United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7508C)

EPA738-R-05-001
January 2005

Reregistration Eligibility Decision for 2,4-DB

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data and public comments received related to the preliminary risk assessments for the herbicide 2,4-DB. The enclosed Reregistration Eligibility Decision (RED) document was approved on January 31, 2005. Public comments and additional data received were considered in this decision.

Based on its review, EPA is now publishing its Reregistration Eligibility Decision (RED) and risk management decision for 2,4-DB and its associated human health and environmental risks. A Notice of Availability will be published in the *Federal Register* announcing the publication of the RED.

The RED and supporting risk assessments for 2,4-DB are available to the public in EPA's Pesticide Docket **OPP-2004-0220** at: http://www.epa.gov/edockets.

The 2,4-DB RED was developed through EPA's public participation process, published in the Federal Register on May 14, 2004, which provides opportunities for public involvement in the Agency's pesticide tolerance reassessment and reregistration programs. Developed in partnership with USDA and with input from EPA's advisory committees and others, the public participation process encourages robust public involvement starting early and continuing throughout the pesticide risk assessment and risk mitigation decision making process. The public participation process encompasses full, modified, and streamlined versions that enable the Agency to tailor the level of review to the level of refinement of the risk assessments, as well as to the amount of use, risk, public concern, and complexity associated with each pesticide. Using the public participation process, EPA is attaining its strong commitment to both involve the public and meet statutory deadlines.

Please note that the 2,4-DB risk assessment and the attached RED document concern only this particular pesticide. This RED presents the Agency's conclusions on the dietary, drinking water, occupational and ecological risks posed by exposure to 2,4-DB alone. This document also contains both generic and product-specific data that the Agency intends to require in Data Call-Ins (DCIs). Note that DCIs, with all pertinent instructions, will be sent to registrants at a later date. Additionally, for product-specific DCIs, the first set of required responses will be due 90 days from the receipt of the DCI letter. The second set of required responses will be due eight months from the receipt of the DCI letter.

As part of the RED, the Agency has determined that 2,4-DB will be eligible for reregistration provided that all the conditions identified in this document are satisfied, including implementation of the risk mitigation measures outlined in Section IV of the document. Sections IV and V of this RED document describe labeling amendments for end-use products and data requirements necessary to implement these mitigation measures. Instructions for registrants on submitting the revised labeling can be found in the set of instructions for product-specific data that accompanies this document.

Should a registrant fail to implement any of the risk mitigation measures outlined in this document, the Agency will continue to have concerns about the risks posed by 2,4-DB. Where the Agency has identified any unreasonable adverse effect to human health and the environment, the Agency may at any time initiate appropriate regulatory action to address this concern. At that time, any affected person(s) may challenge the Agency's action.

If you have questions on this document or the label changes necessary for reregistration, please contact the Chemical Review Manager, Mika J. Hunter, at (703) 308-0041. For questions about product reregistration and/or the Product DCI that accompanies this document, please contact Venus Eagle at (703) 308-8045.

Sincerely,

Debra Edwards, Ph. D.
Director, Special Review and
Reregistration Division

REREGISTRATION ELIGIBILITY DECISION
for
2,4-DB
List A
CASE 0196

Approved By:

Debra Edwards, Ph.D.
Director, Special Review and
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Date

Attachment

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GLOSSARY OF TERMS AND ABBREVIATIONS

