonema costatum, Anabaena flos-aquae,* and a freshwater diatom. Aquatic plant testing is required for metribuzin because it is an herbicide which is relatively mobile (K_{oc}=41), and many of

the uses are 0.5 lb ai/A or less.

Results of Tier II toxicity testing on the technical/TEP material are tabulated below.

Table 23. Nontarget Aquatic Plant Toxicity (Tier II)

Species	% ai	EC50 (ppm)	NOEC or EC05 (ppm)	MRID No. Author/Year	Study Classification
Vascular Plants					
Duckweed *Lemna gibba*	94.2	0.13	0.018	43893501 Boeri et al./1995	supplemental
Nonvascular Plants					
Green algae *Kirchneria subcapitata*	94.1	0.021	0.004	43133601 Gagliano & Orr/1994	core
Marine diatom *Skeletonema costatum*	93.5	0.0087	0.0058	43867701 Bowers/1995	core
Freshwater diatom *Navicula pelliculosa*	99.0	0.0119	0.0089	43826101 Bowers/1995	core
Blue-green algae *Anabaena flos-aquae*	94.2	0.017	0.0097	43893502 Boeri et al/1995	supplemental

The Tier II results indicate that *Skeletonema costatum* is the most sensitive non-vascular aquatic plant. The guideline requirement (123-2) is fulfilled for green algae, marine diatom and freshwater diatom (MRID43867701, 43133601, and 43826101). The guideline requirement (123-2) is not fulfilled for vascular plants and blue-green algae; however, enough information on aquatic plants is available to conduct a risk assessment.

2. Environmental Fate

a. Environmental Fate Assessment

Based on available data, the primary routes of degradation of metribuzin and its main degradates diketo metribuzin (DK) and deaminated diketo metribuzin (DADK) are microbial metabolism and photolytic degradation on soil. These compounds will be available for leaching to ground water and runoff to surface water in many use conditions. This is because metribuzin and its degradates are not volatile. In addition, while the rate of photodegradation is rapid for exposed chemicals, only approximately the top 1mm of soil is actually exposed to sunlight. Once in ground water, metribuzin is expected to persist due to its stability to hydrolysis and the lack of light penetration. Conversely, residues of metribuzin in surface water are not likely to persist in clear,

well-mixed, shallow surface water with good light penetration since parent metribuzin degrades rapidly by aqueous photolysis with a calculated half-life of 4.3 hours. However, if the surface water that receives metribuzin runoff contains significant sediments, metribuzin is expected to persist since it is stable to hydrolysis and since light penetration would be limited.

Parent metribuzin is very stable to abiotic hydrolysis and relatively stable to both aerobic and anaerobic soil metabolism ($T_{1/2}$'s of 106 and 112 days, respectively). Even though direct photolysis in water and on soil appear to degrade metribuzin rapidly in the laboratory ($T_{1/2}$'s of 4.3 hours and 2.5 days), only metribuzin that is on the surface of the soil is affected by photolysis. For that reason, persistence in field soil appears to be more affected by soil metabolism (aerobic and anaerobic) than by photolysis, with field half-lives of 40-128 days. Because of the potential for runoff, photolysis in H_2O results are critical. The major photolytic products were deaminated metribuzin in H_2O and pentylidene and hexylidene metribuzin on soil.

Metribuzin and its degradates diketo metribuzin (DK) and deaminated diketo metribuzin (DADK) are persistent and mobile in soil. They have also been found in ground water in 12 states as a result of normal agricultural applications done under a wide range of hydrogeological and climatic conditions. According to state monitoring data from Wisconsin, documented concentrations in ground water are as high as 54 ppb compared to the Health Advisory of 100 ppb. In a retrospective ground water monitoring study submitted to the Agency, metribuzin was detected in ground water at levels ranging up to 2.3 ppb metribuzin parent and up to 7.6 ppb total metribuzin residues. In surface waters, metribuzin and its degradates have been found in the Midwestern U.S. at several ppb.

b. Environmental Fate and Transport

(1) Degradation

Hydrolysis (161-1)

Metribuzin was stable in sterile aqueous buffer solutions (pH 5, 7, and 9) that were incubated in darkness at 25° C. The guideline requirement was fulfilled (TRID 47017-008).

Aqueous Photolysis (161-2)

Metribuzin had a half-life of 4.3 hours in pH 6.6 water irradiated with natural sunlight in Kansas City, MO at 25 ºC. The identified degradate was deaminated metribuzin (DA; major degradate), and 3 unknown degradates each comprised ≤5.2%. Metribuzin was stable in the dark controls. The guideline requirement was fulfilled (TRID 470173-007).

Soil Photolysis (161-3)

Metribuzin had a half-life of 2.5 days on sandy loam soil irradiated outdoors in Kansas City, Missouri at temperatures up to 31 ºC. The major degradates were deaminated metribuzin (DA), and the distinct photoproducts pentylidene metribuzin and hexylidene metribuzin. Metribuzin was stable in the dark controls. The guideline requirement was fulfilled (MRID 470173-009).

Aerobic Soil Metabolism (162-1)

Metribuzin degraded with a half-life of 106 days in sandy loam soil. The identified major degradates were deaminated, diketo metribuzin (DADK) and diketo metribuzin (DK). The identified minor degradates were deaminated metribuzin (DA), 2-methyl-DADK, 4-methyl-DADK, and 3-amino-DA. The guideline requirement was fulfilled (MRID 40367602).

Anaerobic Soil Metabolism (162-2)

Metribuzin had a half-life of 112 days following 30 days of anaerobic incubation. During the anaerobic portion of the study, the degradates identified were DADK, DA, DK, and 2-methyl-DADK. Seventy-eight to 88 % of all radioactivity was in the organic phase from the methanol extractions of soil and <5 % was in the aqueous phase. The guideline requirement is fulfilled (MRID 40367603).

(2) Mobility

Leaching-adsorption-desorption (163-1)

Unaged leaching-adsorption-desorption. Parent metribuzin was very mobile in sandy (0.58 % OC), sandy loam (0.64 % OC), silt loam (1.68 % OC), and clay loam (1.28 % OC) soils with Freundlich K_{ads} values of 0.25,

0.02, 0.22, and 0.20, respectively. Freundlich K_{des} values were 0.56, 0.14, 0.51, and 0.41, respectively. K_{ocads} were 47, 3, 15, and 17 and K_{ocdes} values were 106, 24, 33, and 36, respectively. The N values were 0.92, 0.66, 0.86, and 0.94 for adsorption and 0.76, 0.60, 0.77, and 0.84 for desorption, respectively. The guideline requirement is fulfilled (MRID 42283001).

Aged leaching-adsorption-desorption. DADK was very mobile in Astatula sand (0.35 % OC), Arkport sandy loam (1.57 % OC), Drummer silt loam (1.92 % OC), and Trix clay (0.52 % OC) soils with Freundlich K_{ads} values of 0.13, 0.47, 0.51, and 0.19, respectively. K_{des} values were 0.21, 1.1, 1.2, and 0.61, respectively. K_{ocads} values were 37, 30, 27, and 36 and K_{ocdes} values were 60, 70, 63, and 117, respectively. N values were 0.86, 0.94, 0.93, and 0.96 for adsorption and 0.80, 0.99, 0.95, and 1.09 for desorption, respectively. The guideline requirement is fulfilled (MRID 43058501).

DK was very mobile in Astatula sand (0.35 % OC), Arkport sandy loam (1.57 % OCM), Drummer silt loam (1.92 % OC), and Trix clay (0.52 % OC) soils with Freundlich K_{ads} values of 0.15, 0.70, 0.95, and 0.29, respectively. K_{des} values were 0.82, 3.3, 1.13, and 0.56, respectively. K_{ocads} values were 43, 45, 50, and 56 and K_{ocdes} values were 236, 211, 59, and 107, respectively. N values were 0.94, 1.0, 0.91, and 0.96 for adsorption and 0.94, 0.1.07, 0.85, and 0.87 for desorption, respectively.

Aged soil column leaching. Metribuzin and its oxidative degradates were very mobile in an aged soil column leaching study. Kansas sandy loam soil spiked with 7.4 ppm of metribuzin was added to sandy loam, silt loam, and silty clay soils packed in 30-cm columns and leached with 50.8 cm of water. The amount of applied radioactivity in the leachate was 23, 42, 28, and 55 % in the silt loam, silty clay, Kansas sandy loam, and California sandy loam. Most of the radioactivity in the leachate was parent metribuzin, and the degradates DA, DADK, and DK ranged from 1-3.1 % of the applied radioactivity. The guideline requirement is fulfilled (Accession # 263702).

(3) Field Dissipation

Terrestrial (164-1)

The calculated half-lives of metribuzin (Sencor 75 DF) in sandy loam soils in California were 128 and 40 days at Watsonville and Fresno, respectively. No leaching of metribuzin or its oxidative degradate DADK were observed below 12 inches of depth at either site except for some detections that were probable

contamination or sampling error in the Fresno site. The other degradates of interest, DA and DK, were not found below 6 inches of depth (MRID 42236101).

The calculated half-lives of metribuzin (Sencor 75 DF) in silty clay loam, muck sandy loam, muck clay loam, and sandy loam soils in Maine, Michigan, and California were 58 to 107 days (MRID 40380901).

The guideline requirement for the terrestrial field dissipation study (164-1) is fulfilled.

Retrospective Ground-Water Monitoring (166-2)

Metribuzin and two of its degradates (DK and DADK) were detected in ground water in a small scale retrospective study conducted in Portage County, Wisconsin on a minor use crop (potatoes). Concentrations ranged up to 2.3 ppb parent metribuzin and 7.6 ppb total residues. Results indicated that metribuzin and its metabolites were extremely persistent under the conditions illustrated by this study, and residues were still detected in ground water over two years after an application (DP Barcode S261873). New monitoring information in Wisconsin indicates that metribuzin can leach to ground water at concentration up to 54 ppb or 54 percent of the lifetime Health Advisory. Residues up to 21 ppb have been detected in Wisconsin drinking water wells. For this reason, the registrant is required to determine those areas that are vulnerable to ground-water contamination by metribuzin and recommend restrictions for its use to prevent continued contamination at these levels

(4) Spray Drift

The registrant is required to submit data to support the Spray Drift data requirements because aerial application of metribuzin may cause damage to nontarget plants due to spray drift. Bayer Corporation is a member of the Spray Drift Task Force (SDTF), and therefore, may elect to satisfy these data requirements through the SDTF. If the registrant wishes to satisfy these data requirements in this manner, the procedures outlined in PR Notice 90-3 should be followed.

c. Water Resources

(1) Ground Water

Background

The requirement for a large-scale ground-water monitoring study for metribuzin was issued in the June 1985 Registration Standard. In an amendment to the Standard, the Agency requested two studies: one to be conducted on a minor use crop and the other to be conducted on a major use crop. In 1987, Bayer (then Mobay) had not yet initiated the studies, and the requirement was changed to a small-scale retrospective study. This monitoring study was designed to evaluate the impact of continued metribuzin use on ground water in a vulnerable area. One small-scale retrospective study was conducted from 1988 to 1989 in Portage County, Wisconsin on potatoes. Results indicated that metribuzin and its metabolites were extremely persistent under the conditions illustrated by this study. Over one year after the final metribuzin application, up to 2.3 ppb metribuzin parent and up to 7.6 ppb total metribuzin residues were detected in ground water on the site. Up to 1.4 ppb metribuzin and 6.7 ppb total residues were still present over two years after the metribuzin application.

Although the small-scale retrospective study on a major use crop has not been conducted, the Agency believes that the determination of those areas that are vulnerable to ground-water contamination by metribuzin will provide more useful information.

Occurrence of Metribuzin in Ground Water

The Pesticides and Ground Water Database (PGWDB) indicates that metribuzin has been detected in ground water in 12 states including Connecticut, Iowa, Illinois, Kansas, Maine, Minnesota, Missouri, New Jersey, Ohio, South Dakota, Virginia, and Wisconsin because of probable nonpoint source use. Concentrations in ground water range up to 25.1 ppb (EPA, 1992). Monitoring for metribuzin in 11 other states did not yield any detections (EPA, 1992).

Recent evidence suggests that metribuzin is likely to be detected in ground waters that are vulnerable to contamination in areas where it is used. According to some of the initial results from the National Water Quality Assessment (NAWQA) Program of the

U.S. Geological Survey (Kolpin and others, in preparation), metribuzin was detected in shallow ground water in both urban and agricultural areas, but the concentrations were low. The herbicide was detected at or above 0.004 ppb in five of the nine agricultural settings examined. The maximum concentration measured in these studies was 0.30 ppb.

In the Central Sands area of Wisconsin, metribuzin is used primarily on potatoes. In this area, metribuzin has been detected in 21 out of 27 monitoring wells and in 91 private drinking water wells. Metribuzin concentrations in ground water are also higher here; up to 54 ppb has been found in the monitoring wells and up to 21 ppb found in the drinking water wells. However, most detections range from about 1 to 5 ppb and the chemical appears to dissipate quickly in the Central Sands area.

Ground-Water Exposure Assessment

Risk Concerns:

Quality of Ground-water resources:

Metribuzin has been detected in a variety of environments in 12 states because of nonpoint source use, although generally below toxicity thresholds for humans and animals. Considering the widespread use of metribuzin and its detection in many states, the Agency is concerned about the degradation of water quality that occurs in metribuzin use areas.

Non-target terrestrial plants:

Concentrations of metribuzin in ground water have not exceeded the LOC for terrestrial plants. However, levels detected in ground water have approached approximately 40 percent of the concentration that could present a risk. Therefore, although there is not a concern at the present time, in areas where irrigation water is contaminated with metribuzin, residues could pose a threat to plants.

Recommendations

1. Metribuzin meets the triggers for classification as a Restricted Use compound for ground-water concerns, as it

is stated in the proposed Restricted Use rule. When the rule becomes final, metribuzin may be considered a candidate for restricted use for ground-water concerns.

2. Metribuzin is clearly a compound that will leach to ground water in vulnerable areas. At the present time, most of the concentrations found in ground water are low compared to the levels of concern for human and ecosystem health. However, in some areas, metribuzin residues have been found in ground water at relatively high levels and the Agency is concerned that these concentrations are 54 percent of the HAL. In addition, concentrations up to 21 percent of the HAL have been found in drinking water wells. For these reasons, the registrant must examine the metribuzin use area, determine those areas that are vulnerable to ground-water contamination by metribuzin and recommend restrictions for its use to prevent continued contamination at these levels.

3. The Agency is requiring that the registrant develop educational materials to inform applicators about the potential problems that metribuzin poses to ground-water quality.

(2) Surface Water

Metribuzin can contaminate surface water at application via spray drift. Substantial fractions of applied metribuzin could be available for runoff to surface waters for several weeks to months post-application (aerobic soil metabolism half-life of 40 and 106 days, terrestrial field dissipation half-lives of 15 to 149 days). Although metribuzin is susceptible to photodegradation on soil (half-life = 2.5 days), its much longer half-lives in terrestrial field dissipation studies reflect that only the metribuzin in approximately the top 1 mm of soil is probably exposed to sunlight. The low soil/water partitioning of metribuzin (SCS/ARS database K_{oc} = 60, Freundlich binding constants < 1) indicates that most of metribuzin runoff will occur via dissolution in runoff water (as opposed to adsorption to eroding soil particulates).

Metribuzin is susceptible to direct aqueous photolysis (half-life 4.3 hours) which should limit its persistence in the water column of well mixed, shallow surface water with low light

attenuation. However, its resistance to abiotic hydrolysis, low volatilization potential (Henry's Law constant = 3.5 X 10^{-11} atm*m^3/mol), only moderate susceptibility to aerobic and anaerobic metabolism and only slightly greater susceptibility to anaerobic metabolism (anaerobic soil metabolism half-life of 25-59 days) should make it more persistent in other types of surface water, particularly those with rather long hydrological residence times. Freundlich soil/water binding constants < 1 and Freundlich exponents close to one indicate that dissolved concentrations of metribuzin in sediment pore water will be greater than concentrations adsorbed to suspended and bottom sediment. Although dissolved metribuzin concentrations in the water column will be lower than dissolved concentrations in the sediment pore water they may be at least somewhat comparable to the concentrations adsorbed to suspended and bottom sediment.

The major degradates of metribuzin in soil include diketo metribuzin (DK) and deaminated diketo metribuzin (DADK). Both are reported to exhibit similar mobility and persistence to that of the parent. Consequently, like metribuzin, both DK and DADK are expected to:

(1) be available for runoff for extended periods due to their persistence in soil,
(2) run off primarily via dissolution in runoff water as opposed to adsorption to eroding soil,
(3) have dissolved concentrations in the water column comparable to concentrations adsorbed to suspended and bottom sediment.

The USGS (Goolsby/Thurman 1991; Goolsby 1995; Goolsby 1996) conducted reconnaissance surveys of numerous midwestern streams in 1989, 1990, 1994, and 1995 to determine pre-application, post-application, and Fall concentrations of various herbicides including metribuzin. Pre-application and Fall metribuzin concentrations were much less than 1 ug/L and generally below the detection limit of 0.05 ug/L. Since post-application samples were generally collected during the first major runoff event after application, the concentrations in those samples may often approximately represent peak concentrations. The 90th percentile (upper 10th percentile) post-application metribuzin concentrations for 1989, 1994, and 1995 were 1.4, 1.2 and 0.5 ug/L, respectively. The 90th percentile concentrations for 1989 and

1994 were comparable, but the 1989 data for 129 streams included nine concentrations (from 2.2 to 7.6 ug/L) greater than the 1994 and 1995 maximums (1.9 and 1.4, respectively) for 50 of those streams.

Based upon data on other major use herbicides, peak metribuzin concentrations in streams may generally be higher than in rivers and reservoirs but elevated levels of metribuzin may be present longer in rivers and reservoirs. Concentrations in edge of the field farm ponds may be substantially greater than in streams.

The USGS (Coupe et al 1995) sampled 8 locations on rivers within the Mississippi Basin from April 1991 through September 1992 and analyzed the samples for numerous insecticides and herbicides including metribuzin. Samples were collected twice per week from May 6 to July 15 1991, once per every two weeks from November 1991 to February 1992, and once per week at other times. Filtered (0.7 u) (dissolved) metribuzin was detected above a detection limit of 0.05 ug/L at all of the locations, but in less than 3% to 28% of the samples at each location. The maximum concentration detected was 0.38 ug/L. Only 5 additional samples had metribuzin concentrations > 0.2 ug/L.

The USGS (Goolsby et al 1993) sampled each of 76 midwestern reservoirs at least eight times from April 1992 through September 93 and analyzed them for various herbicide degradates and herbicides including metribuzin. Metribuzin was detected above a detection limit of 0.05 ug/L in 36/732 = 4.9% of the 732 samples collected from 15/76 = 20% of the 77 reservoirs samples. The only concentrations > 0.5 ug/L were 0.67 ug/L (Huntington Lake IN), 0.67 ug/L (Mississinewa Lake IN), and 0.91 ug/L, and 1.3 ug/L (Salamonie Lake IN).

The State of Illinois (Taylor 1994) recently summarized pesticide data for surface water samples collected from 34 stations from 10/1/85 through 2/15/94. A total of 1278 samples were analyzed for metribuzin at a detection limit of 0.05 ug/L. Apparently assuming non-detects were equal to the detection limit, Illinois reported maximum, 95th percentile and mean unfiltered sample (total) metribuzin concentrations of 3.7 ug/L, 0.11 ug/L, and 0.065 ug/L, respectively.

3. Exposure and Risk Characterization

a. Ecological Exposure and Risk Characterization

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

RQ = EXPOSURE/TOXICITY

RQs are then compared to OPP's levels of concern (LOCs). These LOCs are criteria used by OPP to indicate potential risk to nontarget organisms and the need to consider regulatory action. The criteria indicate that a pesticide used as directed has the potential to cause adverse effects on nontarget organisms. LOCs currently address the following risk presumption categories: (1) **acute high** - potential for acute risk is high and regulatory action may be warranted in addition to restricted use classification (2) **acute restricted use** - the potential for acute risk is high, but this may be mitigated through restricted use classification (3) **acute endangered species** - the potential for acute risk to endangered species is high, and regulatory action may be warranted, and (4) **chronic risk** - the potential for chronic risk is high, and regulatory action may be warranted. Currently, the Agency has no procedures for assessing chronic risk to plants, acute or chronic risks to nontarget insects, or chronic risk from granular/bait formulations to mammalian or avian species.

The ecotoxicity test values (i.e., measurement endpoints) used in the acute and chronic risk quotients are derived from the results of required studies. Examples of ecotoxicity values derived from the results of short-term laboratory studies that assess acute effects are: (1) LC50 (fish and birds) (2) LD50 (birds and mammals (3) EC50 (aquatic plants and aquatic invertebrates) (4) EC25 (terrestrial plants) and (5) EC05 or NOEC (endangered plants). Examples of toxicity test effect levels derived from the results of long-term laboratory studies that assess chronic effects are: (1) LOEC (birds, fish, and aquatic invertebrates) (2) NOEC (birds, fish and aquatic invertebrates) and (3) MATC (fish and aquatic invertebrates). For birds and mammals, the NOEC value is generally used as the ecotoxicity test value in assessing chronic effects. Other values may be used when justified. Generally, the MATC (defined as the geometric mean of the NOEC and LOEC) is used as the ecotoxicity test value in assessing chronic effects to fish and aquatic invertebrates. However, the NOEC is used if the

measurement end point is production of offspring or survival.

Risk presumptions, along with the corresponding RQs and LOCs are tabulated below.

Table 24. Risk Presumptions for Terrestrial Animals

Risk Presumption	RQ	LOC
Birds		
Acute High Risk	EEC[1]/LC50 or LD50/sqft or LD50/day[3]	0.5
Acute Restricted Use	EEC/LC50 or LD50/sqft or LD50/day (or LD50 < 50 mg/kg)	0.2
Acute Endangered Species	EEC/LC50 or LD50/sqft or LD50/day	0.1
Chronic Risk	EEC/NOEC	1
Wild Mammals		
Acute High Risk	EEC/LC50 or LD50/sqft or LD50/day	0.5
Acute Restricted Use	EEC/LC50 or LD50/sqft or LD50/day (or LD50 < 50 mg/kg)	0.2
Acute Endangered Species	EEC/LC50 or LD50/sqft or LD50/day	0.1
Chronic Risk	EEC/NOEC	1

[1] abbreviation for Estimated Environmental Concentration (ppm) on avian/mammalian food items
[2] $\frac{mg/ft^2}{LD50 * wt. of bird}$ [3] $\frac{mg\ of\ toxicant\ consumed/day}{LD50 * wt. of bird}$

Table 25. Risk Presumptions for Aquatic Animals

Risk Presumption	RQ	LOC
Acute High Risk	EEC[1]/LC50 or EC50	0.5
Acute Restricted Use	EEC/LC50 or EC50	0.1
Acute Endangered Species	EEC/LC50 or EC50	0.05
Chronic Risk	EEC/MATC or NOEC	1

[1] EEC = (ppm or ppb) in water

Table 26. Risk Presumptions for Plants

Risk Presumption	RQ	LOC
	Terrestrial and Semi-Aquatic Plants	
Acute High Risk	EEC[1]/EC25	1
Acute Endangered Species	EEC/EC05 or NOEC	1
	Aquatic Plants	
Acute High Risk	EEC[2]/EC50	1
Acute Endangered Species	EEC/EC05 or NOEC	1

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

(1) Exposure and Risk to Nontarget Terrestrial Animals

For pesticides applied as a nongranular product (e.g., liquid, dust), the estimated environmental concentrations (EECs) on food items following product application are compared to LC50 values to assess risk. The predicted 0-day maximum and mean residues of a pesticide that may be expected to occur on selected avian or mammalian food items immediately following a direct single application at 1 lb ai/A are tabulated below.

Table 27. Estimated Environmental Concentrations on Avian and Mammalian Food Items (ppm) Following a Single Application at 1 lb ai/A)

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

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

Predicted residues (EECs) resulting from multiple applications are calculated in various ways. For the purpose of metribuzin the following procedure was used:

(a) Birds

The acute risk quotients for broadcast applications of

nongranular products are tabulated below.

Table 28. Avian Acute Risk Quotients for a Single Application of Nongranular Products (Broadcast) Based on a quail LC50 of 4000.

Site/Application Method	Application Rate (lbs ai/A)	Food Items	Maximum EEC (ppm)	LC50 (ppm)	Acute RQ (EEC/LC50)
sugarcane aerial	6.0	Short grass	1,440	4000	0.36
		Tall grass	660	4000	0.17
		Broadleaf plants/Insects	810	4000	0.20
		Seeds	90	4000	0.02
potato ground	0.9975	short grass	239	4000	0.06
		Tall grass	110	4000	0.03
		Broadleaf plants/Insects	135	4000	0.03
		Seeds	15	4000	0.00
sugarcane ground	4.025	Short grass	966	4000	0.24
		Tall grass	443	4000	0.11
		Broadleaf plants/Insects	543	4000	0.14
		Seeds	60	4000	0.02

Table 29. Avian Acute Risk Quotients for Multiple Applications o f Nongranular Products (Broadcast) Based on a quail LC50 of 4000 ppm. EECs were calculated with the FATE program using the soil metabolic half-life of 106 days.

Site/Application Method	Application Rate in lbs ai/A (No. of Applications)	Food Items	Maximum EEC (ppm)	LC50 (ppm)	Acute RQ (EEC/LC50)
turf ground	0.5 (2)	Short grass	235	4000	0.06
		Tall grass	108	4000	0.03
		Broadleaf plants/Insects	132	4000	0.03
		Seeds	15	4000	0.00
sugarcane ground	4 (2)	Short grass	1836	4000	0.46
		Tall grass	842	4000	0.21
		Broadleaf plants/Insects	1033	4000	0.26
		Seeds	115	4000	0.03

The results indicate that for broadcast applications of nongranular products, avian acute restricted use and endangered species levels of concern are exceeded at registered maximum application rates equal to or above 4.0 lbs ai/A.

The chronic risk quotients for broadcast applications of nongranular products are tabulated below.

Table 30. Avian Chronic Risk Quotients for Nongranular Products (Broadcast) Based on a mallard reproduction NOEC of 368 ppm.

Site/Application Method	Application Rate in lbs ai/A (No. of Applications)	Food Items	Maximum EEC (ppm)	NOEC (ppm)	Chronic RQ (EEC/NOEC)
Sugarcane aerial	4 (2)	Short grass	1836	368	4.99
		Tall grass	842	368	2.29
		Broadleaf plants/Insects	1033	368	2.81
		Seeds	115	368	0.31
Turf ground	0.5 (2)	Short grass	235	368	0.64
		Tall grass	107	368	0.29
		Broadleaf plants/Insects	132	368	0.36
		Seeds	15	368	0.04

The above results indicate that for broadcast applications of nongranular products, the avian chronic level of concern is exceeded at registered maximum application rates equal to or above 4.0 lbs ai/A. If the bobwhite growth NOEC of 62 ppm is used, all rates equal to or greater than 0.5 would exceed the chronic level of concern; however, since there was some doubt whether the effects seen on hatchling growth in the bobwhite study were truly treatment-related, and no effects of this nature were observed in the mallard study, the mallard reproductive NOEC of 368 ppm was used.

(b) Mammals

Birds and mammals have similar responses to xenobiotics, their differences being more quantitative rather than qualitative. Since metribuzin does not present an acute risk to endangered birds, mammals are also presumed to be protected.

Estimating the potential for adverse effects to wild mammals is based upon EEB's draft 1995 SOP of mammalian risk assessments and methods used by Hoerger and Kenaga (1972) as modified by Fletcher *et al.* (1994). The concentration of metribuzin in the diet that is expected to be acutely lethal to 50% of the test population (LC50) is determined by dividing the LD50

value (usually rat LD50) by the percent of body weight consumed. A risk quotient is then determined by dividing the EEC by the derived LC50 value. Risk quotients are calculated for three separate weight classes of mammals (15, 35, and 1000 g), each presumed to consume four different kinds of food (grass, forage, insects, and seeds). The acute risk quotients for broadcast applications of nongranular products are tabulated below.

Table 31. Mammalian (Herbivore/Insectivore) Acute Risk Quotients for Single Application of Nongranular Products (Broadcast) Based on a rat LD50 of 2200 mg/kg.

Site/ Application Method/ Rate in lbs ai/A	Body Weight (g)	% Body Weight Consumed	Rat LD50 mg/kg	EEC Short Grass	EEC Forage & Small Insects	EEC Large Insects	Acute RQ Short Grass	Acute RQ Forage & Small Insects	Acute RQ Large Insects
Sugarcane aerial									
6	15	95	2200	1440	810	90	0.62	0.35	0.04
6	35	66	2200	1440	810	90	0.43	0.24	0.03
6	1000	15	2200	1440	810	90	0.10	0.06	0.01
Potato aerial									
1	15	95	2200	240	135	15	0.10	0.06	0.01
1	35	66	2200	240	135	15	0.07	0.04	0.00
1	1000	15	2200	240	135	15	0.02	0.00	0.00

[1] $RQ = \frac{\text{EEC (mg/kg)}}{\text{LD50 (mg/kg)/ \% Body Weight Consumed}}$

Table 32. Mammalian (Granivore) Acute Risk Quotients for Single Application of Nongranular Products (Broadcast) Based on a rat LD50 of 2200 mg/kg.

Site/ Application Method/Rate in lbs ai/A	Body Weight (g)	% Body Weight Consumed	Rat LD50 (mg/kg)	EEC Seeds	Acute RQ Seeds
Sugarcane aerial					
6	15	21	2200	90	0.01
6	35	15	2200	90	0.01
6	1000	3	2200	90	0.00
Potato aerial					
1	15	21	2200	15	0.00
1	35	15	2200	15	0.00
1	1000	3	2200	15	0.00

[1] $RQ = \frac{\text{EEC (mg/kg)}}{\text{LD50 (mg/kg)/ \% Body Weight Consumed}}$

Table 33. Mammalian (Herbivore/Insectivore) Acute Risk Quotients Multiple Applications of Nongranular Products (Broadcast) Based on a rat LD50 of 2200 mg/kg.

Site/ App. Method/ Rate in lbs ai/A (No. of Apps.)	Body Weight (g)	% Body Weight Consumed	Rat LD50 mg/kg	EEC Short Grass	EEC Forage & Small Insects	EEC Large Insects	Acute RQ Short Grass	Acute RQ Forage & Small Insects	Acute RQ Large Insects
Sugarcane aerial									
4 (2)	15	95	2200	1836	1033	115	0.79	0.45	0.05
4 (2)	35	66	2200	1836	1033	115	0.55	0.31	0.03
4 (2)	1000	15	2200	1836	1033	115	0.13	0.07	0.01
Turf ground									
0.5 (2)	15	95	2200	235	132	15	0.10	0.06	0.01
0.5 (2)	35	66	2200	235	132	15	0.07	0.04	0.00
0.5 (2)	1000	15	2200	235	132	15	0.02	0.01	0.00

[1] $RQ = \frac{\text{EEC (mg/kg)}}{\text{LD50 (mg/kg)/ \% Body Weight Consumed}}$

Table 34. Mammalian (Granivore) Acute Risk Quotients for Multiple Applications Nongranular Products (Broadcast) Based on a rat LD50 of 2200 mg/kg.

Site/ App. Method/ Rate in lbs ai/A (No. of Apps.)	Body Weight (g)	% Body Weight Consumed	Rat LD50 (mg/kg)	EEC Seeds	Acute RQ Seeds
sugarcane aerial					
4 (2)	15	21	2200	115	0.01
4 (2)	35	15	2200	115	0.01
4 (2)	1000	3	2200	115	0.00
turf ground					
0.5 (2)	15	21	2200	15	0.00
0.5 (2)	35	15	2200	15	0.00
0.5 (2)	1000	3	2200	15	0.00

[1] $RQ = \frac{\text{EEC (mg/kg)}}{\text{LD50 (mg/kg)/ \% Body Weight Consumed}}$

The results indicate that for broadcast applications of nongranular products, acute high risk LOCs are exceeded for small herbivorous/insectivorous mammals at application rates greater than or equal to 4.0 lbs ai/A. Restricted use levels of concern are

also exceeded for small herbivorous/insectivorous mammals at application rates greater than or equal to 4.0 lbs ai/A. Endangered species levels of concern are exceeded for herbivorous/insectivorous small mammals at application rates greater than single applications of 1.0 lb ai/A or multiple applications of 0.5 lbs ai/A or greater.

The chronic risk quotients for broadcast applications of nongranular products are tabulated below.

Table 35. Mammalian Chronic Risk Quotients for Nongranular Products (Broadcast) Based on a rat NOEC of 30 ppm in a 2-generation reproduction study. EECs were generated using the FATE program, using the aerobic soil metabolism half-life of 106 days.

Site/Application Method	Application Rate in lbs ai/A (No. of Apps.)	Food Items	Maximum EEC (ppm)	NOEC (ppm)	Chronic RQ (EEC/NOEC)
Sugarcane aerial	4 (2)	Short grass	1836	30	61.20
		Tall grass	842	30	28.07
		Broadleaf plants/Insects	1033	30	34.43
		Seeds	115	30	3.83
Potato ground	1 (1)	Short grass	240	30	8.00
		Tall grass	110	30	3.67
		Broadleaf plants/Insects	135	30	4.50
		Seeds	15	30	0.50
Turf ground	0.5 (2)	Short grass	235	30	7.83
		Tall grass	107	30	3.57
		Broadleaf plants/Insects	132	30	4.4
		Seeds	15	30	0.5

The above results indicate that for broadcast applications of nongranular products, the chronic level of concern for small mammals is exceeded at registered application rates equal to or above 0.5 lbs ai/A.

(c) Insects

Currently, the Agency has no procedure for assessing risk to nontarget insects. Results of acceptable studies are used for

recommending appropriate label precautions.

(1) Exposure and Risk to Nontarget Freshwater Aquatic Animals

The Agency calculates EECs using the GENeric Expected Environmental Concentration Program (GENEEC). The resultant EECs, termed GEECs, are used for assessing acute and chronic risks to aquatic organisms. Acute risk assessments are performed using either 0-day GEEC values for single applications or peak (GEEC) values for multiple applications. Chronic risk assessments are performed using the 21-day GEECs for invertebrates and 56-day GEECs for fish.

The GENEEC program uses a few basic environmental fate chemical parameters and pesticide label application information to provide a rough estimate of the expected environmental concentrations following treatment of 10 hectares. The model calculates the concentration of pesticide in a one hectare, two meter deep pond, taking into account the following: (1) adsorption to soil or sediment (2) soil incorporation (3) degradation in soil before washoff to a water body and (4) degradation within the water body. The model also accounts for direct deposition of spray drift into the water body (assumed to be 1% and 5% of the application rate for ground and aerial applications, respectively). (When multiple applications are permitted: The interval between applications is included in the calculations. The environmental fate parameters used in the model for this pesticide are: soil K_{OC} = 41, solubility = 1200 ppm, aerobic soil metabolism half-life = 106 days, hydrolysis (n/a--"stable"), water photolysis = 4.3 hours, and aquatic metabolism (n/a). GEECs are tabulated below.

Table 36. Estimated Environmental Concentrations (EECs) For Aquatic Exposure

Site	Application Method	Application Rate (lbs ai/A)	# of Apps./ Interval Between Apps.	Initial (PEAK) EEC (ppm)	21-day EEC (ppm)	56-day EEC (ppm)
GENEEC						
Sugarcane	aerial application of liquid formulation	6.00	1	0.39	0.24	0.12
Sugarcane	ground unincorporated	4.00	2 (14 days)	0.07	0.13	0.10
Turf	ground unincorporated	0.50	2 (7 days)	0.024	0.043	0.034
Peas	ground incorporated	0.50	1	0.024	0.015	0.008

(a) Freshwater Fish

Acute and chronic risk quotients are tabulated below.

Table 37. Risk Quotients for Freshwater Fish Based On a Rainbow Trout LC50 of 42 ppm and a Rainbow Trout LOEC of 3.0 ppm.

Site/ Application Method/Rate in lbs ai/A (No. of Apps.)	LC50 (ppm)	LOEC (ppm)	EEC Initial/Peak (ppm)	EEC 56-Day (ppm)	Acute RQ (EEC/LC50)	Chronic RQ (EEC/NOEC or MATC)
sugarcane/aerial 6 (1)	42	3	0.39	0.12	0.01	0.04
sugarcane/ground unincorp. 4 (2)	42	3	0.07	0.10	0.00	0.03
turf/ground unincorp. 0.5 (2)	42	3	0.024	0.034	0.00	0.01
peas/ground incorp. 0.5 (1)	42	3	0.024	0.008	0.00	0.00

The results indicate that no acute or chronic levels of concern for freshwater fish are exceeded at any registered application rate.

(b) Freshwater Invertebrates

The acute and chronic risk quotients are tabulated below.

Table 38. Risk Quotients for Freshwater Invertebrates Based On a Daphnid EC50 of 4.2 ppm and a Daphnid NOEC of 1.29 ppm.

Site/ Application Method/ Rate in lbs ai/A (No. of Apps.)	LC50 (ppm)	NOEC (ppm)	EEC Initial/Peak (ppm)	EEC 21-Day Average	Acute RQ (EEC/LC50)	Chronic RQ (EEC/NOEC or MATC)
sugarcane/aerial 6 (1)	4.2	1.29	0.39	0.12	0.09	0.09
sugarcane/ground unincorp. 4 (2)	4.2	1.29	0.07	0.10	0.02	0.08
turf/ground unincorp. 0.5 (2)	4.2	1.29	0.024	0.043	0.00	0.01
peas/ground incorp. 0.5 (1)	4.2	1.29	0.024	0.008	0.01	0.01

The results indicate that no acute or chronic level of concern is exceeded for freshwater invertebrates at any registered application rate.

(c) Estuarine and Marine Animals

The acute risk quotients are tabulated below.

Table 39. Risk Quotients for Estuarine/Marine Fish Based on a Sheepshead Minnow LC50 of 85 ppm.

Site/ Application Method	Rate in lbs ai/A (No. of Apps.)	LC50 (ppm)	EEC Initial/ Peak (ppm)	Acute RQ EEC/LC50
Sugarcane/ aerial	6 (1)	85	0.39	0.00
Sugarcane/ ground unincorp.	4 (2)	85	0.07	0.00
Turf/ ground unincorp.	0.5 (2)	85	0.024	0.00
Peas/ ground incorp.	0.5 (1)	85	0.024	0.00

The results indicate that no acute level of concern is exceeded for estuarine/marine fish at any registered application rate.

The acute risk quotients for estuarine/marine

invertebrates are calculated below.

Table 40. Risk Quotients for Estuarine/Marine Aquatic Invertebrates Based on a Oyster EC50 of 40.7 ppm.

Site/ Application Method	Rate in lbs as/A (No. of Apps.)	LC50 (ppm)	EEC Initial/ Peak (ppm)	Acute RQ (EEC/LC50)
Sugarcane/ aerial	6 (1)	40.7	0.39	0.01
Sugarcane/ ground unincorp.	4 (2)	40.7	0.07	0.00
Turf/ ground unincorp.	0.5 (2)	40.7	0.024	0.00
Peas/ ground incorp.	0.5 (1)	40.7	0.024	0.00

The results indicate that no acute level of concern is exceeded for estuarine invertebrates any registered application rate.

(2) Exposure and Risk to Nontarget Plants

(a) Terrestrial and Semi-aquatic

Terrestrial and semi-aquatic plants may be exposed to pesticides from runoff, spray drift or volatilization. Semi-aquatic plants are those that inhabit low-lying wet areas that may be dry at certain times of the year. The Agency's runoff scenario is: (1) based on a pesticide's water solubility and the amount of pesticide present on the soil surface and its top one inch (2) characterized as "sheet runoff" (one treated acre to an adjacent acre) for terrestrial plants (3) characterized as "channelized runoff" (10 treated acres to a distant low-lying acre) for semi-aquatic plants and (4) based on % runoff values of 0.01, 0.02, and 0.05 for water solubility of <10 ppm, 10-100 ppm, and >100 ppm, respectively.

Spray drift exposure from ground application is assumed to be 1% of the application rate. Spray drift from aerial, airblast, forced-air, and chemigation applications is assumed to be 5% of the application rate.

EECs are calculated for the following application

methods: (1) unincorporated ground applications, (2) incorporated ground application, and (3) aerial, airblast, forced-air, and chemigation applications. Estimated environmental concentrations for terrestrial and semi-aquatic plants are tabulated below.

Table 41. Estimated Environmental Concentrations (lbs ai/A) For Terrestrial and Semi-Aquatic Plants for a Single Application

Site/ Application Method/No. of Apps./ Rate of Application in lbs ai/A	Minimum Incorporation Depth (in)	Runoff Value	Sheet Run-off (lbs ai/A)	Channelized Run-off (lbs ai/A)	Drift (lbs ai/A)	Total Loading to Adjacent Area (Sheet Run-off+Drift)	Total Loading to Semi-aquatic Area (Channel Run-off+ Drift)
Sugarcane Unincorporated aerial							
6.0		0.05	0.30	3.00	0.06	0.36	3.06
Peas Incorporated Ground							
0.5	1	0.05	0.03	0.30	-	0.03	0.30
Tomato, Chemigation							
1		0.05	0.05	0.50	0.05	0.10	0.55

The EC25 value of the most sensitive species in the seedling emergence study is compared to runoff and drift exposure to determine the risk quotient for those exposure scenarios. The EC25 value of the most sensitive species in the vegetative vigor study is compared to the drift exposure to determine the risk quotient for that exposure scenario.

EECs and acute high risk quotients for terrestrial and semi-aquatic plants based on a single application are tabulated below.

Table 42. Acute High Risk Quotients from a Single Application for Terrestrial and Semi-Aquatic Plants Based On a Turnip Emergence EC25 of 0.008 lbs ai/A and a Turnip Vegetative Vigor EC25 of 0.005 lbs ai/A.

Site, Method and Rate of Application (lbs ai/A)	Seedling Emergence EC25 (lbs ai/A)	Vegetative Vigor EC25 (lbs ai/A)	Drift (lbs ai/A)	Total Loading to Adjacent Area (Sheet Runoff+ Drift)	Total Loading to Semi-aquatic Area (Channelized Run-off+ Drift)	Emergence RQ Terrestrial Plants	Emergence RQ Semi-Aquatic Plants	Vegetative Vigor RQ Terrestrial and Semi-Aquatic Plants
Sugarcane Unincorp. Ground								
6.0	0.008	0.005	0.3	0.36	3.06	45.00	382.50	60.00
Peas Incorp. Ground								
0.5	0.008	0.005	-	0.03	0.30	3.75	37.50	0.00
Tomato, Chemigation								
1	0.008	0.005	0.05	0.1	0.55	12.50	68.75	10.00

The NOEC or EC05 (if a NOEC is unavailable) value of the most sensitive species in the seedling emergence study is compared to runoff and drift exposure to determine the endangered species risk quotient for those exposure scenarios. The NOEC or EC05 value of the most sensitive species in the vegetative vigor study is compared to the drift exposure to determine the endangered species risk quotient for that exposure scenario.

EECs and acute (endangered species) risk quotients for terrestrial and semi-aquatic plants based on a single application are tabulated below.

Table 43. Acute Endangered Species Risk Quotients from a Single Application for Terrestrial and Semi-Aquatic Plants Based On a Turnip Emergence NOEC of 0.007 lbs ai/A and a Turnip Vegetative Vigor NOEC of 0.0028 lbs ai/A.

Site, Method and Rate of Application (lbs ai/A)	Seedling Emergence NOEC or EC05 (lbs ai/A)	Vegetative Vigor NOEC or EC05 (lbs ai/A)	Drift (lbs ai/A)	Total Loading to Adjacent Area (Sheet Runoff+ Drift)	Total Loading to Semi-aquatic Area (Channelized Run-off+ Drift)	Emer-gence RQ Terres-trial Plants	Emer-gence RQ Semi-Aquatic Plants	Vegeta-tive Vigor RQ Terres-trial and Semi-Aquatic Plats
Sugarcane Unincorp. Ground								
6	0.007	0.0028	0.30	0.36	3.06	51.43	437.14	107.14
Peas Incorp. Ground								
0.5	0.007	0.0028	-	0.03	0.3	4.29	42.86	0.00
Tomato, Chemiga-tion								
1	0.007	0.0028	0.05	0.1	0.55	14.29	78.57	17.86

The results indicate that for a single application, acute high risk and endangered species levels of concern are exceeded for terrestrial plants at a registered maximum single application rate equal to or above 0.5 lbs ai/A. For semi-aquatic plants, acute high risk and endangered species levels of concern are exceeded at a registered maximum single application rate equal to or above 0.5 lbs ai/A. Since all registered rates for multiple applications are greater than or equal to 0.5 lbs ai/A, all registered multiple application rates will also exceed acute high risk, restricted use and endangered species levels of concern. Currently, the Agency does not have a procedure for assessing chronic risk to terrestrial and semi-aquatic plants.

(b) Aquatic

Exposure to nontarget aquatic plants may occur through runoff or spray drift from adjacent treated sites or directly from such uses as aquatic weed or mosquito larvae control. An aquatic plant risk assessment for acute high risk is usually made for aquatic vascular plants from the surrogate duckweed *Lemna gibba*. Non-vascular high acute

aquatic plant risk assessments are performed using either algae or a diatom, whichever is the most sensitive species. An aquatic plant risk assessment for acute- endangered species is usually made for aquatic vascular plants from the surrogate duckweed *Lemna gibba*. Runoff and drift exposure is computed from GENEEC. The risk quotient is determined by dividing the pesticide's initial or peak concentration in water by the plant EC_{50} value.

Acute risk quotients for vascular and non-vascular plants are tabulated below.

Table 44. Acute Risk Quotients for Aquatic Plants based upon a Duckweed (*Lemna gibba*) EC_{50} of 0.13 ppm and a Marine Diatom (*Skeletonema costatum*) EC50 of 0.0087 ppm.

Site/ Application Method/ Rate of Application in lbs ai/A (No. of Apps.)	Test Species	EC50 (ppm)	EEC (ppm)	RQ (EEC/ EC50)
Sugarcane Aerial	duckweed	0.13	0.39	3.00
6 (1)	diatom	0.0087	0.39	44.83
Peas Incorp. Ground	duckweed	0.13	0.024	0.18
0.5 (1)	algae or diatom	0.0087	0.024	2.76
Turf Uninc. ground	duckweed	0.13	0.024	0.18
0.5 (2)	algae or diatom	0.0087	0.024	2.76

Endangered species risk quotients for vascular aquatic plants are tabulated below. (Non-vascular endangered species are not known to exist at this time.)

Table 45. Endangered Species Risk Quotients (RQs) for Aquatic Plants based upon a duckweed (*Lemna gibba*) NOEC of 0.018 ppm.

Site/ Application Method/ Rate of Application in lbs ai/A (No. of Apps)	Test Species	NOEC or EC_{05} (ppm)	EEC (ppm)	RQ (EEC/ EC50)
Sugarcane Aerial 6 (1)	duckweed	0.018	0.39	21.67
Peas Incorp. Ground 0.5 (1)	duckweed	0.018	0.024	1.33
Turf 0.5 (2)	duckweed	0.018	0.024	1.33

The results indicate that acute high risk levels of

concern are exceeded for vascular plants at application rates equal to and above 6.0 lbs ai/A, and endangered species levels of concern are exceeded for vascular plants at registered maximum rates equal to or above 0.5 lbs ai/A. The results indicate that acute high risk and endangered species levels of concern are exceeded for nonvascular aquatic plants at registered maximum rates equal to or above 0.5 lbs ai/A. Currently, the Agency does not have a procedure for assessing chronic risk to aquatic plants.

(3) Endangered Species

Endangered species LOCs for birds, mammals, terrestrial plants, and aquatic plants are exceeded for metribuzin.

The Endangered Species Protection Program is expected to become final in the future. Limitations in the use of metribuzin may 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 may 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.

b. Water Resources Risk Implication for Human Health

(1) Ground Water

Metribuzin is clearly a compound that leaches to ground water, but at the present time, the concentrations found in ground water are low compared to the levels of concern for human health. However, in some studies, metribuzin residues have been found in ground water at relatively high levels (14 and 54 ppb).

The lifetime Health Advisory for metribuzin has been established at 100 ppb. Metribuzin has been placed in Cancer Group D (not classifiable as to human carcinogenicity). All metribuzin formulations carry a ground-water advisory on their labels.