a.i.	Active Ingredient
aPAD	Acute Population Adjusted Dose
APHIS	Animal and Plant Health Inspection Service
ARTF	Agricultural Re-entry Task Force
BCF	Bioconcentration Factor
CDC	Centers for Disease Control
CDPR	California Department of Pesticide Regulation
CFR	Code of Federal Regulations
ChEI	Cholinesterase Inhibition
CMBS	Carbamate Market Basket Survey
cPAD	Chronic Population Adjusted Dose
CSFII	USDA Continuing Surveys for Food Intake by Individuals
CWS	Community Water System
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DL	Double layer clothing {i.e., coveralls over SL}
DWLOC	Drinking Water Level of Comparison
EC	Emulsifiable Concentrate Formulation
EDSP	Endocrine Disruptor Screening Program
EDSTAC	Endocrine Disruptor Screening and Testing Advisory Committee
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
EXAMS	Tier II Surface Water Computer Model
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FOB	Functional Observation Battery
FQPA	Food Quality Protection Act
FR	Federal Register
GL	With gloves
GPS	Global Positioning System
HIARC	Hazard Identification Assessment Review Committee
IDFS	Incident Data System
IGR	Insect Growth Regulator
IPM	Integrated Pest Management
RED	Reregistration Eligibility Decision
LADD	Lifetime Average Daily Dose
LC_{50}	Median Lethal Concentration. Statistically derived concentration of a substance expected to cause death in 50% of test animals, usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LCO	Lawn Care Operator
LD_{50}	Median Lethal Dose. Statistically derived single dose causing death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation), expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOAEC	Lowest Observed Adverse Effect Concentration
LOAEL	Lowest Observed Adverse Effect Level
LOC	Level of Concern
LOEC	Lowest Observed Effect Concentration
mg/kg/day	Milligram Per Kilogram Per Day
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MRL	Maximum Residue Level

N/A	Not Applicable
NASS	National Agricultural Statistical Service
NAWQA	USGS National Water Quality Assessment
NG	No Gloves
NMFS	National Marine Fisheries Service
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
NPIC	National Pesticide Information Center
NR	No respirator
OP	Organophosphorus
OPP	EPA Office of Pesticide Programs
ORETF	Outdoor Residential Exposure Task Force
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDCI	Product Specific Data Call-In
PDP	USDA Pesticide Data Program
PF10	Protections factor 10 respirator
PF5	Protection factor 5 respirator
PHED	Pesticide Handler's Exposure Data
PHI	Pre-harvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
PRZM	Pesticide Root Zone Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RPA	Reasonable and Prudent Alternatives
RPM	Reasonable and Prudent Measures
RQ	Risk Quotient
RTU	(Ready-to-use)
RUP	Restricted Use Pesticide
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
SL	Single layer clothing
SLN	Special Local Need (Registrations Under Section 24C of FIFRA)
STORET	Storage and Retrieval
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TRAC	Tolerance Reassessment Advisory Committee
TTRS	Transferable Turf Residues
UF	Uncertainty Factor
USDA	United States Department of Agriculture
USFWS	United States Fish and Wildlife Service
USGS	United States Geological Survey
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

The Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of public comments on the human health and environmental risk assessments for 2,4-DB and 2,4-DB-DMAS and is issuing its risk management decision. The Agency has decided 2,4-DB and 2,4-DB-DMAS are eligible for reregistration provided all measures outlined in this document are implemented. 2,4-DB and 2,4-DB-DMAS are members of the chlorophenoxy class of herbicides, which function by mimicking the action of auxins, plant growth hormones. 2,4-DB and 2,4-DB-DMAS are used to control broadleaf weeds in alfalfa, clover, soybean, peanuts, peppermint, spearmint, and birdsfoot trefoil. 2,4-DB is manufactured as an acid and the dimethylamine salt, 2,4-DB-DMAS. Available data indicate that 2,4-DB-DMAS rapidly dissociates in moist soils and aquatic environments; therefore, environmental risks were only assessed for 2,4-DB. Environmental risks posed by use of 2,4-DB-DMAS were considered to be equivalent to 2,4-DB. End-use products are formulated as either a soluble, emulsifiable, or flowable concentrates (all of which are considered to be liquids). 2,4-DB currently has tolerances of 0.2 ppm (40 CFR 180.331) in/on various commodities of the following crops: alfalfa, clover, mint hay, peanut, soybean, soybean hay, and birdsfoot trefoil. Based on available data, approximately 375,000 pounds of active ingredient are used annually throughout the United States.

Overall Risk Summary

The Agency's human heath risk assessment indicates no risks of concern. An acute dietary risk estimate was completed for females 13-49 years old, the only population subgroup with an acute toxicity endpoint, and is below the Agency's level of concern. Chronic dietary risk estimates were provided for the general U.S. population and all population subgroups. All chronic dietary risk estimates are below the Agency's level of concern. Estimated environmental concentrations of 2,4-DB in drinking water from surface and ground water are below the Agency's Drinking Water Level of Concern (DWLOC). When considering aggregate risk from exposure to food and water (2,4-DB and 2,4-DB-DMAS do not have residential uses), risk estimates are below the Agency's level of concern.

To address worker risks, short-term and intermediate-term occupational scenarios were evaluated. All short-term and intermediate-term margins of exposure (MOEs) are below the Agency's level of concern when applicators are wearing baseline personal protective equipment (PPE). Short-term and intermediate-term exposures for mixers and loaders are below the Agency's level of concern when baseline PPE and chemical resistant gloves are worn. All MOEs for short-term inhalation exposure are below the Agency's level of concern with baseline respiratory equipment (no respirators). Post-application exposure to re-entry workers is possible. Since 2,4-DB and 2,4-DB-DMAS are applied only once or twice per season it is anticipated that exposure will be primarily short-term. Because there is no toxicity endpoint for short-term dermal exposures, short-term post-application risks were not assessed. The amine salt form of 2,4-DB is a Toxicity Category I eye irritant and labels will require protective eye-wear for post-application exposures.

The ecological risk assessment shows that terrestrial plants are at the greatest risk from 2,4-DB and 2,4-DB-DMAS applications. Using the highest application rate and the Texas alfalfa

scenario, acute threatened and endangered species levels of concern were also exceeded for freshwater fish. Small and medium mammalian restricted use and Federally listed threatened and endangered species levels of concern were exceeded using the highest application rates for alfalfa.

Dietary Risk

Acute and chronic dietary (food) risks are below EPA's level of concern for the general U.S. population and all population subgroups. An unrefined acute dietary risk assessment (assumes 100% crop treated and tolerance level residues) was conducted using the Dietary Exposure Evaluation Model (DEEM-FCID™) and Lifeline™ models for all of the supported 2,4-DB and 2,4-DB-DMAS food uses. Risk estimates are provided for females 13-49 years old, the only population subgroup with a toxicity endpoint of concern. Both models showed risk estimates below 1% of the aPAD and therefore were not of concern.

Chronic dietary risk estimates were also made using tolerance level residues and 100% crop treated information. This assessment concludes that for all included commodities, the chronic risk estimates are below the Agency's level of concern for the general U.S. population (<1% of the cPAD) and all population subgroups (〈2.2% of the cPAD) when using the DEEM-FCID™ or Lifeline™ models. Risks, therefore, are not of concern and no mitigation measures are necessary.

Drinking Water Risk

Modeling for surface water and ground water concentrations was performed for three different crop scenarios: alfalfa, peanuts, and soybeans. Several scenarios for each crop were chosen to represent a geographically dispersed range of water concentrations. The scenario that resulted in the highest modeled concentrations was the Texas alfalfa scenario. The estimated concentrations from this scenario were used to determine drinking water risk as well as aggregate risk.

The Agency's DWLOC for acute exposure is 18,000 µg/L. The estimated drinking water concentration (EDWC) used to assess acute dietary risk in surface water is 318.68 µg/L and 0.51 µg/L for ground water. The DWLOC for chronic exposure is 1050 µg/L for the general U.S. population and 290 µg/L for infants less than one years old. The EDWC used to assess chronic (non-cancer) dietary risk from surface water is 72.40 µg/L and 0.51 µg/L for ground water. Both the acute and chronic estimated concentrations are below the DWLOCs for the general U.S. population and all population subgroups. Risks, therefore, are not of concern and no mitigation measures are necessary.

Residential Risk

There are no registered residential uses and no use patterns that would cause residential exposures of 2,4-DB or 2,4-DB-DMAS; therefore, no residential risk assessment was performed.

Aggregate Risk

The aggregate risk assessment integrates the assessments conducted for dietary and drinking water exposure only since there are no registered residential uses of 2,4-DB or 2,4-DB-DMAS. As noted above, the EDWCs for both surface water and ground water are below both the acute and chronic DWLOC, respectively. Therefore, aggregate exposure to 2,4-DB and 2,4-DB-DMAS from food and drinking water is below the Agency's level of concern. No mitigation measures are necessary to reduce risks from aggregate exposures.

Occupational Risk

To address occupational exposure, short-term inhalation, and intermediate-term combined dermal and inhalation risks were assessed. All short-term inhalation and intermediate-term combined dermal/inhalation margins of exposures (MOE) are below the Agency's level of concern when workers are wearing baseline PPE (with mixers and loaders wearing chemical resistant gloves).