(2) Surface Water

Metribuzin 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. Metribuzin has lifetime and 1- and 10-day drinking water health advisories of 100 ug/L and 5000 ug/L, respectively. The low soil/water partitioning of metribuzin and its major degradates probably makes their removal by the primary treatment processes employed by most surface water supply systems ineffective. However, the available data on metribuzin in surface water indicates that it is unlikely that annual average concentrations of metribuzin will exceed the lifetime health advisory or that peak or short term average concentrations will exceed the 1- to 10-day health advisory in surface water source drinking water. Also, no drinking water Health Advisories are available for the major degradates.

(5) Summary Environmental Risk Characterization

A. Avian Species

Acute Risks

Although acute RQs approach, or exceed, the acute high risk LOC (0.5) and acute endangered species LOC (0.1) for certain crop/rate scenarios, the Agency concludes that minimal acute risks exist for these avian species. Our conclusion is based on the observation that metribuzin's dietary LC_{50}s for bobwhite quail and mallard duck are > 4000 ppm and > 5000 ppm, respectively, classifying metribuzin as practically non-toxic. Typically, herbicides that exhibit such toxicity are expected to have minimal acute effects on birds. Further, the typical use rate for metribuzin is 1 lb ai/acre, a rate that does not result in RQs that exceed the LOCs.

The certainty of the above assessment is moderate to high. However, one factor that affects the certainty (and prevents it from being high) is that the acute oral LD_{50} for bobwhite quail exposed to metribuzin is 169.2 mg/kg. This value classifies this pesticide as moderately toxic to quail and indicates that dietary ingestion may underestimate potential acute effects to avian species.

Chronic Risks

The Agency concludes that chronic risks are likely for avian species, including endangered species, for rates of 4 lb ai/acre or higher. However, for the typical use rate of 1 lb ai/acre, RQs do not exceed the LOC of 1.0, and therefore, chronic risks are not likely to occur under these use situations.

The certainty of the above assessment is moderate. The following factors affect the utility of the data in a risk assessment:

1. The avian reproduction studies, using bobwhite quail and mallard duck, did not result in effects on reproductive parameters. Instead, there were reductions in body weights of hatchlings of treated birds.

2. There was some question as to whether the body weight reductions in the bobwhite quail study were treatment-related.

3. Since there were no reproductive parameters affected in the duck study, the highest test concentration, 368 ppm, was considered to be the No Observed Effect Concentration (NOEC) and the Lowest Observable Effect Concentration (LOEC) was not established (i.e., LOEC was > 368 ppm). Since the LOEC was not determined in this study, it is possible that the NOEC would be at a higher concentration.

These factors lead to a conclusion that while the possibility of chronic risk exists, the probability that it will occur may be relatively low.

B. Mammalian Species

Acute

Use applications of 0.5 lb ai/acre and higher resulted in RQs that either exceed the acute endangered species LOC (0.1) or the acute high risk LOC (0.5). However, considering the factors discussed below, the Agency concludes that minimal acute risks exist for these species.

The certainty of the assessment is moderate. This is based on the following:

1. The rat acute oral LD_{50} is > 2000 mg/kg, classifying metribuzin as practically non-toxic. Typically, herbicides that exhibit such toxicity are expected to have minimal acute effects on mammals.

2. However, the laboratory mouse acute oral LD_{50} is approximately 700 mg/kg, a value less than half the 2000 mg/kg value for rats. This lower value raises some question as to differences in sensitivity between species. It is not known how sensitive wild mammals may be to metribuzin. If they are substantially more sensitive, they may be at greater risk than indicated by the RQs.

Therefore, it is only with moderate certainty that the Agency concludes that mammals are not at acute risk from metribuzin applications.

Chronic

The Agency concludes that chronic risks are likely for mammalian species, including endangered species, for rates of 1 lb ai/acre or higher.

The certainty of the above assessment is high because:

1. The available chronic mammalian data appear to be scientifically sound and provide values (NOEC and LOEC) related to effects on reproductive parameters.

2. Metribuzin and/or its degradates persist in the environment, allowing chronic exposure of mammalian species.

C. Aquatic Species

Acute

The Agency concludes that minimal acute risks exist for nontarget aquatic species, including endangered species. Although one RQ (0.09) for sugarcane, at an application rate of 6 lb ai/acre,

exceeds the acute endangered species LOC (0.05) for aquatic invertebrates, the Agency concludes that minimal acute risks exist for these species. This conclusion is based on metribuzin's overall lack of acute toxicity to a variety of freshwater and estuarine/marine species, both vertebrate and invertebrate. Metribuzin ranged from practically non-toxic to slightly toxic for all species except *Daphnia*, which ranged from slightly toxic to moderately toxic. Further, for the typical use rate of 1 lb ai/acre, acute RQs do not exceed the LOCs of 0.5 (non-endangered) or 0.05 (endangered), and therefore, acute risks are not likely to occur under these use situations.

The certainty of the above assessment is moderate to high. However, one factor that affects the certainty (and prevents it from being high) is the sensitivity of *Daphnia* to metribuzin relative to other aquatic organisms. The EC_{50} value of 4.2 ppm is significantly lower than other aquatic LC_{50}/EC_{50} values. This lower value raises some question as to differences in sensitivity between species. It is not known how sensitive wild aquatic organisms may be to metribuzin. If they are substantially more sensitive, they may be at greater risk than indicated by the RQs.

Chronic

The Agency concludes that minimal chronic risks exist for nontarget aquatic species, including endangered species. All RQs are well below the chronic LOC of 1.0.

The certainty of the above assessment is moderate to high because:

1. The available chronic aquatic data appear to be scientifically sound and provide values (NOEC and LOEC) related to effects on reproductive parameters. Although a NOEC was not determined in the rainbow trout early life-stage study, use of the LOEC in developing RQs still resulted in values well below the LOC of 1.0.

2. However, metribuzin and its degradates persist in the aquatic environment, allowing for chronic exposure of aquatic species. Because of this persistence and lack of available chronic aquatic data on degradates, the Agency cannot determine the chronic risks for metribuzin

degradates. This factor affects the certainty and prevents it from being high. However, one chronic aquatic invertebrate study using *Daphnia* and DADK, a degradate of metribuzin, is available. The results from this study are comparable to those using parent compound.

D. Plants

The Agency concludes that risks are likely for nontarget terrestrial and aquatic plant species, including endangered species, for rates of 0.5 lb ai/acre or higher. Routes of exposure include drift and runoff (both channelized and sheet runoff) for such organisms.

The certainty of the above assessment is high because metribuzin is a herbicide and as such is intended to adversely affect plants.

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 metribuzin as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing metribuzin under the conditions specified in the RED. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of metribuzin, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B were sufficient to allow the Agency to assess the registered uses of metribuzin and to determine that metribuzin can be used without resulting in unreasonable adverse effects to humans and the environment if used according to the labels as amended by this RED. The Agency therefore finds that all products containing metribuzin as the active ingredients are eligible for reregistration under the conditions specified in this RED. 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 metribuzin are eligible for reregistration under the conditions specified in this RED, it should be understood that the Agency may take additional appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing metribuzin, 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 Decision

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredient metribuzin, the Agency has sufficient information on the health effects of metribuzin and on its potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that metribuzin products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment. Under the Food Quality Protection Act of 1996, the Agency has determined that there is a reasonable certainty that no harm will result to infants, children or to the general population from aggregate exposure to metribuzin. Significant non-occupational exposures are unlikely, therefore, the only risks considered in the aggregate exposure assessment were those from dietary and drinking water sources. EPA has concluded that consideration of a common mode of toxicity is not appropriate at this time since EPA does not have information to indicate that toxic effects produced by metribuzin would be cumulative with those of any other chemical compounds. Therefore, the Agency concludes that products containing metribuzin for all uses are eligible for reregistration under the conditions specified in the RED.

2. Eligible and Ineligible Uses

The Agency has determined that all uses of metribuzin are eligible for reregistration under the conditions specified in the RED.

C. Regulatory Position

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

1. Food Quality Protection Act Consideration

Determination of Safety for Metribuzin

EPA has determined that the established tolerances for metribuzin 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 metribuzin and other chemicals with a similar mechanism of toxicity.

Determination of safety includes consideration of special sensitivity to children, potential cumulative effects with pesticides that have a common mode of toxicity and aggregate risks resulting from exposure to dietary residues, residues in drinking water, and residential sources.

The available toxicological database for metribuzin does not indicate any special sensitivity for infants and children to metribuzin. Therefore, the Agency concludes that an additional uncertainty factor is not warranted, that the RfD established at 0.013 mg/kg/day is appropriate for assessing aggregate chronic dietary risk to infants and children, and that the NOEL of 15 mg/kg/day used in calculating acute dietary exposure is also appropriate.

EPA does not have, at this time, available data to determine whether metribuzin has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicty, metribuzin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therfore, EPA has not assumed that metribuzin has a common mechanism of toxicity with other substances.

The Agency has determined that significant non-occupational exposures are unlikely. The only risks which must be considered are those from dietary and drinking water sources. There are no chronic homeowner exposure scenarios; therefore, the aggregate acute or chronic risk would be the total dietary risk (food source + drinking water).

The total acute dietary (food and drinking water source) risk assessment was performed for the sub-population females (13+ years). The MOE was 1200 (rounded to two significant digits). Metribuzin's acute dietary MOE greatly exceeds 100; therefore, the Agency considers the MOE to be sufficiently

protective for the acute total dietary (food source and drinking water) risk.

Using the previously described exposure assumptions, the Agency has concluded that for the general population 1% of the RfD will be reserved for exposure to residues of metribuzin in drinking water and 36% of the RfD will be utilized by exposure to residues of metribuzin in food commodities. Thus, the total chronic dietary risk is 37% of the RfD.

When total chronic dietary risk is assessed for the population sub-group with the highest %RfDs (children 1 - 6), the Agency has concluded that 4% of the RfD will be reserved for exposure to residues of metribuzin in drinking water and 75% of the RfD will be utilized by exposure to residues of metribuzin in food commodities. The total chronic dietary risk is 79% of the RfD, thus not exceeding the Agency's risk concern level.

2. Tolerance Reassessment

Tolerances Listed Under 40 CFR §180.332

The tolerances listed under 40 CFR §180.332 are expressed in terms of the combined residues of metribuzin and its triazinone metabolites. A summary of metribuzin tolerance reassessments is presented in Table 46. Tolerance reassessments were prepared for metribuzin and its metabolites DADK, DK, and DA. It should be noted that the registrant has requested that the current tolerance expression be amended to consider only metribuzin and its DADK metabolite. However, the Agency has not received a formal proposal containing additional data and/or discussion concerning this request.

Sufficient data are available to ascertain the adequacy of the tolerances established in 40 CFR §180.332 for the following commodities: barley, grain; barley, straw; carrots; corn, stover (fodder); corn, forage; grass; grass, hay; lentils (dried); lentils, forage; peas; peas (dried); peas, forage; sainfoin; sainfoin, hay; soybeans; soybeans, forage; soybeans, hay; sugarcane; tomatoes; wheat, forage; wheat, grain; and wheat straw. Additional confirmatory data/information are needed before the established tolerances for animal commodities can be reassessed. When tolerances for animal commodities are reassessed, a separate dietary exposure assessment should be made to determine the necessity of including any of these animal metabolites in the tolerance expression.

Tolerances for residues in alfalfa chaff, alfalfa seed, and cannery waste of fresh corn (previously proposed in PP#8F3683/FAP#8H6663) are not needed.

There are presently no registered uses of metribuzin on popcorn. When

acceptable field corn grain data have been submitted and evaluated, the established tolerance for "corn, grain (inc. popcorn)" should be revoked concomitant with the establishment of a tolerance for "corn, field, grain." There are also no registered uses of metribuzin on sweet corn; therefore, the established tolerance for this commodity will be revoked.

The livestock feeds table for Subdivision O (9/95) no longer considers lentil hay, lentil forage, or barley forage to be significant livestock feed stuffs. The established tolerances for lentil vine hay, lentil forage, and barley forage will therefore be revoked.

Tolerances That Need To Be Proposed Under 40 CFR §180.332

The Agency has recently determined that tolerances for aspirated grain fractions should be established based on the use of a pesticide on corn, wheat, sorghum, and soybeans; there are presently registered uses of metribuzin on corn, wheat, and soybeans. The available field corn grain dust data indicate that residues of metribuzin and its metabolites DA and DADK were nondetectable (<0.01 ppm each) and residues of DK were nondetectable (<0.03 ppm) following treatment at 5x. An adequate level for a tolerance for metribuzin residues of concern in/on aspirated grain fractions will be determined when the outstanding data for wheat aspirated grain fractions are submitted.

Food/Feed Additive Issues Under 40 CFR §185.250 and 40 CFR §186.250

Adequate processing studies have been submitted for field corn, potatoes, and soybeans. The field corn and soybean processing studies suggest that no food/feed additive tolerances are needed on the processed commodities of these crops; nondetectable residues in the raw agricultural and processed commodities of these crops were obtained following applications of metribuzin at exaggerated rates. The potato processing study suggests that the established food/feed additive tolerances on processed potato commodities are appropriate.

The livestock feeds table for Subdivision O (9/95) no longer considers sugarcane forage to be a major raw agricultural commodity of sugarcane. Therefore, no tolerance or feeding restrictions are required for this commodity.

The registrant has indicated that additional processing studies on sugarcane, tomatoes, and wheat have been initiated and the results, once completed, will be submitted to EPA for evaluation. The wheat processing study, once completed and evaluated, will be translated to fulfill the reregistration requirements for a barley processing study.

The listing in 40 CFR §186.250 of 0.3 ppm for sugarcane molasses is in error. The Metribuzin Residue Chemistry Science Chapter, dated 12/84, noted that an increase in the feed additive tolerance for sugarcane molasses from 0.3 to 2 ppm was accepted as proposed in FAP#5H5151. This higher tolerance had been established (43 FR 157:35915, 8/24/78).

Alfalfa meal is no longer regulated as a processed feed item of alfalfa (per livestock feeds table for Subdivision O - 9/95). Therefore, a tolerance and supporting residue data are not required for this commodity. Alfalfa meal should, however, be considered in the calculation of livestock diet using the alfalfa hay tolerance level.

Table 46: Tolerance Reassessment Summary

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/[*Correct Commodity Definition*]
Tolerances Listed Under 40 CFR §180.332			
Alfalfa, green	2	TBD [a]	[*Alfalfa, forage*]
Alfalfa, hay	7	TBD [a]	
Asparagus	0.05	0.1	Previously proposed at a different tolerance level in PP#8F3683.
Barley, grain	0.75	0.75	
Barley, straw	1	1	
Carrots	0.3	0.3	
Cattle, fat	0.7	TBD [a]	
Cattle, mbyp	0.7	TBD [a]	
Cattle, meat	0.7	TBD [a]	
Corn, fodder	0.1	0.1	[*Corn, field, fodder*]
Corn, forage	0.1	0.1	[*Corn, field, forage*]
Corn, fresh (inc. sweet K + CWHR)	0.05	Revoke	There are no registered uses of metribuzin on sweet corn; therefore, the established tolerance should be revoked.
Corn, grain (inc. popcorn)	0.05	TBD [a]	There are presently no registered uses of metribuzin on popcorn. When acceptable field corn grain data have been submitted and evaluated, the established tolerance for "corn, grain (inc. popcorn)" should be revoked concomitant with the establishment of tolerance for "Corn, field, grain".
Eggs	0.01	TBD [a]	
Goats, fat	0.7	TBD [a]	
Goats, mbyp	0.7	TBD [a]	
Goats, meat	0.7	TBD [a]	
Grass	2	2	[*Grass, forage*]
Grass, hay	7	7	

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/[*Correct Commodity Definition*]
Hogs, fat	0.7	TBD [a]	
Hogs, mbyp	0.7	TBD [a]	
Hogs, meat	0.7	TBD [a]	
Horses, fat	0.7	TBD [a]	
Horses, mbyp	0.7	TBD [a]	
Horses, meat	0.7	TBD [a]	
Lentils (dried)	0.05	0.05	[*Lentils*]
Lentils, forage	0.5	Revoke	Lentil forage is no longer considered to be a significant livestock feed stuff per Table II (9/95).
Lentils, vine hay	0.05	Revoke	Lentil hay is no longer considered to be a significant livestock feed stuff per Table II (9/95).
Milk	0.05	TBD [a]	
Peas	0.1	0.1	[*Peas, succulent*]
Peas (dried)	0.05	0.05	[*Peas, seed*]
Peas, forage	0.5	0.5	[*Peas, field, forage*]
Peas, vine hay	0.05	4.0	Previously proposed at a different tolerance level in PP#8F3683. [*Peas, field, hay*]
Potatoes	0.6	TBD [a]	
Poultry, fat	0.7	TBD [a]	
Poultry, mbyp	0.7	TBD [a]	
Poultry, meat	0.7	TBD [a]	
Sainfoin	2	2	[*Sainfoin, forage*]
Sainfoin, hay	7	7	
Sheep, fat	0.7	TBD [a]	
Sheep, mbyp	0.7	TBD [a]	
Sheep, meat	0.7	TBD [a]	
Soybeans	0.1	0.3	Previously proposed at a different tolerance level in PP#2F2677.
Soybeans, forage	4	4	
Soybeans, hay	4	4	
Sugarcane	0.1	0.1	
Tomatoes	0.1	0.1	
Wheat, forage	2	2	

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/[*Correct Commodity Definition*]
Wheat, grain	0.75	0.75	
Wheat, straw	1	1	
Tolerances That Need To Be Established Under 40 CFR §180.332			
Aspirated grain fractions	None established	TBD [a]	A tolerance level for aspirated grain fractions may need to be established when the outstanding data for wheat aspirated grain fractions are submitted and evaluated.
Barley, hay	None established	7	Previously proposed in PP#8F3683.
Wheat, hay	None established	7	
TOLERANCES LISTED UNDER 40 CFR §185.250			
Barley, milled fractions (except flour)	3	TBD [a]	The wheat processing study, once completed and evaluated, will be translated to fulfill the reregistration requirements for a barley processing study. [*Barley, milled fractions (exc. flour)*]
Potatoes, processed (inc. potato chips)	3	3	
Sugarcane molasses	2	TBD [a]	[*Sugarcane, molasses*]
Wheat, milled fractions (except flour)	3	TBD [a]	[*Wheat, milled fractions (exc. flour)*]
Tolerances Listed Under 40 CFR §186.250			
Barley, milled fractions (except flour)	3	TBD [a]	The wheat processing study, once completed and evaluated, will be translated to fulfill the reregistration requirements for a barley processing study. [*Barley, milled fractions (exc. flour)*]
Potato waste, processed (dried)	3	3	[*Potatoes, waste from processing*]
Sugarcane bagasse	0.5	Revoke	Sugarcane, bagasse is no longer considered to be a significant livestock feed stuff per Table II (9/95).
Sugarcane molasses	0.3 (in error); 2.0 (correct tolerance) [b]	TBD [a]	[*Sugarcane, molasses*]

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/[*Correct Commodity Definition*]
Tomato pomace, dried	2	Revoke	Dried tomato pomace is no longer considered to be a significant livestock feed stuff per Table II (9/95).
Wheat, milled fractions (except flour)	3	TBD [a]	[*Wheat, milled fractions (exc flour)*]

[a] TBD = These tolerance(s) will be evaluated once confirmatory data is submitted and reviewed.

[b] The currently established tolerance of 0.3 ppm as published in 40 CFR 186.250 for sugarcane molasses is in error. The appropriate tolerance should be 2 ppm (See 43 FR 157:35915, 8/24/78).

CODEX HARMONIZATION

There are no Codex MRLs established or proposed for residues of metribuzin and its triazinone metabolites. Therefore, there are no questions with respect to compatibility of U.S. tolerances with Codex MRLs.

There is a Canadian tolerance of 0.05 ppm for metribuzin and its metabolites for potatoes. Canada also has a negligible residue limit for metribuzin, *per se*, on alfalfa, asparagus, barley, corn, fava beans, lentils, lupine, peas, rapeseed (canola oil), soybeans, sunflowers, tomatoes, wheat, fruit tree orchards (fruit), meat, milk, and eggs.

3. Tolerance Revocations and Import Tolerances

As part of EPA's reregistration eligibility decision for metribuzin, food additive tolerances are no longer needed. Under the new law (FQPA, H.R. 1627), the residues on processed food/feed items will be regulated Section 408. Once a pesticide use is no longer registered in the United States, the related pesticide residue tolerance and/or food/feed additive regulation generally is no longer needed. It is EPA's policy to propose revocation of a tolerance, and/or food/feed additive regulation, following the deletion of a related food use from a registration, or following the cancellation of a related food-use registration. EPA has the responsibility under the Federal Food, Drug, and Cosmetic Act (FFDCA) to revoke a tolerance/regulation on the grounds that the Agency cannot conclude that the tolerance/regulation is protective of the public health.

The Agency recognizes, however, that interested parties may want to retain a tolerance and/or food/feed additive regulation in the absence of a U.S. registration, to allow legal importation of food into the U.S. To assure that all food marketed in the U.S. is safe, under FFDCA, EPA requires the same technical chemistry and toxicology data for such import tolerances (tolerances without

related U.S. registrations) as are required to support U.S. food use registrations and any resulting tolerances. See 40 CFR Part 158 for EPA's data requirements to support domestic use of a pesticide and establishment and maintenance of a tolerance and/or food/feed regulation. In addition, EPA requires residue chemistry data (crop field trials) that are representative of growing conditions in exporting countries in the same manner that EPA requires representative residue chemistry data from different U.S. regions to support domestic use of the pesticide and the tolerance and/or regulation. Additional guidance on the Agency's import tolerance policy will be published in an upcoming *Federal Register* Notice.

Parties interested in supporting an existing metribuzin tolerance as an import tolerance should ensure that all of the data noted above are available to EPA during its further assessments of existing tolerances and regulations, so that the Agency may determine whether maintenance of the tolerance and/or regulation would be protective of the public health."

4. Summary of Risk Management Decisions

The Agency has determined that the current uses of metribuzin exceed levels of concern for, 1) acute and chronic avian and mammalian effects; 2) nontarget terrestrial and aquatic plant species; 3) endangered species; 4) ground water contamination, which could potentially impact drinking water and ecological endpoints; and 5) occupational inhalation exposure.

Several risk mitigation measures to address these concerns have been proposed by the technical registrant, Bayer Corporation. They were considered by the Agency, and are being required. It must be noted that risk mitigation measures are required for all metribuzin registrants.

Below is a brief summary of the Agency's concerns and associated risk mitigation measures.

o There is potential acute and chronic risk concern for avian species, including endangered species, for rates of 4 lb ai/acre or higher. Also, acute and chronic risks are likely for mammalian species, including endangered species, for rates of 1 lb ai/acre or higher. In addition, metribuzin and its degradates are mobile and persist in the environment. Risks are likely for nontarget terrestrial and aquatic plant species, including endangered species, for rates of 0.5 lb ai/acre or higher. Routes of exposure include drift and runoff for such organisms.

Mitigation measures which specifically reduce the exposure of metribuzin to nontarget organisms are: 1) prohibiting aerial application on asparagus and tomatoes; 2) reducing the application rate of metribuzin being applied to

sugarcane via aerial and chemigation methods from 6.0 lb ai/acre to 2.0 lb ai/acre; and 3) spray drift labeling requirements, specified in Section V of this document, Actions Required of Registrants.

o Although presently there are ground water advisories on metribuzin product labels, the Agency is still concerned with potential ground water contamination with metribuzin use. Data currently available to the Agency indicate that metribuzin and its degradates are very mobile and highly persistent and thus have the potential to contaminate ground water and surface water; however, the persistence of parent metribuzin in surface water may be lessened by its susceptibility to photolytic degradation. Metribuzin use could adversely affect ground-water quality, especially in vulnerable areas. Detections have been reported in the "Pesticides in Ground Water Database" (Hoheisel et al., 1992) and other studies. These ground water contamination concerns are enhanced by the widespread use patterns.

Mitigation measures that will reduce the likelihood of metribuzin and its primary degradates contaminating ground and surface water are: 1) specifying Best Management Practices; and 2) determining areas that are vulnerable to ground-water contamination by metribuzin and recommending risk mitigation measures. This information, once submitted and reviewed, will determine the need for additional labeling. Other actions proposed by the registrant include: 1) providing additional information on how levels of detects and nondetects were handled in the small-scale retrospective study which was conducted in Portage County, Wisconsin on potatoes; and 2) providing available historic data on accumulations of metribuzin in surface water over time.

o There is an inhalation toxicity concern for mixer and loaders of the wettable powder formulation for chemigation and aerial application at 6 lbs. ai/acre.