Post-application exposure to re-entry workers is possible because 2,4-DB and 2,4-DB-DMAS can be broadcast applied. Since 2,4-DB and 2,4-DB-DMAS are applied only once or twice per season, it is anticipated that exposure will be primarily short-term. Since an endpoint could not be determined for short-term dermal exposures, short-term post-application risks were not assessed and were determined not to be of concern. The amine form of 2,4-DB is a Toxicity Category I eye irritant and labels will require protective eye-wear for early re-entry workers.

Ecological Risk

The Agency conducted an ecological risk assessment to determine the potential impact of 2,4-DB and 2,4-DB-DMAS use on non-target terrestrial and aquatic organisms. The Agency used modeling to evaluate ecological risks for 2,4-DB and 2,4-DB-DMAS.

The Agency has determined that the risks posed by 2,4-DB and 2,4-DB-DMAS to most mammalian, avian, plant, and aquatic species will be substantially mitigated by adhering to the best aerial application practices and by prohibiting fine application sprays. This mitigation will require changes to current product labeling.

Terrestrial Plants

Potential effects on non-target terrestrial plants are most likely to occur as a result of spray drift and runoff from aerial and ground applications. Because 2,4-DB and 2,4-DB-DMAS are non-selective herbicides, most plants that come in contact with the chemicals are potentially at risk. In order to reduce risks to such plants current product labels will include droplet size restrictions to prevent adverse affects from drift and runoff.

Aquatic Organisms

Although 2,4-DB and 2,4-DB-DMAS are practically non-toxic to slightly toxic to freshwater fish, modeling simulations of the Texas alfalfa scenario indicate an exceedance (RQ=0.09) of the acute threatened and endangered freshwater species LOC based on the one in ten year peak estimated environmental concentration. This exceedance is likely caused by the high runoff vulnerability of the soil in that region. Approximately 0.6% of the alfalfa production can be attributed to Texas agriculture (USDA agricultural statistics). Alfalfa does not grow well

in wet soil conditions and is predominantly grown in areas that have well-drained soil. These data suggest the Texas alfalfa scenario is a unique situation that is likely to represent marginal site conditions for alfalfa production in Texas as well as locations in the U.S. production area with similar site and environmental conditions.

All acute freshwater RQs are not of concern to the Agency. The Agency is requiring additional studies, as listed in Section V of this document, to better understand the potential risk to estuarine and marine invertebrates.

2,4-DB and 2,4-DB-DMAS did not meet the Agency's criteria for conducting a chronic risk assessment. Based upon the use pattern of 2,4-DB and 2,4-DB-DMAS (one to two applications per year), a low acute toxicity profile and rapid degradation to 2,4-D, chronic risks to freshwater, marine, and estuarine fish are not likely to occur. In addition, any potential chronic exposures resulting from 2,4-D will be addressed in the 2,4-D RED.

Birds

Based on the acute toxicity studies submitted for birds, there is a large differential between the acute toxicity when 2,4-DB is administered as a single gavage or when mixed in the feed. When 2,4-DB was administered orally, the acute level of concern (LOC) was exceeded for small birds feeding on short grass and threatened and endangered species LOCs for small and medium birds feeding on short grass, tall grass, and broadleaf plants/insects (LD_{50} [Median Lethal Dose] 1536 mg/kg-bw). When birds were fed 2,4-DB that was mixed in with their feed the LC_{50} values were greater than 5,000 ppm. It is highly unlikely 2,4-DB concentrations would reach this level in the environment. Therefore, the Agency is not concerned with potential acute risks to birds.

Chronic avian studies are generally required when compounds are highly toxic to birds in acute studies, are used repeatedly during a single season, have a long half-life in the soil and in the environment, have high residues in sprayed crops and seed, and have the potential to bioaccumulate in prey species. 2,4-DB and 2,4-DB-DMAS do not fulfill all of these requirements. Therefore, the Agency has placed the chronic bird study on reserve.

Mammals

Predicted residues from all uses of 2,4-DB and 2,4-DB-DMAS are below the acute LOC. When using average labeled application rates aerially applied at one and two applications a season for the crop scenarios modeled (alfalfa, soybeans, and peanuts), acute levels of concern would not likely be exceeded for mammals consuming any of the crops treated with 2,4-DB or 2,4-DB-DMAS.

When using maximum residues and two applications at 1.7 lbs a.e./A, chronic mammalian LOCs are exceeded for the following groups:

- Small mammals feeding on short grass, tall grass, and broadleaf plants and insects; and

- Medium-size mammals feeding on short grass.

No mammalian chronic levels of concern were exceeded for scenarios when considering one or two applications at a rate of 0.40 or 0.45 lbs a.e./A (average labeled rates) and a default half-life of 35 days.

Threatened and Endangered Species

The risk assessment for threatened and endangered species indicates that 2,4-DB and 2,4-DB-DMAS exceed the threatened and endangered species LOCs for the use sites listed below.

Levels of concern for Freshwater fish were exceeded using the Texas alfalfa scenario by drift and runoff. These findings are based solely on the Agency's screening level assessment and do not constitute "may affect" findings under the Endangered Species Act.

Threatened and Endangered levels of concern were exceeded for small mammals feeding on short grass when using the soybean (0.40 lbs a.e./A, aerially applied two times per year with a 21-day application interval) and peanut (0.45 lbs a.e./A aerially applied two times per year with a 21-day application interval) application scenarios. These findings are based solely on the Agency's screening level assessment and do not constitute "may affect" findings under the Endangered Species Act.

Additional exceedances occurred for mammals for the following scenarios:

-Small mammals feeding on short grass, tall grass, and broadleaf plants/insects when single or multiple aerial applications are made to alfalfa;

-Medium-size mammals feeding on short grass, tall grass and broadleaf plants/insects when multiple aerial applications are made to alfalfa and short grass, and broadleaf plants/insects when a single application is made on alfalfa; and

-Small (15 grams) and medium (35 grams) mammals when using the alfalfa application scenario (1.7 lbs a.e./A, two times per year with a 30-day application interval).

The Agency has determined that no threatened and endangered mammals weighing less than 1000 grams inhabit alfalfa fields. Therefore, small mammals will not be affected by use of 2,4-DB and 2,4-DB-DMASin alfalfa related application scenarios.

Levels of concern were exceeded for small and medium size birds feeding on short grass, tall grass, and broadleaf plants/insects when multiple aerial applications are made to alfalfa. As discussed previously, it is highly unlikely that 2,4-DB or 2,4-DB-DMAS concentrations would reach an effect level in the environment. Therefore, the Agency has determined that threatened and endangered birds will not be affected by use of 2,4-DB or 2,4-DB-DMAS.

Levels of concern were exceeded at the highest application rate for plants. Until a species specific assessment for endangered plants is conducted, the mitigation strategy articulated in this document will serve as an interim protection to reduce the likelihood that listed species will be exposed to 2,4-DB and 2,4-DB-DMAS. Additionally, these exceedances are based solely on the Agency's screening level assessment and do not constitute "may affect" findings under the Endangered Species Act.

Regulatory Decision

The Agency has completed its review and has determined that the data are sufficient to support reregistration of all supported products containing 2,4-DB and 2,4-DB-DMAS. The Agency is issuing this RED for 2,4-DB and 2,4-DB-DMAS, as announced in a Notice of Availability published in the *Federal Register*. This RED document includes guidance and time frames for making any necessary label changes for products containing 2,4-DB and 2,4-DB-DMAS.

Summary of Mitigation Measures

The Agency has determined that 2,4-DB and 2,4-DB-DMAS are eligible for reregistration provided the mitigation measures described in this document and the label changes included in Table 21 in Section V of the RED are implemented.

Occupational Risk

Label changes are necessary to comply with updated Worker Protection Standard and other regulations. Labels will be updated to require chemical resistant gloves and protective eye-wear for early re-entry workers. A restricted entry interval (REI) of 48 hours is required because 2,4-DB-DMAS is a Toxicity Category I eye irritant.

Ecological Risk

The Agency has concluded that the risks posed by 2,4-DB and 2,4-DB-DMAS to most mammalian, avian, plant, and aquatic species will be substantially reduced by adhering to best management practices for aerial applications. In addition, labels need to specify medium to coarse droplet size and prohibit fine sprays.