Mitigation measures which specifically reduce potential human health risk of metribuzin use are: 1) reducing the application rate of metribuzin being applied to sugarcane by chemigation and aerial application methods from 6.0 lb ai/acre to 2.0 lb ai/acre; and 2) prohibiting the use of low-pressure or high volume hand wand equipment. As noted previously, although the 70 kg default male body weight was used in calculating the MOEs, if the MOEs were to be re-calculated using the 60 kg default female body weight, the MOEs would only be slightly smaller. Therefore, the acceptable MOEs with mitigation measures all sufficiently exceed 100 so that all MOEs estimated using the default female body weight would also be acceptable.

Based on the Agency's overall risk assessment and risk characterization of

metribuzin, and the mitigation measures required in this document, the Agency believes that human risks associated with metribuzin use will be minimal and that the risks to the environment from metribuzin and its degradates are relatively low. The required rate reductions will adequately reduce the exposure of metribuzin to occupational workers. Although the risk mitigation measures may not quantitatively bring the risks below the level of concern for birds, mammals, and plants; the Agency believes that these measures will substantially reduce the risks. Minimizing spray drift will greatly reduce the risk to nontarget plants. Also, the restrictions placed on the high use rate crop (sugarcane), will greatly reduce the level of concern for birds, mammals and plants.

5. Endangered Species Statement

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 will 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 will occur in the future under the Endangered Species Protection Program.

6. Occupational Labeling Rationale

The Worker Protection Standard (WPS)

Scope of the WPS

On August 21, 1992 the Agency issued worker protection regulations affecting all pesticide products whose labeling reasonably permits use in the production of agricultural plants on any farm forest, nursery or greenhouse. These regulations established certain worker protection requirements (personal protective equipment, restricted entry intervals, etc.). In general, products within the scope of the Worker Protection Standard(WPS) had to bear complying labeling when sold or distributed by the registrant after April 21, 1994.

At this time some of the registered uses of metribuzin are within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS) and some

uses are outside the scope of the WPS. Those that are outside the scope of the WPS include use:

- on pastures or rangelands,
- on plants grown for other than commercial or research purposes, which may include plants in habitations, home fruit and vegetable gardens, and home greenhouses,
- on plants that are in ornamental gardens, parks, golf courses, and public or private lawns and grounds and that are intended only for decorative or environmental benefit,
- in a manner not directly related to the production of agricultural plants, including, for example, control of vegetation along rights-of-way and in other noncrop areas.

A. Personal Protective Equipment/Engineering Controls for Handlers

At this time there are no engineering control requirements, such as closed systems, currently required on labeling for end-use products containing metribuzin, though some metribuzin products are formulated in water-soluble packaging, which is an engineering control for mixing and loading.

B. Occupational-Use Products

EPA has determined that occupational handler exposures and risks generally are the same for WPS and nonWPS uses of metribuzin. Therefore, occupational handler exposures and risks are evaluated jointly. As a result of the reregistration evaluation of the acute and other adverse effects of metribuzin, the Agency has determined that risks to handlers do not warrant the establishment of active-ingredient-based minimum personal protective equipment or engineering-control requirements that would apply to all metribuzin end-use products. Handler PPE requirements for metribuzin are to be based solely on the acute toxicity of individual end-use products.

C. Post-Application/Entry Restrictions

1) Occupational-Use Products (WPS Uses)

Restricted-Entry Interval:

Under the Worker Protection Standard (WPS), interim restricted

entry intervals (REIs) 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.

Since at this time there are no dermal toxicological endpoints of concern and metribuzin is classified as toxicity category IV for acute dermal toxicity, eye irritation potential, and skin irritation potential, EPA is establishing a 12-hour restricted-entry interval for all uses within the scope of the WPS. The Agency believes that the 12 hour REI provides adequate protection for workers reentering treated sites, and that a longer REI is not needed. Although there are no active ingredient specific data on which to base a quantitative estimate of post-application exposure, in the Agency's judgement such workers are not likely to have substantially greater exposure than pesticide handlers (those who mix, load or apply pesticides). The Agency is not calling in post application exposure data at this time, because EPA concludes that there is unlikely to be any significant benefit to users from a shorter REI. In addition, EPA believes that workers reentering a treated site much sooner than 12 hours after application could experience significantly higher dermal exposure through contact with wet surfaces on which the sprays have not completely dried. The Agency doubts that post application exposure studies would support much reduction in the REI for metribuzin products, however, if the registrant would like to reduce the 12 hours REI, post application exposure data would need to be provided to the Agency for review.

The WPS interim REI in effect is 12 hours. EPA notes that the 12-hour interim WPS REI was established because EPA data indicates that metribuzin is classified as toxicity category IV for acute dermal toxicity, eye irritation potential, and skin irritation potential.

EPA notes that the WPS places very specific requirements for persons entering areas during restricted-entry intervals when that entry

involves contact with treated surfaces. EPA believes that existing WPS protections are sufficient to mitigate post-application exposures of workers who contact surfaces treated with metribuzin.

EPA also notes that if metribuzin has been correctly incorporated in soil, the WPS permits workers to enter the treated area during the restricted-entry interval without personal protective equipment or any other restriction if they are performing tasks that do not involve contact with the soil surface.

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 on routine entry to perform hand labor tasks and a requirement that personal protective equipment be worn. Personal protective equipment requirements for persons who must enter areas that remain under a restricted-entry interval are based on the toxicity concerns for 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.

Since metribuzin is classified as category IV for skin irritation potential and IV for acute dermal toxicity, and EPA has determined that no

regulatory action must be taken due to the acute effects or other adverse effects of metribuzin active ingredient, the PPE for dermal protection required for early entry is the minimum early-entry PPE permitted under the WPS. Since metribuzin is classified as toxicity category IV for eye rritation potential, no protective eyewear is required.

WPS Notification Statement

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

2) Occupational-Use Products (NonWPS Uses)

Since EPA has concerns about post-application exposures to persons immediately following nonWPS occupational applications of metribuzin, it is establishing entry restrictions for all nonWPS occupational uses of metribuzin end-use products. For specific language refer to Section V of this document.

D. Additional Labeling Requirements

The Agency is requiring additional labeling statements to be located on all end-use products containing metribuzin. There are also several clarifications that need to be made to the labels. For the specific labeling statements, refer to Section V of this document.

7. Spray Drift Advisory

The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation to develop the best spray drift management practices. The Agency is now requiring interim measures that must be placed on product labels/labeling as specified in Section V. Once the Agency completes its evaluation of the new data base submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, the Agency may impose further refinements in spray drift management practices to further reduce off-target drift and risks associated with this drift.

V. ACTIONS REQUIRED OF REGISTRANTS

This section specifies the 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 metribuzin for the above eligible uses has been reviewed and determined to be substantially complete. All uses of metribuzin are eligible for reregistration, however, the Agency is requiring that the following confirmatory data be submitted to fulfill the generic data requirements for reregistration of metribuzin.

1) Magnitude of residue studies (alfalfa and field corn trials, and field rotational crop studies, additional field trials for field corn and potatoes, and outstanding data for wheat aspirated grain fractions must be submitted).

2) Processing studies for sugarcane and wheat are in progress. These data must be submitted. A processing study for tomatoes was submitted and is currently under review.

3) Certified limits (GLN 62-2) and analytical methods to verify certified limits (GLN 62-3) are required for three impurities related to the active ingredient in the 90% T.

4) Storage stability data for animal commodity samples from the previously evaluated poultry and ruminant feeding studies are required. If the storage intervals and conditions for livestock commodities are not supported by adequate data, additional feeding study data may be required.

5) Confined rotational crop and field rotational crop studies are required.

6) Ground water information. (GLN 166-17)

2. Labeling Requirements for Manufacturing-Use Products

To remain in compliance with FIFRA, manufacturing use product (MP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MP labeling must bear the following statement under

Directions for Use:

"Only for formulation into an Herbicide for those uses that are being supported by MP registrant."

An MP registrant may, at his/her discretion, add one of the following statements to an MP label under

"Directions for Use" to permit the reformulation of the product for a specific use or all additional uses supported by a formulator or user group:

(a) "This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."

(b) "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."

B. 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. Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria 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

a. Worker Protection Standard

Any product whose labeling reasonably permits use in the production of an agricultural plant on any farm, forest, nursery, or greenhouse must comply with the labeling requirements of PR Notice 93-7, "Labeling Revisions Required by the

Worker Protection Standard (WPS), and PR Notice 93-11, "Supplemental Guidance for PR Notice 93-7, which reflect the requirements of EPA' s labeling regulations for worker protection statements (4 0 CFR part 156, subpart K). These labeling revisions are necessary to implement the Worker Protection Standard for Agricultural Pesticides (40 CFR part 170) and must be completed in accordance with, and within the deadlines specified in, PR Notices 93-7 and 93-11. Unless otherwise specifically directed in this RED, all statements required by PR Notices 93-7 and 93-11 are to be on the product label exactly as instructed in those notices.

After April 21, 1994, except as otherwise provided in PR Notices 93-7 and 93-11, all products within the scope of those notices must bear WPS PR Notice complying labeling when they are distributed or sold by the primary registrant or any supplementally registered distributor.

After October 23, 1995, except as otherwise provided in PR Notices 93-7 and 93-11, all products within the scope of those notices must bear WPS PR Notice complying labeling when they are distributed or sold by any person.

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.

b. Occupational/Residential Labeling

PPE Requirements for Pesticide Handlers

Sole-active-ingredient end-use products that contain metribuzin must be revised to adopt the handler personal protective equipment requirements set forth in this section. Any conflicting PPE requirements on their current labeling must be removed.

Multiple-active-ingredient end-use products that contain metribuzin must compare the handler personal protective equipment requirements set forth in this section to the PPE requirements on their current labeling and retain the more protective. For guidance on which PPE is considered more protective, see PR Notice 93-7.

1. WPS and nonWPS uses

a) Minimum (baseline) PPE requirements --

For all formulations: EPA is not establishing active-ingredient-based minimum (baseline) PPE or engineering control requirements for

metribuzin end-use products.

b) Actual end-use product PPE requirements -- 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 most protective PPE must be placed on the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

c) Placement in labeling --The personal protective equipment 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.

d) Entry Restrictions

Sole-active-ingredient end-use products that contain metribuzin must be revised to adopt the entry restrictions set forth in this section. Any conflicting entry restrictions on their current labeling must be removed.

Multiple-active-ingredient end-use products that contain metribuzin must compare the entry restrictions set forth in this section to the entry restrictions on their current labeling and retain the more protective. A specific time-period in hours or days is considered more protective than "sprays have dried" or "dusts have settled."

2. WPS uses

Restricted-entry interval -- A 12-hour restricted entry interval (REI) is required for uses within the scope of the WPS (see PR Notice 93-7) on all end-use products with WPS uses (see tests in PR Notices 93-7 and 93-11).

Early-Entry Personal Protective Equipment (PPE)-- The PPE required for early entry is:
--coveralls,
--chemical-resistant gloves,
--shoes plus socks.

Placement on the 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.

3. NonWPS uses

Entry restrictions --

Spray Applications: The entry restriction for all nonWPS uses applied as a spray is:

"Do not enter or allow others to enter the treated area until sprays have dried. If soil incorporation is required following the application, do not enter or allow others to enter the treated area (except those persons involved in the incorporation) until the incorporation is complete. If the incorporation is accomplished by watering-in, do not enter or allow others to enter the treated area until the surface is dry following the watering-in."

Dry (Fertilizer) Applications: The entry restriction for all nonWPS uses applied dry is:

"Do not enter or allow others to enter the treated area until dusts have settled. If soil incorporation is required following the application, do not enter or allow others to enter the treated area (except those persons involved in the incorporation) until the incorporation is complete. If the incorporation is accomplished by watering-in, do not enter or allow others to enter the treated area until the surface is dry following the watering-in."

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 restriction in that box.

If no WPS uses are on label: Add the appropriate nonWPS entry restriction to the labels of all end-use products, except products primarily intended for homeowner use, in a section in the Directions For Use with the heading: "Entry Restrictions:"

The Agency is requiring the following labeling statements to be located on all end-use products containing metribuzin 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, 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

"Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions are available 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."

Optional Soil incorporation statement

"Exception: if the product is soil-incorporated or watered-in, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated."

c. Environmental Hazard Statements

"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 contaminate water when disposing of equipment wash water or rinsate."

d. Application Restrictions

The labels of all metribuzin end-use products must be revised to bear the following application restrictions under the **Directions for Use Section:**

For asparagus and tomato uses:
"Aerial application is prohibited"

For aerial application on sugarcane:
"To assure that spray will not adversely affect adjacent sensitive nontarget plant, apply this product by aircraft at a minimum upwind distance of 400 ft from sensitive plants."

For all uses:
"low-pressure and high volume hand wand equipment is prohibited"

e. Application Rates

The labels of metribuzin end-use products must be revised to bear the following application rates under the **Crop Uses Section** for the respective crops:

For the aerial and chemigation application methods of metribuzin on sugarcane:
" A maximum application rate of 2.0 lb ai/acre.

C. Spray Drift Labeling

The following language must be placed on each product label that can be applied aerially:

Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment-and-weather-related factors determine the potential for spray drift. The applicator and the grower are responsible for considering all these factors when making decisions.

The following drift management requirements must be followed to avoid off-target drift movement from aerial applications to agricultural field crops. These requirements do not apply to forestry applications, public health uses or to applications using dry formulations.

1. The distance of the outer most nozzles on the boom must not exceed 3/4 the length of the wingspan or rotor.

2. Nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees.

Where states have more stringent regulations, they should be observed.

The applicator should be familiar with and take into account the information

covered in the Aerial Drift Reduction Advisory Information.

The following aerial drift reduction advisory information must be contained in the product labeling:

[This section is advisory in nature and does not supersede the mandatory label requirements.]

INFORMATION ON DROPLET SIZE

The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. Applying larger droplets reduces drift potential, but will not prevent drift if applications are made improperly, or under unfavorable environmental conditions (see Wind, Temperature and Humidity, and Temperature Inversions).

CONTROLLING DROPLET SIZE

- Volume - Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets.

- Pressure - Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure.

- Number of nozzles - Use the minimum number of nozzles that provide uniform coverage.

- Nozzle Orientation - Orienting nozzles so that the spray is released parallel to the airstream produces larger droplets than other orientations and is the recommended practice. Significant deflection from horizontal will reduce droplet size and increase drift potential.

- Nozzle Type - Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles. Solid stream nozzles oriented straight back produce the largest droplets and the lowest drift.

BOOM LENGTH

For some use patterns, reducing the effective boom length to less than 3/4 of the

wingspan or rotor length may further reduce drift without reducing swath width.

APPLICATION HEIGHT

Applications should not be made at a height greater than 10 feet above the top of the largest plants unless a greater height is required for aircraft safety. Making applications at the lowest height that is safe reduces exposure of droplets to evaporation and wind.

SWATH ADJUSTMENT

When applications are made with a crosswind, the swath will be displaced downward. Therefore, on the up and downwind edges of the field, the applicator must compensate for this displacement by adjusting the path of the aircraft upwind. Swath adjustment distance should increase, with increasing drift potential (higher wind, smaller drops, etc.)

WIND

Drift potential is lowest between wind speeds of 2-10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application should be avoided below 2 mph due to variable wind direction and high inversion potential. NOTE: Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift.

TEMPERATURE AND HUMIDITY

When making applications in low relative humidity, set up equipment to produce larger droplets to compensate for evaporation. Droplet evaporation is most severe when conditions are both hot and dry.

TEMPERATURE INVERSIONS

Applications should not occur during a temperature inversion because drift potential is high. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source

or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing.

SENSITIVE AREAS

The pesticide should only be applied when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g. when wind is blowing away from the sensitive areas).

D. OTHER LABELING REQUIREMENTS

Clarifications that need to be made to the label are:

1) On several labels the maximum lb per acre application rate when applied once a year is different from the application rate per year.

2) Labels should include registration number/site/rate/appl. method, etc for items such as aerial application.

3) Labels should clearly state approved methods of application.

Label revisions are required for alfalfa and winter wheat. For alfalfa, the registrant must amend all pertinent labels to specify a maximum seasonal rate which must be consistent with the available (and required) residue data. A previous recommendation to establish a 180-day PHI (pre-harvest interval) for alfalfa grown for seed based on available data is no longer applicable since presently there are no registered uses of metribuzin on alfalfa grown for seed. For winter wheat, the registrant must amend all pertinent labels to specify an appropriate PHI consistent with that reflected in the residue data used to support the tolerance.

Because finite residues were observed at all plantback intervals tested in the confined rotational study, field rotational crop studies (GLN 165-2) are required. The available field rotational crop studies must be replaced. In the absence of adequate field rotational crop studies a label restriction stating "Do not rotate to any crop not on the metribuzin label" must be added to all pertinent labels.

When end-use product DCIs are developed (e.g., at issuance of the RED), the Agency should require that all end-use product labels (e.g., MAI labels, SLNs,

and products subject to the generic data exemption) be amended such that the uses on these labels are consistent with the uses on the basic producer labels.

D. 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 metribuzin products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED. Registrants and persons other than registrants remain obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.

VI. APPENDICES

APPENDIX A. Table of Use Patterns Subject to Reregistration

Appendix A is 126 pages long and is not being included. Copies of Appendix A are available upon request per the instructions in Appendix D

GUIDE TO APPENDIX B

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

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	**Chemical Identity**	All	00147003, 00161509, 41284401
61-2A	**Start. Mat. & Mnfg. Process**	All	41696401
61-2B	**Formation of Impurities**	All	00147003, 42598203
62-1	**Preliminary Analysis**	All	41284401
62-2	**Certification of limits**	All	00156321, 00156322, **Data Gap**
62-3	**Analytical Method**	All	00147003, 41284401, **Data Gap**
63-2	**Color**	All	00147003, 00156324
63-3	**Physical State**	All	00147003, 00156324
63-4	**Odor**	All	00165012, 00156324, 00147003
63-5	**Melting Point**	All	00165012, 00156324, 00147003
63-6	**Boiling Point**	N/R	
63-7	**Density**	All	00165012,00156324, 00147003
63-8	**Solubility**	All	42425601
63-9	**Vapor Pressure**	All	00147003
63-10	**Dissociation Constant**	All	00165012,00156324, 00147003
63-11	**Octanol/Water Partition**	All	00165012, 00156324, 00147003
63-12	**pH**	All	00165012, 00156324, 00147003

REQUIREMENT		USE PATTERN	CITATION(S)
63-13	**Stability**	All	00165012, 00147003
63-14	**Oxidizing/Reducing Action**	All	43168201
63-15	**Flammability**	N/R	
63-16	**Explodability**	All	00147003
63-17	**Storage stability**	All	00156324
63-18	**Viscosity**	N/R	
63-19	**Miscibility**	N/R	
63-20	**Corrosion characteristics**	All	00147003
63-21	**Dielectric breakdown volt**	N/R	
64-1	**Submittal of Samples**	N/R	
ECOLOGICAL EFFECTS			
71-1A	**Acute Avian Oral - Quail/Duck**	A,B	ACC# 255025
71-1B	**Acute Avian Oral - Quail/Duck TEP**	N/R	
71-2A	**Avian Dietary - Quail**	A,B	ACC# 262228
71-2B	**Avian Dietary - Duck**	A,B	00065507
71-3	**Wild Mammal Toxicity**	N/R	
71-4A	**Avian Reproduction - Quail**	A,B	43926601
71-4B	**Avian Reproduction - Duck**	A,B	43860501
71-5A	**Simulated Field Study**	N/R	
71-5B	**Actual Field Study**	N/R	

Data Supporting Guideline Requirements for the Reregistration of Metribuzin

REQUIREMENT		USE PATTERN	CITATION(S)
72-1A	**Fish Toxicity Bluegill**	A,B	ACC# 255025, 40098001
72-1B	**Fish Toxicity Bluegill - TEP**	A,B	ACC# 255025
72-1C	**Fish Toxicity Rainbow Trout**	A,B	ACC# 255025, 40098001
72-1D	**Fish Toxicity Rainbow Trout- TEP**	A,B	ACC# 255025, 090427
72-2A	**Invertebrate Toxicity**	A,B	42447801
72-2B	**Invertebrate Toxicity - TEP**	N/R	
72-3A	**Estuarine/Marine Toxicity - Fish**	A	42094502
72-3B	**Estuarine/Marine Toxicity - Mollusk**	A	00161503, 42094501
72-3C	**Estuarine/Marine Toxicity - Shrimp**	A	00106197
72-3D	**Estuarine/Marine Toxicity Fish- TEP**	N/R	
72-3E	**Estuarine/Marine Toxicity Mollusk - TEP**	N/R	
72-3F	**Estuarine/Marine Toxicity Shrimp - TEP**	N/R	
72-4A	**Early Life Stage Fish**	A,B	42447801
72-4B	**Life Cycle Invertebrate**	A,B	42447802
72-5	**Life Cycle Fish**	N/R	
72-6	**Aquatic Organism Accumulation**	N/R	
72-7A	**Simulated Field - Aquatic Organisms**	N/R	

REQUIREMENT		USE PATTERN	CITATION(S)
72-7B	**Actual Field - Aquatic Organisms**	N/R	
122-1A	**Seed Germination/Seedling Emergence**	N/R	
122-1B	**Vegetative Vigor**	N/R	
122-2	**Aquatic Plant Growth**	N/R	
123-1A	**Seed Germination/Seedling Emergence**	A,B	43208301, 42447803
123-1B	**Vegetative Vigor**	A,B	42447803
123-2	**Aquatic Plant Growth**	A,B	43893501, 43133601, 43867701, 43826101
124-1	**Terrestrial Field**	N/R	
124-2	**Aquatic Field**	N/R	
141-1	**Honey Bee Acute Contact**	A	028772
141-2	**Honey Bee Residue on Foliage**	N/R	
141-5	**Field Test for Pollinators**	N/R	
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	A,B,C	00106158
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	A,B,C	00106149
81-3	**Acute Inhalation Toxicity - Rat**	A,B,C	00157524
81-4	**Primary Eye Irritation - Rabbit**	A,B,C	00106158
81-5	**Primary Dermal Irritation - Rabbit**	A,B,C	00106158

Data Supporting Guideline Requirements for the Reregistration of Metribuzin

REQUIREMENT		USE PATTERN	CITATION(S)
81-6	**Dermal Sensitization - Guinea Pig**	A,B,C	41555101
81-7	**Acute Delayed Neurotoxicity - Hen**	N/R	
82-1A	**90-Day Feeding - Rodent**	N/R	
82-1B	**90-Day Feeding - Non-rodent**	N/R	
82-2	**21-Day Dermal - Rabbit/Rat**	A,B,C	43970701
82-3	**90-Day Dermal - Rodent**	N/R	
82-4	**90-Day Inhalation - Rat**	A,B,C	00153706
82-5A	**90-Day Neurotoxicity - Hen**	N/R	
82-5B	**90-Day Neurotoxicity - Mammal**	N/R	
83-1A	**Chronic Feeding Toxicity - Rodent**	A,B,C	00061261, 42672501
83-1B	**Chronic Feeding Toxicity - Non-Rodent**	A,B,C	00061260
83-2A	**Oncogenicity - Rat**	A,B,C	42672501, 00061261
83-2B	**Oncogenicity - Mouse**	A,B,C	00087795
83-3A	**Developmental Toxicity - Rat**	A,B,C	00163802
83-3B	**Developmental Toxicity - Rabbit**	A,B,C	41249201, 00087796
83-4	**2-Generation Reproduction - Rat**	A,B,C	40838401
84-2A	**Gene Mutation (Ames Test)**	A,B,C	86770, 00157527
84-2B	**Structural Chromosomal Aberration**	A,B,C	00087766, 00086767, 00086765, 00086768
84-4	**Other Genotoxic Effects**	A,B,C	41555102

Data Supporting Guideline Requirements for the Reregistration of Metribuzin

REQUIREMENT		USE PATTERN	CITATION(S)
85-1	**General Metabolism**	A,B,C	40255503
85-2	**Dermal Penetration**	Waived	
86-1	**Domestic Animal Safety**	N/R	
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
132-1A	**Foliar Residue Dissipation**	N/R	
132-1B	**Soil Residue Dissipation**	N/R	
133-3	**Dermal Passive Dosimetry Exposure**	N/R	
133-4	**Inhalation Passive Dosimetry Exposure**	N/R	
231	**Estimation of Dermal Exposure at Outdoor Sites**	N/R	
232	**Estimation of Inhalation Exposure at Outdoor Sites**	N/R	
233	**Estimation of Dermal Exposure at Indoor Sites**	N/R	
234	**Estimation of Inhalation Exposure at Indoor Sites**	N/R	
ENVIRONMENTAL FATE			
160-5	**Chemical Identity**	N/R	
161-1	**Hydrolysis**	A,B	0015730
161-2	**Photodegradation - Water**	A,B	TRID 470173-007
161-3	**Photodegradation - Soil**	A	470173-009

Data Supporting Guideline Requirements for the Reregistration of Metribuzin

REQUIREMENT		USE PATTERN	CITATION(S)
161-4	**Photodegradation - Air**	N/R	
162-1	**Aerobic Soil Metabolism**	A,B	40367602
162-2	**Anaerobic Soil Metabolism**	A	40367603
162-3	**Anaerobic Aquatic Metabolism**	N/R	
162-4	**Aerobic Aquatic Metabolism**	N/R	
163-1	**Leaching/Adsorption/Desorption**	A,B	42283001, 43058501, ACC# 263702
163-2	**Volatility - Lab**	N/R	
163-3	**Volatility - Field**	N/R	
164-1	**Terrestrial Field Dissipation**	A,B	42236101, 40380901
164-2	**Aquatic Field Dissipation**	N/R	
164-3	**Forest Field Dissipation**	N/R	
164-5	**Long Term Soil Dissipation**	N/R	
165-1	**Confined Rotational Crop**	A	40838402, **DATA GAP**
165-2	**Field Rotational Crop**	A	40838402, **DATA GAP**
165-3	**Accumulation - Irrigated Crop**	N/R	
165-4	**Bioaccumulation in Fish**	N/R	
165-5	**Bioaccumulation - Aquatic NonTarget**	N/R	
166-1	**Ground Water - Small Prospective**	A,B	**DATA GAP**
166-2	**Ground Water - Small Retrospective**	A,B	41422001

Data Supporting Guideline Requirements for the Reregistration of Metribuzin

REQUIREMENT		USE PATTERN	CITATION(S)
166-3	**Ground Water - Irrigated Retrospective**	N/R	
201-1	**Droplet Size Spectrum**	A,B	**Task Force**
202-1	**Drift Field Evaluation**	A,B	**Task Force**
RESIDUE CHEMISTRY			
171-4A	**Nature of Residue - Plants**	A,B	42967901, 42903601, 42967901, 00024737, 00036112, 00036219, 00036220, 00045257, 00045258, 00045260, 00045275, 00045278, 00045279, 00045280, 00106168
171-4B	**Nature of Residue - Livestock and Poultry**	A,B	00036105, 00036107, 00045263, 00106164, 42598201, 00036106, 00045262, 42598202

Data Supporting Guideline Requirements for the Reregistration of Metribuzin

REQUIREMENT		USE PATTERN	CITATION(S)
171-4C	**Residue Analytical Method - Plants**	A,B	00015412, 00015414, 00029800, 00036427, 00032428, 00032429, 00036216, 00036432, 00036433, 00036776, 00036782, 00039530, 00045256, 00054354, 00054369, 00069067, 00087925, 00087926, 00106163, 00106164, 00106165, 00106168, 00106169, 00106173, 00106179, 00106180, 00106182, 00106183, 00106185, 00106193, 00106199, 00106203, 00106205, 00106211, GS0181-006, GS0181-007, 41021001
171-4D	**Residue Analytical Method - Animal**	A,B	00036431,00045282, 43218205, 43218206
171-4E	**Storage Stability**	A,B	00036441, 00036777, 00036778, 00054355, 00054356, 00054358, 00054360, 00054363, 00054366, GS0181-002, 41020601, 43218201, 43218202, 43218203, 43218204, 43218205, 43218206, 43218207, 43252601, **Data Gap**
171-4G	**Magnitude of Residues in Fish**	N/R	
171-4H	**Magnitude of Residues - Irrigated Crop**	N/R	
171-4I	**Magnitude of Residues - Food Handling**	N/R	
171-4J	**Magnitude of Residues - Meat/Milk/Poultry/Egg**	A,B	00045283, 00045284, 00045286, 00036772, 00106199, 00045284, 00045286

Data Supporting Guideline Requirements for the Reregistration of Metribuzin

REQUIREMENT		USE PATTERN	CITATION(S)
171-4K	**Crop Field Trials**	A,B	
	Root and Tuber Vegetables Group		00144087, 00162025
	- Carrots		00026411, 00039525, 00039531, 00078436, 00078438, 00105212, 00106191, 00106199,
	- Potatoes		00106203, 00106205, 00106797, **Data Gap**
			00106179
	Legume Vetetables (Dry or Succulent) Group		00106179, 40277903,
	- Lentils		00015773, 00024503, 00064797, 00101537,
	-Peas (dry and succulent)		00106215, GS0181-003, 40277904
	-Soybeans		
			00106179
	Foliage of Legume Vegetables Group		00106179, 40277903
	- Lentil forage		00015773, 00015949, 00067433, 00086681,
	- Pea vines and hay		00087925, 00101537, 00106183, 00106215, 40277904, 42598200
	- Soybean forage and hay		
			00106180, 00106212
	Fruiting Vegetables Group		
	- Tomatoes		00036428, 00036444, 00087926, 00106182,
	Cereal Grains Group		00106185

REQUIREMENT	USE PATTERN	CITATION(S)
		00078943, 00106173, **Data gap**
- Wheat grain		00036426, 00036435, 00036439, 00036445, 00067425, 00087926, 00106173, 00106182, 00106184, 00106185, 40277905, 40367601, 40367604
Forage, Fodder, and Straw of Cereal Grains Group		
- Barley forage, hay, and straw		00036434, 00036440, 00045255, 00087926, 00106182, 00106185
- Corn, field, fodder and forage		00036429, 00036443, 00078942, 00078943, 00106173, 40277901, 40367605, 40371701
- Wheat forage, hay, and straw		00036426, 00036435, 00036439, 00036445,00067425, 00087926, 00106173, 00106182, 00106185, 40277905
Grass, Forage, Fodder, and Hay Group		
- Grass forage and hay		00036438, 00036770, 00036780
Non-grass Animal Feeds Group		
- Alfalfa forage and hay		00036437, 00036769, 00036779, 00106182, 00106185, 40277902,
- Sainfoin forage and hay		
Miscellaneous Commmodities		
- Asparagus		00036436, 00036781

REQUIREMENT		USE PATTERN	CITATION(S)
	- Aspirated grain fractions		43293201, **Data Gap**
	- Sugarcane		0010668, 00106190, 0016202
171-4l	**Magnitude of the Residues in Processed Food/Feed**	A,B	**Data Gap**
	- Barley (hulls, bran, flour, and pearl barley)		00036428, 00036444, 00087926, 00106182, 00106185, **Data gap**
	- Corn, field [wet milled (starch, crude oil, and refined oil); dry milled (grits, meal, flour, crude oil, and refined oil)]		40367605, 43293201
	- Potatoes (granules/flakes, chips, wet peel, and dried peel)		00036110, 00036112
	- Soybeans (meal, hulls, crude oil, and refined oil)		
	- Sugarcane (bagasse, molasses, and refined sugar)		Mobay Report Nos. 82828
	- Tomatoes (wet pomace, dried pomace, puree, paste, and juice)		00106180, 00106190, 00106202, **Data gap**
	- Wheat, milled fractions		00106180, 00106212

Data Supporting Guideline Requirements for the Reregistration of Metribuzin

REQUIREMENT		USE PATTERN	CITATION(S)
11-4j	**Magnitude of the Residue in Meat, Milk, Poultry, and Eggs**		
	- Cattle, goats, hogs, horses, and sheep		00045283
	- Poultry		00045284, 00045286
	- Milk		00036772, 00106199
	- Eggs		00045284, 00045286
	Reduction of Residues		
171-5		N/R	
	Proposed Tolerance		
171-6		N/R	
171-7	**Support for Tolerance**	N/R	
171-13	**Analtyical Reference Standard**	N/R	

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

00015412 Analytical Biochemistry Laboratories (1976) Recovery of Sencor and Metabolites from Soybeans: Report No. 51072. (Unpublished study received Jan 19, 1977 under 100-583; prepared for Mobay Chemical Corp., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 095747-W)

00015414 Thornton, J.S. (1974) A Modified Gas Chromatographic Method for the Determination of Sencor and Its Deaminated Diketo Metabolite in Soybeans: Report No. 42232. Method dated Dec 4, 1974. (Unpublished study received Jan 19, 1977 under 100-583; prepared by Mobay Chemical Corp., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:095748-V)

00015773 Searcy, S.; Herman, D.; Slagowski, J.L. (1978) Metolachlor (Dual¬(R)æ 8E); Metribuzin (Sencor 50W); Paraquat (2Cl): AG-A No. 4894 I,II. (Unpublished study including letter dated May 23, 1978 from J.D. Riggleman to Robert A. Kahrs, received Mar 16, 1979 under 100-583; prepared in cooperation with E.I. du Pont de Nemours & Co., Inc. and Chevron Chemical Co., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:237821-O)

00015949 Analytical Biochemistry Laboratories (1977) Chemagro Agricultural Division--Mobay Chemical Corporation Residue Experiment: MW-HR409-75: Report No. 51071. (Unpublished study including report nos. 51065, 51069 and 51070, received Jan 19, 1977 under 100583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 095747-AH)

00024503 Monsanto Company (1974) Summary of Residue Data. (Unpublished study received Jan 16, 1978 under 524-285; CDL:232680-B)

00024737 Hilton, H.W.; Nomura, N.S.; Kameda, S.S.; et al. (1976) Some patterns of herbicide and growth regulator intake, persistence, and distribution in sugarcane. Archives of Environmental Contamination and Toxicology 4(4):385-394. (Also~In~unpublished submission received Jul 19, 1978 under 201-403; submitted by Shell Chemical Co., Washington, D.C.; CDL:234470-AP)

00026411 Mobay Chemical Corporation (1977) ¢Residue Data for Sencor, Alachlor in Potatoes*. (Unpublished study received Jan 2, 1980 under WA 79/88; prepared in cooperation with Analytical Biochemistry Laboratories, Inc., submitted by State of Washington for Monsanto Co., Washington, D.C.; CDL:241541-A)

00029800 Thornton, J.S.; Schumann, S.A.; Boughton, P.J.; et al. (1974) A Gas Chromatographic Method for the Determination of Sencor and Its Deaminated Diketo Metabolite in Soybeans. Rev. Method no. 30387 dated Apr 11, 1972. (Unpublished study received Dec 21, 1974 under 5G1580; prepared by Baychem Corp., submitted by American Cyanamid Co., Princeton, N.J.; CDL:094331-J)

00032428 Stanley, C.W.; Thornton, J.S. (1972) A Gas Chromatographic Method for the Determination of Sencor and Metabolites in Sugarcane and Products: Report No. 35115. Method dated Dec 7, 1972. (Unpublished study received Jul 2, 1975 under 239-2186; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:119807-E)

BIBLIOGRAPHY

MRID	CITATION
00032429	Baychem Corporation (1973) Recovery of Sencor from Dry Soybeans: Report No. 35413. (Unpublished study received Jul 2, 1975 under 239-2186; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:119807-F)
00036105	Murphy, J.J.; Jacobs, K.; Lamb, D.W. (1974) The Metabolism of Sencor in a Dairy Cow: Report No. 40708. (Unpublished study received Oct 10, 1974 under 5F1559; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:095130-B)
00036106	Bell, R.L.; Murphy, J.J. (1974) The Metabolism of Sencor in Chickens: Report No. 40712. Rev. (Unpublished study received Oct 10, 1974 under 5F1559; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:095130-C)
00036107	Shaw, H.R., II; Murphy, J.J. (1974) The Metabolic Fate of ¢5-14C* Sencor in Pigs: Report No. 40768. (Unpublished study received Oct 10, 1974 under 5F1559; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:095130-D)
00036110	Thornton, J.S. (1974) Effect of Commercial Processing on Residues of Sencor in Potatoes: Report No. 42341. (Unpublished study received on unknown date under 5F1559; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:095987-B)
00036112	Simmons, C.E.; Gronberg, R.R. (1974) The Fate of Carbon-14-Labeled Sencor in Potatoes Processed by Pan or French Frying: Report No. 42452. (Unpublished study received on unknown date under 5F1559; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:095987-D)
00036216	Stanley, C.W. (1974) Comparison of Hydrolysis Methods for Sencor from Alfalfa: Report No. 40977. (Unpublished study received on unknown date under 4F1432; submitted by Chemagro Corp., Kansas City, Mo.; CDL:095519-A)
00036219	Morgan, J.G. (1972) Preliminary Studies on the Metabolism of Sencor in Tomatoes: Report No. 35013. (Unpublished study received Sep 27, 1973 under 4F1432; submitted by Chemagro Corp., Kansas City, Mo.; CDL:095519-F)
00036220	Morgan, J.G. (1973) Metabolism of Sencor in Tomatoes: Report No. 35969. (Unpublished study received Sep 27, 1973 under 4F1432; submitted by Chemagro Corp., Kansas City, Mo.; CDL: 095519-G)
00036426	Chemagro Corporation (1974) Chemagro Division of Baychem Corporation Residue Experiment 661-4828-73H: Report No. 41349. (Unpublished study including report nos. 41350 and 41351, received May 14, 1975 under 5F1628; prepared in cooperation with Cannon Laboratories, CDL:094425-A)

BIBLIOGRAPHY

MRID	CITATION
00036427	Cannon Laboratories (1974) Recovery of Sencor and Dadk from Barley and Wheat Grain: Report No. 41352. (Unpublished study received May 14, 1975 under 5F1628; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:094425-B)
00036428	Chemagro Corporation (1974) Chemagro Division of Baychem Corporation Residue Experiment 661-Extra-73D: Report No. 41353. (Unpublished study including report nos. 41354, 41355, 41356..., received May 14, 1975 under 5F1628; prepared in cooperation with Cannon Laboratories; CDL:094425-C)
00036429	Morse Laboratories (1974) Chemagro Agricultural Division--Mobay Chemical Corporation Residue Experiment 361-4701-73H: Report No. 41820. (Unpublished study including report nos. 41822, 41823, 41824..., received May 14, 1975 under 5F1628; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:094425-D)
00036431	Sandie, F.E.; Gronberg, R.R. (1975) A Gas Chromatographic Method for Determining Residues of Sencor and Metabolites in Animal Tissues, Milk and Eggs: Report No. 42257. Method dated May 5, 1975. (Unpublished study received May 14, 1975 under 5F1628; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL: 094425-F)
00036432	Cannon Laboratories (1974) Recovery of Sencor from Barley and Wheat Straw: Report No. 42292. (Unpublished study received May 14, 1975 under 5F1628; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:094425-G)
00036433	Mobay Chemical Corporation (1974) Recovery of Sencor and Metabolites from Barley and Wheat Straw: Report No. 42293. (Unpublished study received May 14, 1975 under 5F1628; CDL:094425-H)
00036435	Mobay Chemical Corporation (1974) Raw Data and Chromatograms for Analysis of Sencor and Dadk on Wheat Straw: Report No. 42295. (Unpublished study received May 14, 1975 under 5F1628; CDL: 094425-J)
00036436	Mobay Chemical Corporation (1974) Chemagro Agricultural Division-Mobay Chemical Corporation Residue Experiment 661-47795-72H: Report No. 42326. (Unpublished study including report no. 42328, received May 14, 1975 under 5F1628; CDL:094425-K)
00036437	Mobay Chemical Corporation (1974) Chemagro Agricultural Division-Mobay Chemical Corporation Residue Experiment 661-4779A-72H: Report No. 42327. (Unpublished study including report nos. 42329, 42330 and 42332, received May 14, 1975 under 5F1628; CDL: 094425-L)
00036438	Mobay Chemical Corporation (1974) Chemagro Agricultural Division-Mobay Chemical Corporation Residue Experiment 661-4714 Extra-72H: Report No. 42331. (Unpublished study including report

no. 42333, received May 14, 1975 under 5F1628; CDL:094425-M)

00036439 Mobay Chemical Corporation (1974) Chemagro Agricultural Division-Mobay Chemical Corporation Residue Experiment 661-4832-73H: Report No. 42350. (Unpublished study including report nos. 42351, 42352, 42353..., received May 14, 1975 under 5F1628; prepared in cooperation with Cannon Laboratories; CDL:094425-N)

00036440 Mobay Chemical Corporation (1974) Chemagro Agricultural Division-Mobay Chemical Corporation Residue Experiment 661-4822-73H: Report No. 42363. (Unpublished study including report nos. 42364, 42365, 42366..., received May 14, 1975 under 5F1628; prepared in cooperation with Cannon Laboratories; CDL:094425-O)

00036441 Mobay Chemical Corporation (1974) The Effect of Frozen Storage at 0 to -10¬oæF on Sencor and Metabolite Residue in Milk: Report No. 42372. (Unpublished study received May 14, 1975 under 5F1628; CDL:094425-P)

00036443 Chemagro Corporation (1974) Chemagro Division of Baychem Corporation Residue Experiment 661-4710-73D: Report No. 40910. (Unpublished study including report nos. 40911, 40912, 40913..., received May 14, 1975 under 5F1628; prepared in cooperation with Morse Laboratories, submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:094424-C)

00036444 Mobay Chemical Corporation (1974) Raw Data and Chromatograms for the Analysis of Sencor and DADK in Barley Grain: Report No. 41237. Rev. (Unpublished study received May 14, 1975 under 5F1628; CDL:094424-D)

00036445 Cannon Laboratories (1974) Chemagro Division of Baychem Corporation Residue Experiment: 263-4839-73H: Report No. 41339. (Unpublished study including report nos. 41341, 41342, 41343..., received May 14, 1975 under 5F1628; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:094424-E)

00036769 Mobay Chemical Corporation (1974) Chemagro Agricultural Division-Mobay Chemical Corporation Residue Experiment 861-4708A-72D: Report No. 42374. (Unpublished study including report nos. 42466, 42467, 42468..., received May 14, 1975 under 5F1628; CDL: 094426-B)

00036770 Mobay Chemical Corporation (1974) Chemagro Agricultural Division-Mobay Chemical Corporation Residue Experiment: 861-4708 G-72H: Report No. 42375. (Unpublished study received May 14, 1975 under 5F1628; CDL:094426-C)

00036772 Mobay Chemical Corporation (1974) Chemagro Agricultural Division-Mobay Chemical Corporation Residue Experiment AH-71A-851: Report No. 42449. (Unpublished study received May 14, 1975 under 5F1628; CDL:094426-E)

00036776 Mobay Chemical Corporation (1974) Recovery of Sencor from Sainfoin: Report No. 42470.

MRID	CITATION

(Unpublished study received May 14, 1975 under 5F1628; CDL:094426-I)

00036777 Mobay Chemical Corporation (1974) The Effect of Frozen Storage at 0 to -10¬oæF on Sencor Residues in Green Alfalfa: Report No. 42471. (Unpublished study received May 14, 1975 under 5F1628; CDL:094426-J)

00036778 Mobay Chemical Corporation (1974) The Effect of Frozen Storage at 0 to -10¬oæF on Sencor Residues in Poultry Tissues and Eggs: Report No. 42451. (Unpublished study received May 14, 1975 under 5F1628; CDL:094426-K)

00036779 Mobay Chemical Corporation (1975) Chemagro Agricultural Division-Mobay Chemical Corporation Residue Experiment 263-4701-72H: Report No. 42484. (Unpublished study including report nos. 42485, 42486, 42487..., received May 14, 1975 under 5F1628; CDL: 094427-A)

00036780 Mobay Chemical Corporation (1974) Chemagro Agricultural Division-Mobay Chemical Corporation Residue Experiment 661-4704 Extra72H: Report No. 42492. (Unpublished study received May 14, 1975 under 5F1628; CDL:094427-B)

00036782 Morris, R.A. (1975) Interference Study for the Residue Method for Sencor and Its Metabolites in Various Crops: Report No. 42735. (Unpublished study received May 14, 1975 under 5F1628; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:094427-D)

00039525 American Cyanamid Company (1975) General Summary: Prowl Herbicide and Its Metabolite and Sencor Residues in or on Potatoes. Summary of studies 095485-Q through 095485-S. (Unpublished study received Feb 9, 1976 under 6G1739; CDL:095485-K)

00039530 Devine, J.M.; Thornton, J.S.; Stanley, C.W. (1975) Sencor (Bay 94337): The Gas Chromatographic Determination of Sencor ¢4Amino-6-t-butyl-3-(methylthio)-1,2,4-triazin-5(4H)-one* from Fortified Potatoes: Report No. C-767. Includes method, report no. 33005, dated Apr 14, 1972. (Unpublished study received Feb 9, 1976 under 6G1739; prepared in cooperation with Chemagro Corp., submitted by American Cyanamid Co., Princeton, N.J.; CDL: 095485-P)

00039531 Devine, J.M.; Nzewi, G.I.; Boughton, P.J.; et al. (1975) Prowl¬(R)æ (CL 92,553): Determination of CL 92,553 ¢N-(1-Ethylpropyl)-3,4dimethyl-2,6-dinitrobenzenamide*, CL 202,347 ¢4-(¢1-Ethylpropyl* amino)-2-methyl-3,5-dinitro benzyl alcohol* and Sencor ¢4-Amino6-t-butyl-3-(methylthio)-1,2,4-triazin-5(4H)-one* Residues in Potatoes: Report No. C-787. (Unpublished study received Feb 9, 1976 under 6G1739; submitted by American Cyanamid Co., Princeton, N.J.; CDL:095485-Q)

00045255 Chemagro Corporation (1975) Supplement to Synopsis of the Effects of Sencor on the Environment. Summary of studies 094871-C through 094871-F, 094871-I through 094871-O, 094871-Q through 094871-S. (Supplement no. 1; unpublished study received Mar 7, 1975 under 5F1559; submitted by

Mobay Chemical Corp., Kansas City, Mo.; CDL:094871-A)

00045256 Stanley, C.W.; Schumann, S.A. (1969) A Gas Chromatographic Method for the Determination of Bay 94337 Residues in Potatoes, Soybeans, and Corn: Report No. 25,838. Method dated Oct 16, 1969. (Unpublished study received Mar 7, 1975 under 5F1559; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:094871-B)

00045257 Robinson, R.A.; Gronberg, R.R.; Shaw, H.R., II (1970) Bay 94337 Metabolism in Plants: Report No. 26,175. Rev. (Unpublished study received Mar 7, 1975 under 5F1559; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:094871-C)

00045258 Gronberg, R.R.; Flint, D.R.; Shaw, H.R.; et al. (1971) The Metabolism of Sencor (Bay 94337) in Soybean Plants: Report No. 29800. (Unpublished study received Mar 7, 1975 under 5F1559; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:094871-D)

00045260 Church, D.D.; Flint, D.R. (1973) The Metabolism of Sencor in Potatoes: Report No. 32047. Rev. (Unpublished study received Mar 7, 1975 under 5F1559; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:094871-F)

00045262 Morgan, J.G.; Flint, D.R. (1972) Sencor Residues in Chicken Eggs and Tissue: Report No. 33226. (Unpublished study received Mar 7, 1975 under 5F1559; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:094871-H)

00045263 Flint, D.R.; Shaw, H.R., II (1972) Residues in Tissue and Milk from Goats Treated Daily with Sencor-14C in the Diet: Report No. 33255. (Unpublished study received Mar 7, 1975 under 5F1559; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:094871-I)

00045275 Morgan, J.G. (1974) The Metabolism of Sencor in Seedling Potatoes: Report No. 40564. (Unpublished study received Mar 7, 1975 under 5F1559; submitted by Mobay Chemical Corp., Kansas City, Mo., CDL:094870-C)

00045278 Stanley, C.W.; Flint, D.R. (1974) The Metabolism of Sencor in Alfalfa: Report No. 40853. (Unpublished study received Mar 7, 1975 under 5F1559; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:094870-I)

00045279 Hargroder, T.G.; Rogers, R.L. (1974) Behavior and fate of Metribuzin in soybean and hemp sesbania. Weed Science 22(3):238-245. (Also~In~unpublished submission received Mar 7, 1975 under 5F1559; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:094870-J)

00045280 Schumacher, R.W. (1974) Metabolism of Metribuzin in Soybeans and Soil: Report No. 40865. Doctoral dissertation, Univ. of Kentucky. (Unpublished study received Mar 7, 1975 under 5F1559;

submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL: 094870-K)