Data Requirements

Additional confirmatory data is required to complete the reregistration of 2,4-DB and 2,4-DB-DMAS. A complete list of data gaps is presented in Appendix B (Table of Generic Data Requirements) as well as in Appendix E (the Generic Data Call-In) at the end of this document.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984 and amended again by the Pesticide Registration Improvement Act of 2003 to set time frames for the issuance of Reregistration Eligibility Decisions. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (EPA or the Agency). Reregistration involves a thorough review of the scientific database 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 or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require tolerance reassessment. The Agency has decided that, for those chemicals that have tolerances and are undergoing reregistration, the tolerance reassessment will be initiated through this reregistration process. The Act also requires that by 2006, EPA must review all tolerances in effect on the day before the date of the enactment of the FQPA. FQPA also amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to require a safety finding in tolerance reassessment based on factors including consideration of cumulative effects of chemicals with a common mechanism of toxicity. This document presents the Agency's revised human health and ecological risk assessments; and the Reregistration Eligibility Decision (RED) for 2,4-DB and 2,4-DB-DMAS.

2,4-DB and 2,4-DB-DMAS are plant growth regulators and systemic herbicides registered for use on alfalfa, clover, peanuts, soybeans, peppermint, spearmint, and trefoil. 2,4-DB is currently manufactured as the acid (2,4-DB) and the dimethylamine salt (2,4-DB-DMAS or 2,4-DB-DMA). Because of similarities in metabolism and degradation in animals, plants, and the environment, 2,4-DB and 2,4-DB-DMAS were considered equivalent in the risk assessments. An exception is that 2,4-DB-DMAS is a Toxicity Category I severe eye irritant, and 2,4-DB is a Category III eye irritant. The qualitative nature of the 2,4-DB residue in plant and livestock commodities is adequately understood based on acceptable metabolism studies in alfalfa, peanuts, soybeans, dairy cows and laying hens. Because tolerances are currently expressed as the combined residue of 2,4-DB and 2,4-DB-DMAS, the remainder of this document will only refer to 2,4-DB (unless specifically noted).

The Agency has concluded that the FQPA Safety Factor for 2,4-DB and 2,4-DB-DMAS should be removed (equivalent to 1X) based on: (1) exposure databases are complete for 2,4-DB and 2,4-DB-DMAS and the risk assessment for each potential exposure scenario includes all metabolites and/or degradates of concern and, (2) the risk assessment does not underestimate the potential risk for infants and children.

Risks summarized in this document are those that result only from the use of the active ingredients 2,4-DB and 2,4-DB-DMAS. The Food Quality Protection Act (FQPA) requires that 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

reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect that would occur at a higher level of exposure to any of the substances individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for 2,4-DB and any other substances. 2,4-DB does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that 2,4-DB has a common mechanism of toxicity with other substances. However, 2,4-DB produces the break-down product 2,4-D, which is a registered active ingredient. Risks posed to humans and the environment from 2,4-D are addressed in the 2,4-D RED. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of 2,4-DB. In an effort to simplify the RED, the information presented herein is summarized from more detailed information which can be found in the technical supporting documents for 2,4-DB referenced in this RED. The revised risk assessments and related addenda are not included in this document, but are available in the Public Docket at http://www.epa.gov/edocket.

This document consists of six sections. Section I is the introduction. Section II provides a chemical overview, a profile of the use and usage of 2,4-DB, and its regulatory history. Section III, Summary of 2,4-DB Risk Assessment, gives an overview of the human health and environmental assessments, based on the data available to the Agency. Section IV, Risk Management, Reregistration, and Tolerance Reassessment Decision, presents the reregistration eligibility and risk management decisions. Section V, What Registrants Need to Do, summarizes the necessary label changes based on the risk mitigation measures outlined in Section IV. Finally, the Appendices list all use patterns eligible for reregistration, bibliographic information, related documents and how to access them, and Data Call-In (DCI) information.