00045282 Sandie, F.E.; Gronberg, R.R. (1974) A Gas Chromatographic Method for Determining Residues of Sencor and Metabolites in Animal Tissues, Milk and Eggs: Report No. 42257. Method dated Dec 5, 1974. (Unpublished study received Mar 7, 1975 under 5F1559; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL: 094870-M)

00045283 Mobay Chemical Corporation (1974) ¢Sencor Residues in Cattle*: Report No. 42373. (Unpublished study received Mar 7, 1975 under 5F1559; CDL:094870-N)

00045284 Mobay Chemical Corporation (1974) ¢Sencor Residues in Poultry*: Report No. 42448. (Unpublished study received Mar 7, 1975 under 5F1559; CDL:094870-O)

00045286 Mobay Chemical Corporation (1974) ¢Sencor Residues in Eggs*: Report No. 42450. (Unpublished study received Mar 7, 1975 under 5F1559; CDL:094870-Q)

00054354 Thornton, J.S.; Stanley, C.W. (1972) A Gas Chromatographic Method for the Determination of Residues of Sencor and Its Metabolites in Potatoes: Report No. 33005. Method dated Apr 14, 1972. (Unpublished study received Aug 14, 1980 under 3125-314; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:243067-B)

00054355 Thornton, J.S. (1972) Effect of Room Temperature Storage on Residues of Sencor and Metabolites in Mature Potatoes: Report No. 33058. (Unpublished study received Aug 14, 1980 under 3125314; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL: 243067-C)

00054356 Mobay Chemical Corporation (1972) Effect of Frozen Storage at 0¬oæF on Sencor and DADK Residues in Soybeans: Report No. 33289. (Unpublished study received Aug 14, 1980 under 3125-314; CDL: 243067-D)

00054358 Mobay Chemical Corporation (1973) The Effect of Frozen Storage at 0 to -10¬oæF on Sencor Residues in Potatoes: Report No. 35845. (Unpublished study received Aug 14, 1980 under 3125-314; CDL: 243067-F)

00054360 Mobay Chemical Corporation (1974) The Effect of Frozen Storage at 0 to -10¬oæF on Sencor Residues in Green Alfalfa: Report No. 42471. (Unpublished study received Aug 14, 1980 under 3125314; CDL:243067-M)

00054363 Mobay Chemical Corporation (1975) The Effect of Frozen Storage at 0 to -10¬oæF on Sencor¬(TM)æ and Metabolite Residues in Green Peas: Report No. 44621. (Unpublished study received Aug 14, 1980 under 3125-314; CDL:243067-P)

00054366 Mobay Chemical Corporation (1974) The Effect of Frozen Storage at 0 to -10¬oæF on¬(R)æSencor

Residues in Tomatoes: Report No. 47371. (Unpublished study received Aug 14, 1980 under 3125314; CDL:243067-S)

00054369 Thornton, J.S.; Stanley, O.W. (1977) Gas chromatographic determination of Sencor and metabolites in crops and soil. Journal of Agricultural and Food Chemistry 25(2):380-386. (Submitter report no. 52909; also~In~unpublished submission received Aug 14, 1980 under 3125-314; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:243067-W)

00061260 Loser, E.; Mirea, D. (1974) Bay 94 337: Chronic Toxicity Studies on Dogs (Two-Year Feeding Experiment): Report No. 4887; Report No. 41814. (Unpublished study received on unknown date under 5F1559; prepared by Bayer, AG, submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:094258-J)

00061261 Loser, E.; Mohr, U. (1974) Bay 94337: Chronic Toxicity Studies on Rats (Two-Year Feeding Experiment): Report No. 4888; Report No. 41816. (Unpublished study received on unknown date under 5F1559; prepared by Bayer, AG and Medizinische Hoschule Hannover, submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:094259-A)

00064797 Wilson, G.R.; Baszis, S.R.; Steinmetz, J.R.; et al. (1980) Residues of Acetochlor in Soybean and Corn Grain following Preemergent Treatment with Acetochlor Alone or in Tank-mix Combinations with Atrazine, Linuron and Metribuzin: Report No. MSL-1242. Final rept. (Unpublished study received Dec 12, 1980 under 524-EX-56; submitted by Monsanto Co., Washington, D.C.; CDL: 099813-A)

00065507 Lamb, D.W.; Burke, M.A. (1977) Dietary Toxicity of ~(R)æSencor Technical to Bobwhite Quail and Mallard Ducks: Report No. 51593. (Unpublished study received Apr 13, 1977 under 3125-270; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:229312-A)

00067425 Monsanto Company (1980) Residues of Glyphosate and Other Herbicides in Wheat following Chemical Fallow Applications of Roundup¬(R)æ Tank Mix Combinations. Includes method dated Jul 1, 1979 and undated methods entitled: 2,4-D in wheat forage, straw and grain; Dicamba in wheat forage, straw and grain; Residues of alachlor in wheat grain, forage and straw; Atrazine in wheat forage, straw and grain; Cyanazine in wheat forage, straw and grain; Metribuzin and metabolites in wheat forage, straw and grain. (Unpublished study, including published data, received Dec 29, 1980 under 524-308; CDL:243990-A; 243991)

00067433 Harrison, S.L.; Boros, E.J. (1980) Chloramben, Trifluralin & Metribuzin (+ DADK) Analyses of Soybeans Treated with Amiben + Treflan + Sencor or Lexone Tank Mix PPI: Project Report 10123/1280A. (Unpublished study received Dec 19, 1980 under 264-138; prepared in cooperation with Southern Illinois Univ., Plant & Soil Science Dept. and others, submitted by Union Carbide Agricultural Products Co., Inc., Ambler, Pa.; CDL:243984-F)

00069067 Thornton, J.S. (1974) A Gas Chromatographic Method for the Determination of Sencor and

MRID	CITATION

Metabolites in Various Crops: Report No. 40901. Method dated Dec 11, 1974. (Unpublished study received Sep 13, 1976 under 3125-277; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:226759-H)

00078436 Wilson, G.R.; Dubelman, S. (1981) Residues of Alachlor in Potatoes following Preemergent and Lay-by Treatment with Lasso¬(R)æ Alone or in Tank-mix Combinations with Metribuzin: Report No. MSL1559. Final rept. (Unpublished study received Aug 7, 1981 under 1F2551; submitted by Monsanto Co., Washington, D.C.; CDL: 070279-A)

00078438 Stauffer Chemical Company (1980) Eptam 7-E + Metribuzin Tank Mix on Potatoes: Summary of Crop Residue Data. (Compilation; unpublished study received Jul 27, 1981 under 476-2154; CDL:245620-B)

00078943 Mobay Chemical Corporation (1981) Addition to Synopsis of Sencor Residue Chemistry on Various Crops: Addition No. 5. (Compilation; unpublished study received Jul 13, 1981 under 3125-314; CDL:245573-A)

00086681 Mobay Chemical Corporation (1981) Addition to Synopsis of Sencor: Residue Chemistry on Soybeans. Summary of studies 246225-B and 246225-C. (Compilation; unpublished study received Oct 29, 1981 under 3125-277; CDL:246225-A)

00086765 Machemer, L.; Lorke, D. (1974) Evaluation of the Mutagenic Potential of ¬(R)æSencor in an~in vivo~Cytogenetic Study on Spermatogonia of Chinese Hamster: Report No. 4961; 43067. (Unpublished study received Nov 3, 1981 under 3125-270; prepared by Bayer AG, West Germany, submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:246226-A)

00086766 Machemer, L.; Lorke, D. (1974) Evaluation of ¬(R)æSencor for Mutagenic Effects on the Mouse: Report No. 4942; 43068. (Unpublished study received Nov 3, 1981 under 3125-270; prepared by Bayer AG, West Germany, submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:246226-B)

00086767 Machemer, L.; Lorke, D. (1975) ¬(R)æSencor: Dominant Lethal Study on Male Mice To Test for Mutagenic Effects: Report No. 5523; 45023. (Unpublished study received Nov 3, 1981 under 3125-270; prepared by Bayer AG, West Germany, submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:246226-C)

00086770 Inukai, H.; Iyatomi, A. (1977) Bay 94337: Mutagenicity Test on Bacterial Systems: Report No. 67; 54127. (Unpublished study received Nov 3, 1981 under 3125-270; prepared by Nitokuno Agricultural Chemicals Institute, Japan, submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:246226-F)

00087795 Hayes, R.H.; Lamb, D.W.; Mallicoat, D.R.; et al. (1981) Metribuzin (¬(R)æ Sencor) Oncogenicity Study in Mice: 80050. (Unpublished study received Nov 23, 1981 under 3125-270; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:246397-A)

BIBLIOGRAPHY

MRID **CITATION**

00087796 Unger, T.M.; Shellenberger, T.E. (1981) A Teratological Evaluation of Sencor¬(R)æ in Mated Female Rabbits: 80051. Final rept. (Unpublished study received Nov 23, 1981 under 3125-270; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:246397-B)

00087925 Mobay Chemical Corporation (1978) ¬(R)æSencor Residue Chemistry on Soybeans: Supplement No. 5. (Compilation; unpublished study received Dec 16, 1981 under 3125-277; CDL:246510-A)

00087926 Mobay Chemical Corporation (1981) ¬(R)æ Sencor Residue Chemistry on Various Crops: Addition No. 7. (Compilation; unpublished study received Dec 23, 1981 under 3125-277; CDL:246509-A)

00101537 Lauer, R.; Dubelman, S. (1982) Residues of Alachlor in Soybeans Following Preemergent Treatment with Lasso ME Alone or in Tankmix Combinations with Roundup, Linuron and Metribuzin: Report No. MSL 2084. (Unpublished study received May 10, 1982 under 524-344; submitted by Monsanto Co., Washington, DC; CDL: 070844-B)

00105212 Frank, R.; Sieck, R.; Shuey, E. (1979) Oryzalin and Metribuzin Residues in White Potatoes When Surface Applied to Control Weeds. (Unpublished study received Jul 1, 1982 under 1471-96; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, IN; CDL:070954-A)

00106149 Crawford, C.; Anderson, R. (1972) The Acute Dermal Toxicity of Sencor Technical and Sencor 50% Wettable Powder to Rats and Rabbits: Report No. 33123. (Unpublished study received May 17, 1972 under 3125-270; submitted by Mobay Chemical Corp., Kansas City, MO; CDL:051077-A)

00106158 Kimmerle, G.; Solecke, B.; Lorke (1969) Bay 94 337 Toxicological Studies from Dr. George Kimmerle, M.D. and Dr. Brigitte Solecke, V.M.D.: Report No. 1574; 25942. (Unpublished study received Jul 3, 1971 under 0G0940; prepared by Farbenfabriken Bayer, AG, W. Ger., submitted by Mobay Chemical Corp., Kansas City, MO; CDL: 091606-I)

00106163 Mobay Chemical Corp. (1969) Bay 94337 Metabolic, Analytical, and Residue Information on Potatoes and Soybeans. (Compilation; unpublished study received Jan 16, 1970 under 0G0940; CDL: 091607-A)

00106164 Mobay Chemical Corp. (1972) Sencor (Bay 94337) Metabolic, Analytical, and Residue Information on Soybeans. (Compilation; unpublished study received Oct 5, 1972 under 2F1274; CDL:091806-A; 091807)

00106165 Thornton, J. (1973) Effect of Cooking (Steaming) on the Release of Sencor Residues from Soybeans: Report No. 36826. (Unpublished study received Oct 6, 1972 under 2F1274; submitted by Mobay Chemical Corp., Kansas City, MO; CDL:091809-A)

00106168 Mobay Chemical Corp. (1973) Sencor: Metabolic, Analytical, and Residue Information for Sugarcane (Hawaii). (Compilation; unpublished study received Mar 30, 1973 under 4F1432; CDL:

093822-A; 093820)

00106169 Mobay Chemical Corp. (1972) Sencor (BAY 94337): Metabolic, Analytical, and Residue Information on Tomatoes. (Compilation; unpublished study received Apr 25, 1972 under 4F1432; CDL: 093821-A)

00106173 Mobay Chemical Corp. (1975) Sencor: Analytical, Metabolic, and Residue Information for Various Crops. (Compilation; unpublished study received May 14, 1975 under 5F1628; CDL:094423-A)

00106179 Mobay Chemical Corp. (1975) Sencor ... Residue Chemistry on Lentils and Peas: Document No. AS76-788. (Compilation; unpublished study received Jun 29, 1976 under 3125-277; CDL:095551-A)

00106180 Mobay Chemical Corp. (1976) Addition No. 1 to Brochure Entitled: Sencor: Residue Chemistry on Tomatoes: Document No. AS76-549. (Compilation; unpublished study received May 6, 1976 under 6F1783; CDL:095907-A)

00106182 Mobay Chemical Corp. (1977) Sencor Residue Chemistry on Various Crops: Addition No. 1 to Brochure Entitled: Sencor Analytical, Metabolic, and Residue Information for Various Crops: Document No. AS 77-1557. (Compilation; unpublished study received Sep 21, 1977 under 3125-277; CDL:096367-A)

00106183 Mobay Chemical Corp. (1977) Sencor Residue Chemistry on Soybeans: Supplement No. 4 to Brochure Entitled: Sencor (Formerly Bay 94337) Metabolic, Analytical and Residue Information on Soybeans: Document No. AS 78-153. (Compilation; unpublished study received Feb 13, 1978 under 3125-277; CDL:096820-A)

00106184 Kadoum, A.; Gronberg, R. (1978) Effect of Dry Milling and Gluten Processing on Sencor and DADK Residues in Wheat Grain: Document No. AS78-1271; Report No. 66113. (Unpublished study received Jun 16, 1978 under 3125-277; prepared by Kansas State Univ., Dept. of Entomology, submitted by Mobay Chemical Corp., Kansas City, MO; CDL:097164-A)

00106185 Mobay Chemical Corp. (1978) Sencor Residue Chemistry on Various Crops: Addition No. 3 to Brochure Entitled: Sencor Analytical, Metabolic and Residue Information for Various Crops: Document No. AS78-1274. (Compilation; unpublished study received Jun 16, 1978 under 3125-277; CDL:097165-A)

00106190 Chemagro Corp. (1975) ¢Residues of Sencor in Sugarcane*. (Compilation; unpublished study received Oct 8, 1975 under 4F1432; CDL:098168-F)

00106191 Houseworth, L. (1979) Residues of Metolachlor and Metribuzin in Potato Tubers Resulting from the Use of Metolachlor and Metolachlor/Metribuzin Tank Mixes for Weed Control in Potato Culture: Report No.: ABR-79040. (Unpublished study received Apr 25, 1979 under 100-583; submitted by

Ciba-Geigy Corp., Greensboro, NC; CDL:098227-A)

00106193 Thornton, J.; Schumann, S. (1971) A Gas Chromatographic Method for the Determination of Sencor and Its Deaminated Diketo Metabolite in Potatoes and Soybeans: Report No. 30387. (Unpublished study received on unknown date under 0G0940; submitted by Chemagro Corp., Kansas City, MO; CDL:098576-A)

00106197 Heitmuller, T. (1975) Acute Toxicity of Sencor to Eastern Oysters (Crassostrea virginica), Pink Shrimp (Penaeus duorarum), and Fiddler Crabs (Uca pugilator): ¢submitter* 43851. (Unpublished study received Aug 19, 1975 under 3125-294; prepared by Bionomics--EG & G, Inc., submitted by Mobay Chemical Corp., Kansas City, MO; CDL:165011-A)

00106199 Mobay Chemical Corp. (1973) Sencor (Formerly BAY 94337): Metabolic, Analytical, Residue, and Flavor Evaluation for Potatoes. (Compilation; unpublished study received Mar 8, 1973 under 3125-EX120; CDL:127000-A; 127001)

00106202 Mobay Chemical Corp. (1976) Sencor: Residue Chemistry on Sugarcane: Addition No. 2 to Brochure Entitled: Sencor: Metabolic, Analytical and Residue Information for Sugarcane (Hawaii): Document No. AS76-1245. (Compilation; unpublished study received Sep 10, 1976 under 3125-277; CDL:226131-A)

00106203 Mobay Chemical Corp. (1973) Addition No. 1 to Brochure Entitled: Sencor: Residue Chemistry on Potatoes: Document No. AS77-47. (Compilation; unpublished study received Jan 24, 1977 under 3125-277; CDL:228041-A)

00106205 Mobay Chemical Corp. (1973) Addition No. 2 to Brochure Entitled: Sencor: Residue Chemistry on Potatoes. (Compilation; unpublished study received Nov 30, 1977 under 3125-314; CDL:232357-A)

00106211 Mobay Chemical Corp. (1978) Sencor Residue Chemistry on Various Crops: Addition No. 2, Feb 3, 1978, to Brochure Entitled: Sencor Analytical, Metabolic and Residue Information for Various Crops (Dated January 23, 1975): Document No. AS78-1882. (Compilation; unpublished study received Sep 11, 1978 under 3125-314; CDL: 235087-A)

00106212 Mobay Chemical Corp. (1978) Sencor Residue Chemistry on Tomatoes: Addition No. 2, May 3, 1978, to Brochure Entitled: Sencor (Bay 94337) Metabolic, Analytical and Residue Information on Tomatoes (Dated Apr 25, 1972): Document No. AS78-2011. (Compilation; unpublished study received Oct 3, 1978 under 3125-314; CDL: 235319-A)

00106215 BASF Wyandotte Chemical Corp. (1978) Basalin Herbicide Amended Registration: Basalin Tank Mixture and Sequential Application with Metribuzin: Residue Chemistry--Part 03. (Compilation; unpublished study received Nov 8, 1978 under 7969-46; CDL: 235698-B)

00106797 American Cyanamid Co. (1978) Amounts of Residues of Prowl, Its Metabolite (CL 202,347)

BIBLIOGRAPHY

MRID **CITATION**

Metribuzin (Sencor or Lexone) and Eptam in or on Potatoes. (Compilation; unpublished study received Oct 5, 1978 under 241-243; CDL:097433-A; 097434)

00144087 Interregional Research Project No. 4 (1983) The Results of Tests on the Amount of Metribuzin Residues Remaining in or on Carrots. Unpublished compilation. 51 p.

00147003 Mobay Chemical Corp. (1985) Product Chemistry of Sencor Technical. Unpublished study. 104 p.

00153706 Thyssen, J. (1981) DIC 1468: (Sencor Active Ingredient): Subacute Inhalation Studies with Rats: Report No. 9679. Unpublished study prepared by Bayer AG, Institute of Toxicology. 126 p.

00156321 Talbott, T. (1980) The Composition of Sencor: Report No. 68761. Unpublished study prepared by Mobay Chemical Corp. 11 p.

00156322 Johnson, M. (1985) Maximum and Minimum Certified Limits for Sencor 50% Wettable Powder (Repacking): GLC Determination of Sencor and Bay 98719 (N-Methyl Isomer): Report No. 90369: C-28.1. Unpublished study. 13 p.

00156324 Mobay Chemical Corp. (1985) Product Chemistry of Sencor Technical: Brochure 1433: Supplement 1 ?to Brochure 1388. Unpublished compilation. 81 p.

00157524 Shiotsuka, R. (1986) Acute Inhalation Toxicity Study with Metribuzin (Sencor) in Rats: Study No. 85-041-18: Mobay Report No. 91754. Unpublished study prepared by Mobay Chemical Corp. 20 p.

00157527 Yang, L. (1986) CHO/HGPRT Mutation Assay in the Presence and Absense of Exogenous Metabolic Activation: Test Article: Sencor Technical (Metribuzin): Final Report: MA Study No. T4485.332. Unpublished Mobay Report No. 91760 prepared by Microbiological Associates, Inc. 17 p.

00157530 Morgan, J. (1986) The Hydrolysis of Sencor-5-?carbon 14: Mobay Report No. 91764. Unpublished study prepared by Mobay Chemical Corp. 11 p.

00157531 Morgan, J. (1986) The Photodecomposition of Sencor-5-?Carbon 14 on Soil: Mobay Report No. 91765. Unpublished study prepared by Mobay Chemical Corp. 26 p.

00161503 Nicholson, R.; Surprenant, D. (1986) Acute Toxicity of Sencor to Sheephead Minnow (Cyprinodon variegatus): Study No. 274-1285-6105-500: Report No. BW-86-2-1942. Unpublished study prepared by Springborn Bionomics, Inc. 20 p.

00161509 Talbott, T. (1983) Maximum and Minimum Certified Limits for Sencor: Report No. 86268. Unpublished study prepared by Mobay Corporation. 4 p.

00162025 Maitlen, J. (1985) Report of Residue Analysis: Metribuzin ?Carrots: Rept. No. PCY 85-12.

BIBLIOGRAPHY

MRID **CITATION**

Unpublished study prepared by Yakima Agricultural Research Laboratory, U.S. Dept. of Agriculture. 20 p.

00163802 Kowalski, R.; Clemens, G.; Bare, J.; et al. (1986) A Teratology Study with Sencor Technical (Metribuzin) in the Rat: 91330. Unpublished study prepared by Miles Laboratories, Inc. 212 p.

00165012 Betker, W. (1986) The Solubility, Melting Point and Density of Technical Sencor: Report No. 90935. Unpublished study prepared by Mobay Corp. 5 p.

40255503 Cain, K.; Hanlon, C.; Lane, J. (1987) The Excretion and Metabolism of Sencor by Rats: Lab Project ID: Mobay No. 94605. Unpublished study prepared by Mobay Corp. 62 p.

40277901 Loeffler, W. (1987) Sencor--Magnitude of Residue on Corn: Laboratory Project ID: SE-3086-86: Sencor Objective No. 3086. Unpublished Mobay report 94739 prepared by Morse Laboratories, Inc. 93 p.

40277902 Loeffler, W. (1987) Sencor--Magnitude of Residue on Seed Alfalfa: Laboratory Project ID: SE-3222-86: Sencor Objective No. 3222. Unpublished Mobay report 94745 prepared by Morse Laboratories, Inc. 57 p.

40277903 Loeffler, W. (1987) Sencor--Magnitude of Residue on Dry Peas: Laboratory Project ID: SE-1523-86: Sencor Objective No. 1523. Unpublished Mobay report 94735 prepared by Morse Laboratories, Inc. 46 p.

40277904 Loeffler, W. (1987) Sencor--Magnitude of Residue on Soybeans: Laboratory Project ID: SE-3745-86: Sencor Objective No. 3745. Unpublished Mobay report 94737 prepared by Morse Laboratories, Inc. 77 p.

40277905 Loeffler, W. (1987) Sencor--Magnitude of Residue on Wheat: Laboratory Project ID: SE-3052-85/86: Sencor Objective No. 3052. Unpublished Mobay report 94742 prepared by Morse Laboratories, Inc. 84 p.

40367601 Delk, J. (1987) Sencor Magnitude of Residues on Wheat and Wheat Processing Products: Lab. Proj. ID. SE-3052-85/86. Unpublished Mobay Study 94743 prepared by Morse Laboratories, Inc. 25 p.

40367602 Detra, R.; Lane, J.; Thyssen, M. (1987) Degradation of Sencor in Aerobic Sandy Loam: Rept. No. 94880. Unpublished study prepared by Mobay Corp. 44 p.

40367603 Detra, R.; Thyssen, M. (1987) Degradation of Sencor in Anaerobic Sandy Loam: Rept. No. 94881. Unpublished study prepared by Mobay Corp. 43 p.

40367604 Calovich, C. (1987) Summary of Residue Data on Wheat Potential for Secondary Residues in Animal Tissues and Products. Unpublished Mobay study 94744 prepared by Mobay Corp. and Morse

Laboratories, Inc. 13 p.

40367605 Delk, J. (1987) Sencor Magnitude of Residues on Corn and Corn Processing Products. Unpublished Mobay compilation 94740 prepared by Harris Laboratories, Inc. and Texas A & M Univ. System. 123 p.

40371701 Calovich, C. (1987) Summary of Residue Data on Corn Potential for Secondary Residues in Animal Tissues and Products: Sencor: Laboratory Project ID: SE-3086-86. Unpublished study prepared by Morse Laboratories, Inc. 12 p.

40380901 Delk, J. (1987) Dissipation of Sencor and its Oxidative Metabolites in Field Soil: Laboratory Project ID: SR-8300-87. Unpublished Mobay report no. 95000 prepared by Morse Laboratories Inc. 198 p.

40577701 Naidu, M. (1988) Metribuzin Confined Accumulation Study on Peanuts: Laboratory Project ID AMR-563-86. Unpublished study prepared by Research and Development Division, E. I. du Pont de Nemours and Company, Inc. 47 p.

40802701 Anderson, L. (1988) SENCOR Magnitude of Residue on Asparagus: Project ID. SE-1855-85. Unpublished study prepared by Morse Laboratories. 100 p.

40838401 Porter, M.; Jasty, V.; Hartnagel, R. (1988) A Two-Generation Reproduction Study in Rats with Sencor Technical (Metribuzin): Report No. 98295: MTD0080. Unpublished study prepared by Miles, Inc. 1025 p.

40838402 Christopher, R.; Lane, J.; Parker, G. (1988) Residues of Metribuzin (Sencor) in Rotational Crops and Soils: Report No. 98324: Project No. SE-052301. Unpublished study prepared by Mobay Corp. 45 p.

41020601 Burge, C.; Parker, G. (1988) Stabliity of Metribuzin and Ethiozin Metabolite Residues in Biological Matrices During Frozen Storage: Report NO. 98504. Unpublished study prepared by Mobay Corporation. 62 p.

41021001 Ver Hey, M. (1988) Sencor, Sencor DA, Sencor DK and Sencor DADK: Multiresidue Method Trial: Final Report: Mobay 1093: SE161601. Unpublished study prepared by Colorado Analytical Research & Development Corp. 496 p.

41249201 Clemens, G.; Hartnagel, R. (1989) Teratology Study in the Rabbit with Sencor Technical (Metribuzin): Project ID 99654. Unpublished study prepared by Miles, Inc. 131 p.

41284401 Talbott, T. (1989) Product Chemistry of Sencor Technical: Lab Project Number: 86268 : 91780 : 93048. Unpublished study prepared by Mobay Corp. 168 p.

41422001 Mulford, D.; Clay, V.; Lane, J.; et al. (1990) Small-scale Retrospective Ground Water Monitoring for

BIBLIOGRAPHY

MRID	CITATION

Metribuzin and Its Metabolites: Lab Project Number: 98510: SE-7000-87-R-1. Unpublished study prepared by Mobay Corp. 2381 p.

41555102 Murli, H. (1990) Mutagenicity Test on Sencor Technical in an In Vitro Cytogenetic Assay Measuring Chromosonal Aberration Frequen cies in Chinese Hamster Ovary (CHO) Cells: Lab Project Number: 10857-0-437. Unpublished study prepared by Hazleton Labs America, Inc. 55 p.

41696401 Talbott, T. (1989) Sencor: Product Chemistry: Lab Project Number: ANR-01189: ANR-01289: BR 1662. Unpublished study prepared by Mobay Corp. 29 p.

42094501 Gagliano, G. (1991) Raw Data Supplement for Acute Toxicity of Sencor Technical to Eastern Oysters (Crassostrea virginica): Lab Project Number: 274-1285-6105-504: 91755-1. Unpublished study prepared by Springborn Bionomics, Inc. 11 p.

42094502 Gagliano, G. (1991) Raw Data Supplement for Acute Toxicity of Sencor Technical to Sheepshead Minnow (Cyprindon variegatus): Lab Project Number: 274-1285-6105-500: 91756-1. Unpublished study prepared by Springborn Bionomics, Inc. 13 p.

42236101 Grace, T.; Cain, K. (1990) Dissipation of Metribuzin in California Soils: Lab Project Number: SE830089R01; 100170; ML022101. Unpublished study prepared by Plant Sciences, Inc.; Siemer and Assoc's., Inc. and NET Atlantic, Inc. 3154 p.

42283001 Daly, D. (1988) Soil Adsorption/Desorption with ¢Carbon 14*-Sencor: Lab Project Number: #36997. Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc. 54 p.

42425601 Fontaine, L. (1992) Supplemental Product Chemistry of Sencor Technical: Lab Project Number: 90935: BR 1802. Unpublished study prepared by Miles, Inc. 11 p.

42447801 Gagliano, G.; Roney, D. (1992) Early Life Stage Toxicity of Sencor Technical to the Rainbow Trout (Oncorhynchus mykiss) under Flow-through Conditions: Lab Project Number: 103249: SE842201. Unpublished study prepared by Miles, Inc. 87 p.

42447802 Gagliano, G.; Bowers, L. (1992) Chronic Toxicity of Sencor Technical to the Waterflea (Daphnia magna) under Flow-through Conditions: Lab Project Number: 103248: SE840701. Unpublished study prepared by Miles, Inc. 75 p.

42447803 Burge, C. (1992) Tier 2 Seed Germination, Seed Emergence, and Seedling Vigor Nontarget Phytotoxicity Study Using Metribuzin: Lab Project Number: 103800: SE201601. Unpublished study prepared by Miles, Inc. 90 p.

42598200 Miles Inc. (1992) Supplemental submission of residue and product chemistry data in support of the registration standard for Metribuzin (Sencor Metribuzin Herbicide). Transmittal of 3 studies.

BIBLIOGRAPHY

MRID	CITATION
42598202	Christopher, R.; Muller, S. (1986) Distribution and Metabolism of Sencor in Laying Hens: Lab Project Number: SE-4-P: 94234. Unpublished study prepared by Mobay Corp. 62 p.
42598203	Fontaine, L. (1992) Product Chemistry of Sencor Technical: A Supplement: Lab Project Number: ANR-00892: BR 1815. Unpublished study prepared by Miles, Inc. 11 p.
42672501	Christenson, W.; Wahle, B. (1993) Technical Grade Metribuzin (Sencor): A Combined Chronic Toxicity/Oncogenicity Feeding Toxicity Study in the Rat: Lab Project Number: 88-271-BM: 103970. Unpublished study prepared by Miles Inc. 4593 p.
42903601	Morgan, J. (1993) Addendum 2: Characterization of Metribuzin Metabolites in Wheat Grain Aqueous Phase Reply to EPA Review. Lab Project Number: SE041601. Unpublished study prepared by Miles Inc. Research & Development Dept. 7 p.
42967901	Lenz, M.; Marlow, V.; Fig, P.; et al. (1993) Characterization for Two Metabolites of (carbon 14)-Metribuzin in Soybeans: Lab Project Number: 94593-1: SE041602. Unpublished study prepared by Miles Inc. 23 p.
43058501	Blumhorst, M.; Halarnkar, P. (1993) Soil Adsorption/Desorption of Metribuzin-DK: Lab Project Number: 122S17: SE182101: 106233. Unpublished study prepared by Bio-Analytical Services, Inc. 58 p.
43133601	Gagliano, G.; Orr, W. (1994) Acute Toxicity of SENCOR Technical to the Green Alga (Selenastrum capricornutum): Lab Project Number: SE881402. Unpublished study prepared by Miles, Inc. Sponsor report number: 106417. 33 p.
43168201	Fontaine, L. (1994) Product Chemistry of SENCOR Technical: Lab Project Number: 106482: BR 1871. Unpublished study prepared by Miles, Inc. 16 p.
43208301	Johns, C. (1994) Tier 2 Seed Germination and Seed Emergence Nontarget Phytotoxicity Study Using Metribuzin: Lab Project Number: SE201602: 106568. Unpublished study prepared by Miles Inc. 44 p.
43218201	Murphy, J.; Jacobs, K. (1974) Stability of SENCOR and Its Metabolites Under Frozen Storage: Lab Project Number: 40707R. Unpublished study prepared by Miles Inc. 11 p.
43218202	Gronberg, R. (1994) A Gas Chromatographic Method for the Determination of SENCOR and Metabolites in Various Crops: Reformat: Lab Project Number: 40901R. Unpublished study prepared by Miles Inc. 21 p.
43218203	Gronberg, R. (1994) A Gas Chromatographic Method for the Determination of SENCOR and Metabolites in Various Crops: Response to an EPA Inquiry Regarding Analysis of Aged Radioactive

MRID CITATION

Tissues with the Enforcement Method: Lab Project Number: 40901R-1. Unpublished study prepared by Miles Inc. 10 p.

43218204 Gronberg, R. (1994) A Gas Chromatographic Method for the Determination of SENCOR and Metabolites in Various Crops: Method Update: Lab Project Number: 40901R-2. Unpublished study prepared by Morse Laboratories, Inc. and Chemonics Industries. 10 p.

43218205 Gronberg, R. (1994) A Gas Chromatographic Method for the Determining Residues of SENCOR and Metabolites in Animal Tissues, Milk and Eggs: Reformat: Lab Project Number: 42257R. Unpublished study prepared by Miles Inc. 39 p.

43218206 Gronberg, R. (1994) A Gas Chromatographic Method for the Determining Residues of SENCOR and Metabolites in Animal Tissues, Milk and Eggs: Response to an EPA Inquiry Regarding Analysis of Aged Radioactive Tissues with the Enforcement Method: Lab Project Number: 42257R-1. Unpublished study prepared by Miles Inc. 12 p.

43218207 Minor, R. (1994) Review of the Storage Stability Data on Metribuzin and Its Metabolites in Crops and Processed Products: Lab Project Number: 102615: SE161601: SE131602. Unpublished study prepared by Ricerca, Inc. 1587 p.

43253601 Minor, R. (1994) Replies to Comments and Questions from EPA's Review of Data Submitted in Response to the Data Call-in (DCI) for Metribuzin: (Data submitted as alternate to Craven Laboratories generated data): Lab Project Number: 106566. Unpublished study prepared by Miles Inc. 103 p.

43826101 Bowers, L. (1995) Acute Toxicity of (carbon 14)-Sencor to the Freshwater Diatom (Navicula pelliculosa): Lab Project Number: 106975: SE881601. Unpublished study prepared by Bayer Corp. 33 p.

43860501 Hancock, G. (1995) Effect of Technical SENCOR on Mallard Reproduction: Lab Project Number: SE740801: 106983. Unpublished study prepared by Bayer Corp. 107 p.

43867701 Bowers, L. (1995) Toxicity of (carbon 14)-Sencor to the Marine Diatom, Skeletonema costatum: Lab Project Number: SE881602: 106992. Unpublished study prepared by Bayer Corp. 34 p.

43893501 Boeri, R.; Magazu, J.; Ward, T. (1995) Toxicity of Sencor to the Duckweed, Lemna gibba G3: (Amended Report): Lab Project Number: 667-MI: 106982. Unpublished study prepared by T. R. Wilbury Labs, Inc. 32 p.

43926601 Hancock, G. (1996) Effect of Technical SENCOR on Northern Bobwhite Reproduction: Lab Project Number: SE741701: 106984. Unpublished study prepared by Bayer Corp. 110 p.

43970701 Flucke, W.; Hartmann, E. (1989) DIC 1468 Technical Grade: (Common Name: Metribuzin):

BIBLIOGRAPHY

MRID	CITATION

Subacute Dermal Toxicity Study in Rabbits: Lab Project Number: 99683: 18195: T 3029453. Unpublished study prepared by Bayer Ag. 220 p.

44009900 Bayer Corp. (1996) Submission of Pesticide Use and Exposure/Risk to Non-Target Organisms Data in Support of RED for Metribuzin. Transmittal of 1 Study.

44009901 Ellisor, G.; Van Goethem, D.; Dannenberg, I. et al. (1996) Metribuzin Use Patterns, Exposure Assessment, Toxicological Endpoints, and Margins of Safety Estimates: Lab Project Number: 107305. Unpublished study prepared by Bayer Corp. 44 p.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

GENERIC AND PRODUCT SPECIFIC 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 A of this Notice, the Data Call-In Chemical Status Sheet, to submit certain data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. 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 7; or

2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3 (for both generic and product specific data), the Requirements Status and Registrant's Response Form, (see section III-B); or

3. Why you believe EPA should not require your submission of data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2. All products are listed on both the generic and product specific Data Call-In Response Forms. Also included is a list of all registrants who were sent this Notice (Attachment 5).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this

information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 3-31-99).

This Notice is divided into six sections and seven 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 - Generic Data Call-In and Product Specific Data Call-In Response Forms with Instructions (Form A)
3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms with Instructions (Form B)
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(s) and reevaluated the data needed to support continued registration of the subject active ingredient(s). This reevaluation identified additional data necessary to assess the health and safety of the continued use of products containing this active ingredient(s). You have been sent this Notice because you have product(s) containing the subject active ingredients.

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The data required by this Notice are specified in the Requirements Status and Registrant's Response Forms: Attachment 3 (for both generic and product specific data requirements). Depending on the results of the studies required in this Notice, additional studies/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 the Requirements Status and Registrant's Response Forms (Attachment 3) within the timeframes 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 (Telephone number: 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].

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

You must use the correct forms and instructions when completing your response to this Notice. The type of Data Call-In you must comply with (Generic or Product Specific) is specified in item number 3 on the four Data Call-In forms (Attachments 2 and 3).

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for generic and 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

1. Generic Data Requirements

The options for responding to this Notice for generic data requirements are: (a) voluntary cancellation, (b) delete use(s), (c) claim generic data exemption, (d) agree to satisfy the generic data requirements imposed by this Notice or (e) request a data waiver(s).

A discussion of how to respond if you choose the Voluntary Cancellation option, the Delete Use(s) option or the Generic Data Exemption option is presented below. A discussion of the various options available for satisfying the generic 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.

Two forms apply to generic data requirements, one or both of which must be used in responding to the Agency, depending upon your response. These two forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, (contained in Attachments 2 and 3, respectively).

The Data Call-In Response Forms must be submitted as part of every response to this Notice. The Requirements Status and Registrant's Response Forms also must be submitted if you do not qualify for a Generic Data Exemption or are not requesting voluntary cancellation of your registration(s). Please note that the company's authorized representative is required to sign the first page of both Data Call-In Response Forms and the Requirements Status and Registrant's Response Forms (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.

a. 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 completed Generic and Product Specific Data Call-In Response Forms (Attachment 2), indicating your election of this option. Voluntary cancellation is item number 5 on both Data Call-In Response Form(s). If you choose this option, these are the only forms 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.

b. Use Deletion -

You may avoid the requirements of this Notice by eliminating the uses of your product to which the requirements apply. If you wish to amend your registration to delete uses, you must submit the Requirements Status and Reqistrant's Response Form (Attachment 3), a completed application for amendment, a copy of your proposed amended labeling, and all other information required for processing the application. Use deletion is option number 7 under item 9 in the instructions for the Requirements Status and Reqistrant's Response Forms. You must also complete a Data Call-In Response Form by signing the certification, item number 8. Application forms for amending registrations may be obtained from the Registration Support Branch, Registration Division, Office of Pesticide Programs, EPA, by calling (703) 308-8358.

If you choose to delete the use(s) subject to this Notice or uses subject to specific data requirements, further sale, distribution, or use of your product after one year from the due date of your 90 day response, is allowed only if the product bears an amended label.

c. Generic Data Exemption -

Under section 3(c)(2)(D) of FIFRA, an applicant for registration of a product is exempt from the requirement to submit or cite generic data concerning an active ingredient if the active ingredient in the product is derived exclusively from purchased, registered pesticide products containing the active ingredient. EPA has concluded, as an exercise of its discretion, that it normally will not suspend the registration of a product which would qualify and continue to qualify for the generic data exemption in section 3(c)(2)(D) of FIFRA. To qualify, all of the following requirements must be met:

(i). The active ingredient in your registered product must be present solely because of incorporation of another registered product which contains the subject active ingredient and is purchased from a source not connected with you;

(ii). Every registrant who is the ultimate source of the active ingredient in your product subject to this DCI must be in compliance with the requirements of this Notice and must remain in compliance; and

(iii). You must have provided to EPA an accurate and current "Confidential Statement of Formula" for each of your products to which this Notice applies.

To apply for the Generic Data Exemption you must submit a completed Data Call-In Response Form, Attachment 2 and all supporting documentation. The Generic Data Exemption is item number 6a on the Data Call-In Response Form. If you claim a generic data exemption you are not required to complete the Requirements Status and Registrant's Response Form. Generic Data Exemption cannot be selected as an option for responding to product specific data requirements.

If you are granted a Generic Data Exemption, you rely on the efforts of other persons to

provide the Agency with the required data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Data Call-In Notice, the Agency will consider that both they and you are not compliance and will normally initiate proceedings to suspend the registrations of both your and their product(s), unless you commit to submit and do submit the required data within the specified time. In such cases the Agency generally will not grant a time extension for submitting the data.

d. Satisfying the Generic Data Requirements of this Notice

There are various options available to satisfy the generic data requirements of this Notice. These options are discussed in Section III-C.1. of this Notice and comprise options 1 through 6 of item 9 in the instructions for the Requirements Status and Registrant's Response Form and item 6b on the Data Call-In Response Form. If you choose item 6b (agree to satisfy the generic data requirements), you must submit the Data Call-In Response Form and the Requirements Status and Registrant's Response Form as well as any other information/data pertaining to the option chosen to address the data requirement. Your response must be on the forms marked "GENERIC" in item number 3.

e. Request for Generic Data Waivers.

Waivers for generic data are discussed in Section III-D.1. of this Notice and are covered by options 8 and 9 of item 9 in the instructions for 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.

2. Product Specific Data Requirements

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 choose 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.2. A discussion of options relating to requests for data waivers is contained in Section III-D.2.

Two forms apply to the product specific data requirements one or both of which must be used in responding to the Agency, depending upon your response. These forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, for product specific data (contained in Attachments 2 and 3, respectively). 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 also must be submitted for each product listed on the Data Call-In Response Form unless the voluntary cancellation option is selected. 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.

a. 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 both the Generic and Product Specific Data Call-In Response Forms. If you choose this option, you must complete both Data Call-In response forms. These are the only forms that you are required to complete.

If you choose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

b. 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.2. of this Notice and comprise options 1 through 6 of item 9 in the instructions for the product specific Requirements Status and Registrant's Response Form and item numbers 7a and 7b (agree to satisfy the product specific data requirements for an MUP or EUP as applicable) on the product specific Data Call-In Response Form. Note that the options available for addressing product specific data requirements differ slightly from those options for fulfilling generic data requirements. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements. It is important to ensure that you are using the correct forms and instructions when completing your response to the Reregistration Eligibility Decision document.

c. Request for Product Specific Data Waivers.

Waivers for product specific data are discussed in Section III-D.2. of this Notice and are covered by option 7 of item 9 in the instructions for the Requirements Status and Registrant's Response Form. If you choose this option, you must submit the Data Call-In Response Form and the Requirements Status and Registrant's Response Form as well as any other information/data pertaining to the option chosen to address the data requirement. Your response must be on the forms marked "PRODUCT SPECIFIC" in item number 3.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

1. Generic Data

If you acknowledge on the Generic Data Call-In Response Form that you agree to satisfy

the generic data requirements (i.e. you select item number 6b), then you must select one of the six options on the Generic 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 you to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified timeframe (Developing Data)
(2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1. Developing Data

If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG) and be in conformance with the requirements of PR Notice 86-5. In addition, certain studies require Agency approval of test protocols in advance of study initiation. Those studies for which a protocol must be submitted have been identified in the Requirements Status and Registrant's Response Form and/or footnotes to the form. If you wish to use a protocol which differs from the options discussed in Section II-C of this Notice, you must submit a detailed description of the proposed protocol and your reason for wishing to use it. The Agency may choose to reject a protocol not specified in Section II-C. If the Agency rejects your protocol you will be notified in writing, however, you should be aware that rejection of a proposed protocol will not be a basis for extending the deadline for submission of data.

A progress report must be submitted for each study within 90 days from the date you are required to commit to generate or undertake some other means to address that study requirement, such as making an offer to cost share or agreeing to share in the cost of developing that study. This 90-day progress report must include the date the study was or will be initiated and, for studies to be started within 12 months of commitment, the name and address of the laboratory(ies) or individuals who are or will be conducting the study.

In addition, if the time frame for submission of a final report is more than 1 year, interim reports must be submitted at 12 month intervals from the date you are required to commit to

generate or otherwise address the requirement for the study. In addition to the other information specified in the preceding paragraph, at a minimum, a brief description of current activity on and the status of the study must be included as well as a full description of any problems encountered since the last progress report.

The time frames in the Requirements Status and Registrant's Response Form are the time frames that the Agency is allowing for the submission of completed study reports or protocols. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the 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

If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3. Offer to Share in the Cost of Data Development

If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other

registrant(s) developing the data has refused to accept the 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 to 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 burden 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 normally will 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 '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, means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 also must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants also must 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 usually are not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If EPA has previously reviewed a protocol for a study you are submitting, you must identify any action taken by the Agency on the protocol and must indicate, as part of your certification, the manner in which all Agency comments, concerns, or issues were addressed in the final protocol and study.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such 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 also should be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally, your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria, as well as a certification regarding protocol compliance with Agency requirements.

Option 6. Citing Existing Studies

If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable, or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core-minimum." For ecological effects studies, the classification generally would be a rating of "core." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option, you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form 8570-31, Certification with Respect to Data Compensation Requirements.

2. Product Specific Data

If you acknowledge on the product specific Data Call-In Response Form that you agree to satisfy the product specific data requirements (i.e. you select option 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 -- The requirements for developing product specific data are the same as those described for generic data (see Section III.C.1, Option 1) except that normally no protocols or progress reports are required.

Option 2. Agree to Share in Cost to Develop Data -- If you enter into an agreement to cost share, the same requirements apply to product specific data as to generic data (see Section III.C.1, Option 2). However, 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.

Option 3. Offer to Share in the Cost of Data Development --The same requirements for generic data (Section III.C.I., Option 3) apply to this option. This option only applies to acute toxicity and certain efficacy data as described in option 2 above.

Option 4. Submitting an Existing Study -- The same requirements described for generic data (see Section III.C.1., Option 4) apply to this option for product specific data.

Option 5. Upgrading a Study -- The same requirements described for generic data (see Section III.C.1., Option 5) apply to this option for product specific data.

Option 6. Citing Existing Studies -- The same requirements described for generic data (see Section III.C.1., Option 6) apply to this option for product specific data.

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, and in the generic data requirements section (III.C.1.), as appropriate.

III-D REQUESTS FOR DATA WAIVERS

1. Generic Data

There are two types of data waiver responses to this Notice. The first is a request for a low volume/minor use waiver and the second is a waiver request based on your belief that the data requirement(s) are not appropriate for your product.

a. Low Volume/Minor Use Waiver

Option 8 under item 9 on the Requirements Status and Registrant's Response Form. Section 3(c)(2)(A) of FIFRA requires EPA to consider the appropriateness of requiring data for low volume, minor use pesticides. In implementing this provision, EPA considers low volume pesticides to be only those active ingredients whose total production volume for all pesticide registrants is small. In determining whether to grant a low volume, minor use waiver, the Agency will consider the extent, pattern and volume of use, the economic incentive to conduct the testing, the importance of the pesticide, and the exposure and risk from use of the pesticide. If an active ingredient is used for both high volume and low volume uses, a low volume exemption will not be approved. If all uses of an active ingredient are low volume and the combined volumes for all uses are also low, then an exemption may be granted, depending on review of other information outlined below. An exemption will not be granted if any registrant of the active ingredient elects to conduct the testing. Any registrant receiving a low volume minor use waiver must remain within the sales figures in their forecast supporting the waiver request in order to remain qualified for such waiver. If granted a waiver, a registrant will be required, as a condition of the waiver, to submit annual sales reports. The Agency will respond to requests for waivers in writing.

To apply for a low volume, minor use waiver, you must submit the following information, as applicable to your product(s), as part of your 90-day response to this Notice:

(i). Total company sales (pounds and dollars) of all registered product(s) containing the active ingredient. If applicable to the active ingredient, include foreign sales for those products that are not registered in this country but are applied to sugar (cane or beet), coffee, bananas, cocoa, and other such crops. Present the above information by year for each of the past five years.

(ii) Provide an estimate of the sales (pounds and dollars) of the active ingredient for each major use site. Present the above information by year for each of the past five years.

(iii) Total direct production cost of product(s) containing the active ingredient by year for the past five years. Include information on raw material cost, direct labor cost, advertising, sales and marketing, and any other significant costs listed separately.

(iv) Total indirect production cost (e.g. plant overhead, amortized plant and equipment) charged to product(s) containing the active ingredient by year for the past five years. Exclude all non-recurring costs that were directly related to the active ingredient, such as costs of initial registration and any data development.