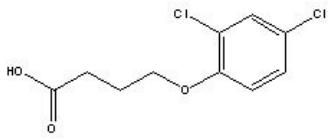
II. Chemical Overview

A. Regulatory History

2,4-DB and 2,4-DB-DMAS have been registered for use on broadleaf weeds since 1958. Currently, there are six products containing 2,4-DB (four technical products and two end-use-product) and 15 products containing 2,4-DB-DMAS (one formulation intermediate and fourteen end-use-products) registered under Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). There is one Section 24© Special Local Need (SLN) registration for 2,4-DB-DMAS use on mint in Idaho.

B. Chemical Identification

1. Technical 2,4-DB



Common name: 2,4-DB

Chemical name: 4-(2,4-dichlorophenoxy) butyric acid, 4-(2,4-dichlorophenoxy) butanoic acid

Chemical Family: Chlorophenoxy herbicide

Empirical formula: $C_{10}H_{10}Cl_2O_3$

CAS Registry No.: 94-82-6

Case number: 0196

OPP Chemical Code: 030801

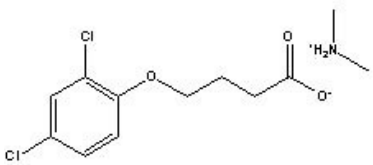
Molecular weight: 249.1

Trade name: Bakker Herbicide, Butoxone Herbicide

Basic manufacturer: Aceto Agricultural Chemicals Company, A. H. Marks & Company Ltd., Atanor S.A., Drexel Chemical Company (suspended).

Technical 2,4-DB acid is in the form of flakes/powder and is off-white in color. 2,4-DB has a melting point of 113.5-117.5 ° C. The water solubility of 2,4-DB is 46 ppm at 25 °C. 2,4-DB has a vapor pressure of 7.1 x 10^{-7} mm Hg at 23.6 °C.

2. 2,4-DB-DMAS (dimethylamine salt)



Common name: 2,4-DB-DMAS

Chemical name: Dimethylamine 4-(2,4-dichlorophenoxy) butyrate

Chemical Family: Chlorophenoxy herbicide

Empirical formula: $C_{12}H_{17}Cl_2NO_3$

CAS Registry No.: 2758-42-1

Case number: 0196

OPP Chemical Code: 030819

Molecular weight: 293.9

Trade name: Butoxone Herbicide, Butyrac, Hellion

Formulation intermediate manufacturer: A.H Marks & Company Ltd.

Technical 2,4-DB-DMAS is a light orange to brown viscous liquid. 2,4-DB-DMAS is miscible in water. 2,4-DB-DMAS has a melting point of 117-119 °. Water solubility and vapor pressure values were not provided in supporting documents.

C. Use Profile

The following is information on the currently registered uses of 2,4-DB and 2,4-DB-DMAS products and an overview of use sites and application methods. A detailed table of the uses of 2,4-DB and 2,4-DB-DMAS eligible for reregistration is contained in Appendix A.

Type of Pesticide: Herbicide (systemic)

Summary of Use:

Food: 2,4-DB is used on alfalfa, clover, peppermint, spearmint, peanuts, soybeans, and birdsfoot trefoil. 2,4-DB-DMAS is used on alfalfa, peanuts, and soybeans.

Non-Food: Agricultural fallow/idle land (2,4-DB-DMAS)

Residential: None

Target Pests: Used to control several broadleaf weeds, including annual morning glory, pigweed, prickly lettuce, and velvetleaf.

Formulation Types: All end-use products are liquids; formulated either as soluble, emulsifiable, or flowable concentrates.

Method and Rates of Application:

Equipment: Applied either as a broadcast application or a directed spray by ground or aerial application.

Application Rates: Maximum labeled application rates for food/feed crops are 1.5 lbs a.i./A (2,4-DB) and 1.7 lbs a.e./A (2,4-DB-DMAS). Rates of 2,4-DB-DMAS are expressed as acid equivalents (a.e.) in this document to compare application rates of the amine salt with the acid due to the nature of the amine salt to rapidly dissociate to 2,4-DB.

Timing: Broadcast applications of 2,4-DB and 2,4-DB-DMAS are made during the early growing season, whereas directed sprays are applied during late season.

D. Estimated Usage of Pesticide

Table 1 summarizes the best estimates available for the uses of 2,4-DB. The estimate for total domestic use (annual poundage) is 375,000. Peanuts is the leading commodity with 30% of 2,4-DB use and 35% of acres treated. The table below is compiled from information provided by the Biological and Economic Analysis Division's screening level usage report. It does not include all crops that 2,4-DB is used on.