(v) A list of each data requirement for which you seek a waiver. Indicate the type of waiver sought and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

(vi) A list of each data requirement for which you are not seeking any waiver and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

(vii) For each of the next ten years, a year-by-year forecast of company sales (pounds and dollars) of the active ingredient, direct production costs of product(s) containing the active ingredient (following the parameters in item 2 above), indirect production costs of product(s) containing the active ingredient (following the parameters in item 3 above), and costs of data development pertaining to the active ingredient.

(viii) A description of the importance and unique benefits of the active ingredient to users. Discuss the use patterns and the effectiveness of the active ingredient relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient, providing information that is as quantitative as possible. If you do not have quantitative data upon which to base your estimates, then present the reasoning used to derive your estimates. To assist the Agency in determining the degree of importance of the active ingredient in terms of its benefits, you should provide information on any of the following factors, as applicable to your product(s): (a) documentation of the usefulness of the active ingredient in Integrated Pest Management, (b) description of the beneficial impacts on the environment of use of the active ingredient, as opposed to its registered alternatives, (c) information on the breakdown of the active ingredient after use and on its persistence in the environment, and (d) description of its usefulness against a pest(s) of public health significance.

Failure to submit sufficient information for the Agency to make a determination regarding a request for a low volume/minor use waiver will result in denial of the request for a waiver.

b. Request for Waiver of Data

Option 9, under Item 9, on the Requirements Status and Registrant's Response Form. This option may be used if you believe that a particular data requirement should not apply because the requirement is inappropriate. You must submit a rationale explaining why you believe the data requirements should not apply. You also must submit the current label(s) of your product(s) and, if a current copy of your Confidential Statement of Formula is not already on file you must submit a current copy.

You will be informed of the Agency's decision in writing. If the Agency determines that the data requirements of this Notice are not appropriate to your product(s), you will not be required to supply the data pursuant to section 3(c)(2)(B). If EPA determines that the data are required for your product(s), you must choose a method of meeting the requirements of this Notice within the time frame provided by this Notice. Within 30 days of your receipt of the Agency's written decision, you must submit a revised Requirements Status and Registrant's Response Form indicating the option chosen.

2. Product Specific Data

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 product specific 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.

SECTION 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:

   i. 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.

   ii. Fulfill the commitment to develop and submit the data as required by this Notice; or

   iii. 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 generally would 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 also must 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 a 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 must include completed Data Call-In Response Forms (Attachment 2)and completed Requirements Status and Registrant's Response Forms (Attachment 3), for both (generic and 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 Generic and Product Specific Data Call-In Response Forms need be submitted.

The Office of Compliance (OC) of the Office of Enforcement and Compliance Assurance (OECA), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachments

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Generic Data Call-In and Product Specific Data Call-In Response Forms with Instructions
3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms with Instructions
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice
6 - Confidential Statement of Formula, Cost Share and Data Compensation Forms

Metribuzin DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding this product specific data requirements and procedures established by this Notice, please contact Jean Holmes at (703) 308-8008.

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

Jean Holmes
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: **Metribuzin**

Metribuzin DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Generic Data Call-In Notice because you have product(s) containing Metribuzin.

This Generic Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of Metribuzin. This attachment is to be used in conjunction with (1) the Generic Data Call-In Notice, (2) the Generic Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 2), (4) a list of registrants receiving this DCI (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), and (6) the Cost Share and Data Compensation Forms in replying to this Metribuzin Generic Data Call In (Attachment F). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the generic database for Metribuzin are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional product chemistry data on Metribuzin are needed. These data are needed to fully complete the reregistration of all eligible Metribuzin products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact Jean Holmes at (703) 308-8008.

All responsades to this Notice for the generic data requirements should be submitted to:

Jean Holmes, Chemical Review Manager
PRB
Special Review and Registration Division (H7508W)
Office of Pesticiafde Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: Metribuzin

Instructions For Completing The "Data Call-In Response Forms" For The Generic And Product Specific Data Call-In

INTRODUCTION

These instructions apply to the Generic and Product Specific "Data Call-In Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-Ins as part of EPA's Reregistration Program under the Federal Insecticide, Fungicide, and Rodenticide Act. If you are an end-use product registrant only and have been sent this DCI letter as part of a RED document you have been sent just the product specific "Data Call-In Response Forms." Only registrants responsible for generic data have been sent the generic data response form. **The type of Data Call-In (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form.**

Although the form is the same for both generic and product specific data, instructions for completing these forms are different. Please read these instructions carefully before filling out the forms.

EPA has developed these forms individually for each registrant, and has preprinted these forms with a number of items. DO NOT use these forms for any other active ingredient.

Items 1 through 4 have been preprinted on the form. Items 5 through 7 must be completed by the registrant as appropriate. Items 8 through 11 must be completed by the registrant before submitting a response to the Agency.

The 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, Mail Code 2136, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS
Generic and Product Specific Data Call-In

Item 1. **ON BOTH FORMS**: This item identifies your company name, number and address.

Item 2. **ON BOTH FORMS:** This item identifies the case number, case name, EPA chemical number and chemical name.

Item 3. **ON BOTH FORMS:** This item identifies the type of Data Call-In. The date of issuance is date stamped.

Item 4. **ON BOTH FORMS:** This item identifies the EPA product registrations relevant to the data call-in. Please note that you are also responsible for informing the Agency of your response regarding any product that you believe may be covered by this Data Call-In but that is not listed by the Agency in Item 4. You must bring any such apparent omission to the Agency's attention within the period required for submission of this response form.

Item 5. **ON BOTH FORMS:** Check this item for each product registration you wish to cancel voluntarily. If a registration number is listed for a product for which you previously requested voluntary cancellation, indicate in Item 5 the date of that request. Since this Data Call-In requires both generic and product specific data, you must complete item 5 on both Data Call-In response forms. You do not need to complete any item on the Requirements Status and Registrant's Response Forms.

Item 6a. **ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and you are eligible for a Generic Data Exemption for the chemical listed in Item 2 and used in the subject product. By electing this exemption, you agree to the terms and conditions of a Generic Data Exemption as explained in the Data Call-In Notice.

If you are eligible for or claim a Generic Data Exemption, enter the EPA registration Number of each registered source of that active ingredient that you use in your product.

Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and any other outstanding Data Call-In Notice), and incorporate that product into all your products, you may complete this item for all products listed on this form. If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources are registered), you may not claim a Generic Data Exemption and you may not select this item.

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS
Generic and Product Specific Data Call-In

Item 6b. **ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and if you are agreeing to satisfy the generic data requirements of this Data Call-In. Attach the Requirements Status and Registrant's Response Form that indicates how you will satisfy those requirements.

NOTE: **Item 6a and 6b are not applicable for Product Specific Data.**

Item 7a. **ON THE PRODUCT SPECIFIC DATA FORM:** 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."

FOR BOTH MUP and EUP products

You should also respond "yes" to this item (7a for MUP's and 7b for EUP's) if your product is identical to another product and you qualify for a data exemption. You must provide the EPA registration numbers of your source(s); do 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.

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.

NOTE: **Item 7a and 7b are not applicable for Generic Data.**

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS
Generic and Product Specific Data Call-In

Item 8. **ON BOTH FORMS:** This certification statement must be signed by an authorized representative of your company and the person signing must include his/her title. Additional pages used in your response must be initialled and dated in the space provided for the certification.

Item 9. **ON BOTH FORMS:** Enter the date of signature.

Item 10. **ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.

Item 11. **ON BOTH FORMS:** Enter the phone number of your company contact.

Note: You may provide additional information that does not fit on this form in a signed letter that accompanies your response. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

Instructions For Completing The "Requirements Status and Registrant's Response Forms" For The Generic and Product Specific Data Call-In

INTRODUCTION

These instructions apply to the Generic and Product Specific "Requirements Status and Registrant's Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-In's as part of EPA's reregistration program under the Federal Insecticide, Fungicide, and Rodenticide Act. If you are an end-use product registrant only and have been sent this DCI letter as part of a RED document you have been sent just the product specific "Requirements Status and Registrant's Response Forms." Only registrants responsible for generic data have been sent the generic data response forms. **The type of Data Call-In (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form.**

Although the form is the same for both product specific and generic data, instructions for completing the forms differ slightly. Specifically, options for satisfying product specific data requirements do not include (1) deletion of uses or (2) request for a low volume/minor use waiver. Please read these instructions carefully before filling out the forms.

EPA has developed these forms individually for each registrant, and has preprinted these forms to include certain information unique to this chemical. DO NOT use these forms for any other active ingredient.

Items 1 through 8 have been preprinted on the form. Item 9 must be completed by the registrant as appropriate. Items 10 through 13 must be completed by the registrant before submitting a response to the Agency.

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS"

Generic and Product Specific Data Call-In

Item 1. **ON BOTH FORMS:** This item identifies your company name, number and address.

Item 2. **ON THE GENERIC DATA FORM:** This item identifies the case number, case name, EPA chemical number and chemical name.

ON THE PRODUCT SPECIFIC DATA FORM: This item identifies the case number, case name, and the EPA Registration Number of the product for which the Agency is requesting product specific data.

Item 3. **ON THE GENERIC DATA FORM:** This item identifies the type of Data Call-In. The date of issuance is date stamped.

ON THE PRODUCT SPECIFIC DATA FORM: This item identifies the type of Data Call-In. The date of issuance is also date stamped. Note the unique identifier number (ID#) assigned by the Agency. This ID number must be used in the transmittal document for any data submissions in response to this Data Call-In Notice.

Item 4. **ON BOTH FORMS:** This item identifies the guideline reference number of studies required. These guidelines, in addition to the requirements specified in the Data Call-In 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. **ON BOTH FORMS:** This item identifies the study title associated with the guideline reference number and whether protocols and 1, 2, or 3-year progress reports are required to be submitted in connection with the study. As noted in Section III of the Data Call-In Notice, 90-day progress reports are required for all studies.

If an asterisk appears in Item 5, EPA has attached information relevant to this guideline reference number to the Requirements Status and Reqistrant's Response Form.

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND

REGISTRANT'S RESPONSE FORMS"

Generic and Product Specific Data Call-In

Item 6. **ON BOTH FORMS:** This item identifies the code associated with the use pattern of the pesticide. In the case of efficacy data (product specific requirement), the required study only pertains to products which have the use sites and/or pests indicated. A brief description of each code follows:

A	Terrestrial food
B	Terrestrial feed
C	Terrestrial non-food
D	Aquatic food
E	Aquatic non-food outdoor
F	Aquatic non-food industrial
G	Aquatic non-food residential
H	Greenhouse food
I	Greenhouse non-food crop
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

Item 7. **ON BOTH FORMS:** This item identifies the code assigned to the substance that must be used for testing. A brief description of each code follows:

EUP	End-Use Product
MP	Manufacturing-Use Product
MP/TGAI	Manufacturing-Use Product and Technical Grade Active Ingredient
PAI	Pure Active Ingredient
PAI/M	Pure Active Ingredient and Metabolites
PAI/PAIRA	Pure Active Indredient or Pute Active Ingredient Radiolabelled
PAIRA	Pure Active Ingredient Radiolabelled
PAIRA/M	Pure Active Ingredient Radiolabelled and Metabolites
PAIRA/PM	Pure Active Ingredient Radiolabelled and Plant Metabolites
TEP	Typical End-Use Product
TEP ___%	Typical End-Use Product, Percent Active Ingredient Specified
TEP/MET	Typical End-Use Product and Metabolites
TEP/PAI/M	Typical End-Use Product or Pure Active Ingredient and

	Metabolites
TGAI	Technical Grade Active Ingredient
TGAI/PAI	Technical Grade Active Ingredient or Pure Active Ingredient
TGAI/PAIRA	Technical Grade Active Ingredient or Pure Active Ingredient Radiolabelled
TGAI/TEP	Technical Grade Active Ingredient or Typical End-Use Product
MET	Metabolites
IMP	Impurities
DEGR	Degradates
*	See: guideline comment

Item 8. This item completed by the Agency identifies the time frame allowed for submission of the study or protocol identified in item 5.

ON THE GENERIC DATA FORM: The time frame runs from the date of your receipt of the Data Call-In notice.

ON THE PRODUCT SPECIFIC DATA FORM: The due date for submission of product specific studies begins from the date stamped on the letter transmitting the Reregistration Eligibility Decision document, and not from the date of receipt. However, your response to the Data Call-In itself is due 90 days from the date of receipt.

Item 9. **ON BOTH FORMS:** Enter the appropriate Response Code or Codes to show how you intend to comply with each data requirement. Brief descriptions of each code follow. The Data Call-In Notice contains a fuller description of each of these options.

Option 1. **ON BOTH FORMS:** (Developing Data) I will conduct a new study and submit it within the time frames specified in item 8 above. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice and that I will provide the protocols and progress reports required in item 5 above.

Option 2. **ON BOTH FORMS:** (Agreement to Cost Share) I have entered into an agreement with one or more registrants to develop data jointly. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to sharing in the cost of developing data as outlined in the Data Call-In Notice.

However, for Product Specific Data, I understand that this option is available for acute toxicity or certain efficacy data **ONLY** if

the Agency 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.

Option 3. **ON BOTH FORMS:** (Offer to Cost Share) I have made an offer to enter into an agreement with one or more registrants to develop data jointly. I am also submitting a completed "Certification of offer to Cost Share in the Development of Data" form. 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 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 apply as well.

However, for Product Specific Data, I understand that this option is available only for acute toxicity or certain efficacy data and only if the Agency indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option.

Option 4. **ON BOTH FORMS:** (Submitting Existing Data) I will submit an existing study by the specified due date that has never before been submitted to EPA. By indicating that I have chosen this option, I certify that this study meets all the requirements pertaining to the conditions for submittal of existing data outlined in the Data Call-In Notice and I have attached the needed supporting information along with this response.

Option 5. **ON BOTH FORMS:** (Upgrading a Study) I will submit by the specified due date, or will cite data to upgrade a study that EPA has classified as partially acceptable and potentially upgradeable. By indicating that I have chosen this option, I certify that I have met all the requirements pertaining to the conditions for submitting or citing existing data to upgrade a study described in the Data Call-In Notice. I am indicating on attached correspondence the Master Record Identification Number (MRID) that EPA has assigned to the data that I am citing as well as the MRID of the study I am attempting to upgrade.

Option 6. **ON BOTH FORMS:** (Citing a Study) I am citing an existing study that has been previously classified by EPA as acceptable, core, core minimum, or a study that has not yet been reviewed by the Agency. If reviewed, I am providing the Agency's classification of the study.

However, for Product Specific Data, 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 the Agency 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). If I cite another registrant's data, I will submit a completed "Certification With Respect To Data Compensation Requirements" form.

FOR THE GENERIC DATA FORM ONLY: The following three options (Numbers 7, 8, and 9) are responses that apply only to the "Requirements Status and Registrant's Response Form" for generic data.

Option 7. (Deleting Uses) I am attaching an application for amendment to my registration deleting the uses for which the data are required.

Option 8. (Low Volume/Minor Use Waiver Request) I have read the statements concerning low volume-minor use data waivers in the Data Call-In Notice and I request a low-volume minor use waiver of the data requirement. I am attaching a detailed justification to support this waiver request including, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

Option 9. (Request for Waiver of Data) I have read the statements concerning data waivers other than lowvolume minor-use data waivers in the Data Call-In Notice and I request a waiver of the data requirement. I am attaching a rationale explaining why I believe the data requirements do not apply. I am also submitting a copy of my current labels. (You must also submit a copy of your Confidential Statement of Formula if not already on file with EPA). I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

FOR PRODUCT SPECIFIC DATA: The following option (number 7) is a response that applies to the "Requirements Status and Registrant's Response Form" for product specific data.

Option 7. (Waiver Request) I request a waiver for this study because it is inappropriate for my product. 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" form specifying 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.

Item 10. **ON BOTH FORMS:** This item must be signed by an authorized representative of your company. The person signing must include his/her title, and must initial and date all other pages of this form.

Item 11. **ON BOTH FORMS:** Enter the date of signature.

Item 12. **ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.

Item 13. **ON BOTH FORMS:** Enter the phone number of your company contact.

NOTE: You may provide additional information that does not fit on this form in a signed letter that accompanies this your response. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled this

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EPA'S BATCHING OF METRIBUZIN PRODUCTS FOR MEETING REREGISTRATION ACUTE TOXICITY DATA REQUIREMENTS

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 metribuzin as an active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrant's 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.

Eighty-six products were found which contain metribuzin as an active ingredient. These products have been placed into five batches and a "no batch" category in accordance with the active and inert ingredients, type of formulation and current labeling. Although some products are not batched together, acute data requirements may still be satisfied through bridging or citing data on a product in another batch or in the "no batch" category. With batching, acute data on any product in a batch will support all other product within that batch. Bridging, however, is a "one-way" citation from a more acutely toxic to a less acutely toxic product. Acceptable bridging strategies are described prior to the following tables. Table 1 identifies the products in each batch. Table 2 lists the products which have been placed in the "no batch" category.

- With the exception of eye irritation, batch 1, 3, 4 or 5 products may be supported by acute data on the technical active ingredient.
- With the exception of eye irritation, products in batch 3 may be supported by acute data on products in batch 4 and products in batch 4 may be supported by acute data on products in batch 3.
- With the exception of eye irritation, EPA Reg. No. 3125-294 (no batch) may be supported by acute data supporting any batch 4 product.
- Products in batch 5 may be supported by any category III or IV acute data supporting any batch 1 product.

Table 1

Batch	EPA Reg. No.	% active ingredient	Formulation Type
1	3125-277	50.0	Solid
	3125-305	50.0	Solid
	CA79023400	50.0	Solid
2	352-444	Metribuzin 64.3 Chlorimuron ethyl 10.7	Solid
	352-448	Metribuzin 68.5 Chlorimuron ethyl 6.5	Solid

Batch	EPA Reg. No.	% active ingredient	Formulation Type
	352-549	Metribuzin 68.5 Chlorimuron ethyl 6.5	Solid
3	352-390	75.0	Solid
	352-550	75.0	Solid
	LA81003200	75.0	Solid
	OR90002600	75.0	Solid
	OR90002800	75.0	Solid
	WA90003700	75.0	Solid
	WA96000100	75.0	Solid

Batch	EPA Reg. No.	% active ingredient	Formulation Type
4	3125-325	75.0	Solid
	3125-402	75.0	Solid
	AL81002500	75.0	Solid
	AZ88002800	75.0	Solid
	CA87003900	75.0	Solid
	CA89000400	75.0	Solid
	GA84000600	75.0	Solid
	IA91000100	75.0	Solid
	IA92000200	75.0	Solid
	IA92000300	75.0	Solid
	ID81004600	75.0	Solid
	ID87000500	75.0	Solid
	ID87001700	75.0	Solid
	ID95000400	75.0	Solid
	IN93000200	75.0	Solid
	KS92000300	75.0	Solid
	MI92000100	75.0	Solid
	MN93000100	75.0	Solid
	MO84000300	75.0	Solid
	MO93000300	75.0	Solid
	MO93000400	75.0	Solid
	NC84000500	75.0	Solid
	NC86000600	75.0	Solid
	ND93000500	75.0	Solid
	ND93000600	75.0	Solid

Batch	EPA Reg. No.	% active ingredient	Formulation Type
	NE91000400	75.0	Solid
	NE92000400	75.0	Solid
	NE92000500	75.0	Solid
	NM94000200	75.0	Solid
	OH93000200	75.0	Solid
	OH93000300	75.0	Solid
	OK94000200	75.0	Solid
	OR81004000	75.0	Solid
	OR85002000	75.0	Solid
	OR87000200	75.0	Solid
	OR90002500	75.0	Solid
	PR90000100	75.0	Solid
	PR90000200	75.0	Solid
	SC81001800	75.0	Solid
	TX93001700	75.0	Solid
	VA93000800	75.0	Solid
	WA85000500	75.0	Solid
	WA86001500	75.0	Solid
	WA87000800	75.0	Solid
	WA93000300	75.0	Solid
	WA94004100	75.0	Solid
	WY95000300	75.0	Solid
5	3125-314	41.0	Liquid
	AL81002600	41.0	Liquid
	AR79001400	41.0	Liquid

Batch	EPA Reg. No.	% active ingredient	Formulation Type
	CA79023500	41.0	Liquid
	GA80002100	41.0	Liquid
	ID81004500	41.0	Liquid
	ID87000400	41.0	Liquid
	ID87001600	41.0	Liquid
	ME79000900	41.0	Liquid
	MO79001200	41.0	Liquid
	MS80000200	41.0	Liquid
	ND93000400	41.0	Liquid
	OR81003900	41.0	Liquid
	OR85001900	41.0	Liquid
	OR87000100	41.0	Liquid
	WA81004100	41.0	Liquid
	WA85000600	41.0	Liquid
	WA86001600	41.0	Liquid
	WA87000700	41.0	Liquid

The following table lists products that were either considered not to be similar or the Agency lacked sufficient information for decision making and were not placed in any batch. The registrants of these producs are responsible for meeting the acute toxicity data requirements separately or through the accepted bridging scheme presented below.

Table 2 (No Batch)

EPA Reg. No.	% active ingredient	Formulation Type
3125-270	90.0	Solid
3125-294	70.0	Solid

EPA Reg. No.	% active ingredient	Formulation Type
3125-366	Metribuzin 15.0 Metalochlor 70.0	Liquid
3125-375	Metribuzin 14.0 Trifluralin 28.0	Liquid
55947-166	Metribuzin 10.0 Dicamba 66.0	Solid
CA84000700	75.0	Solid
ID90000200	15.0	Liquid

LIST OF REGISTRANTS RECEIVING THIS DCI
(Please remove this page and insert registrants mailing list)

Instructions for Completing the Confidential Statement of Formula

The Confidential Statement of Formula (CSF) Form 8570-4 must be used. Two legible, signed copies of the form are required. Following are basic instructions:

a. All the blocks on the form must be filled in and answered completely.

b. If any block is not applicable, mark it N/A.

c. The CSF must be signed, dated and the telephone number of the responsible party must be provided.

d. All applicable information which is on the product specific data submission must also be reported on the CSF.

e. All weights reported under item 7 must be in pounds per gallon for liquids and pounds per cubic feet for solids.

f. Flashpoint must be in degrees Fahrenheit and flame extension in inches.

g. For all active ingredients, the EPA Registration Numbers for the currently registered source products must be reported under column 12.

h. The Chemical Abstracts Service (CAS) Numbers for all actives and inerts and all common names for the trade names must be reported.

i. For the active ingredients, the percent purity of the source products must be reported under column 10 and must be exactly the same as on the source product's label.

j. All the weights in columns 13.a. and 13.b. must be in pounds, kilograms, or grams. In no case will volumes be accepted. Do not mix English and metric system units (i.e., pounds and kilograms).

k. All the items under column 13.b. must total 100 percent.

1. All items under columns 14.a. and 14.b. for the active ingredients must represent pure active form.

m. The upper and lower certified limits for ail active and inert ingredients must follow the 40 CFR 158.175 instructions. An explanation must be provided if the proposed limits are different than standard certified limits.

n. When new CSFs are submitted and approved, all previously submitted CSFs become obsolete for that specific formulation.

Confidential Business Information: Does Not Contain National Security Information (E.O. 12065) Form Approved. OMB No. 2070-0060. Approval Expires 2/28/94

EPA

United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

1. Name and Address of Applicant/Registrant *(Include ZIP Code)*

2. Name and Address of Producer *(Include ZIP Code)*

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

EPA USE ONLY	10. Components in Formulation *(List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.)*	11. Supplier Name & Address	12. EPA Reg. No.	13. Each Component in Formulation a. Amount	13. b. % by Weight	14. Certified Limits % by Weight a. Upper Limit	14. b. Lower Limit	15. Purpose in Formulation
16. Typed Name of Approving Official				17. Total Weight	100%			

18. Signature of Approving Official	19. Title	20. Phone No. *(Include Area Code)*	21. Date

EPA Form 8570-4 (Rev. 12-90) **Previous editions are obsolete.** If you can photocopy this, please submit an additional copy. White - EPA File Copy (original) Yellow - Applicant copy

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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 in 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)

EPA Form 8570-32 (5/91) Replaces EPA form 8580 which is obselete

United States Environmental Protection Agency
Washington, DC 20460

Form Approved
OMB No. 2070-0107, 2070-0057
Approval Expires 3-31-99

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

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 reregistratiion 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 Metribuzin that my 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 are available on the Internet at on WWW.EPA.GOV., or contact Jean Holmes at (703)-308-8008.

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 Metribuzin.

The following documents are part of the Administrative Record for Metribuzin 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