Table 1. 2,4-DB Usage Summary of Major Use Sites

Site	Lbs. Active Ingredient Applied (Weighted Average)	Percent Crop Treated (Likely Maximum)	Percent Crop Treated (Weighted Average)
Peanuts	100,000	40	35
Alfalfa	50,000	< 2.5	< 1
Soybeans	40,000	< 2.5	< 1

III. Summary of 2,4-DB Risk Assessments

The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments, and to help the reader better understand the conclusions reached in the assessments. The human health and ecological risk assessment documents and supporting information listed in Appendix C were used to formulate the safety finding and regulatory decision for 2,4-DB and 2,4-DB-DMAS. While the risk assessments and related addenda are not included in this document, they are available from the OPP Public Docket and may also be accessed on the Agency's website at http://epa.gov/dockets. Hard copies of these documents may be found in the OPP public docket under docket number OPP-2004-0220. The OPP public docket is located in Room 119, Crystal Mall II, 1801 Bell Street, Arlington, VA, and is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m.

A. Human Health Risk Assessment

1. Toxicity of 2,4-DB

A brief overview of the toxicity studies used for determining endpoints in the dietary risk assessments are outlined below in Table 2. Further details on the toxicity of 2,4-DB can be found in the "2,4-DB and 2,4-DB-DMA Toxicology Chapter for RED," dated July 20, 2004; "2,4-DB Acute and Chronic Dietary Exposure Assessments for the Reregistration Eligibility Decision," dated July 13, 2004; "2,4-DB and 2,4-DB-DMA Human Health Risk Assessment," dated July 20, 2004; and "2,4-DB and 2,4-DB-DMA - Report of the Hazard Identification Assessment Review Committee." These documents are available on Agency's website in the EPA Docket at http://www/epa.gov/edockets.

The Agency has reviewed all toxicity studies submitted for 2,4-DB and has determined that the toxicological database is sufficient for reregistration. The studies have been submitted to support guideline requirements. Major features of the toxicology profile are presented below. Both 2,4-DB and 2,4-DB-DMAS were shown to be of low toxicity, with the exception of an eye irritation study with 2,4-DB-DMAS, which was Toxicity Category I due to persistent corneal opacity, iritis, and erythema.

Table 2. Acute Toxicity of 2,4-DB Technical

Guideline No./ Study Type	MRID Number	Results	Toxicity Category
870.1100 Acute Oral Toxicity	00128854 0092159	LD_{50} = 1935 mg/kg LD_{50} = 1715 mg/kg	III
870.1200 Acute Dermal Toxicity	0128854	LD_{50} = > 2000mg/kg	III
870.1300 Acute Inhalation Toxicity	41774001	LC_{50} > 2.3 mg/L	IV
870.2400 Acute Eye Irritation	0128854 00092160	Eye irritation with complete clearing by day 7	III
870.2500 Acute Dermal Irritation	0128854	No irritation	IV
870.2600 Skin Sensitization	43593904	Under review	—

Table 3. Acute Toxicity of 2,4-DB-DMAS Technical (26% active ingredient)

Guideline No./ Study Type	MRID Number	Results	Toxicity Category
870.1100 Acute Oral Toxicity	41224401	LD_{50} = 3583 mg/kg	III
870.1200 Acute Dermal Toxicity (rabbit)	41224402	LD_{50} > 2000 mg/kg	III
870.1300 Acute Inhalation Toxicity	41370101	LC_{50} > 7.98 mg/L	IV
870.2400 Acute Eye Irritation	41958001	Persistent corneal opacity, iritis, erythema	I
870.2500 Acute Dermal Irritation	250871	Irritation score = 1.99	IV
870.2600 Skin Sensitization	43968911	Under review	---

Toxicity endpoints and doses were selected from rat studies rather than dog studies, because of differences in the elimination of phenoxyacetic compounds in dogs compared to other mammalian species. 2,4-DB is eliminated from the body through the kidneys and the rate of urinary excretion is proportional to the plasma compound concentration. Therefore, species with a longer excretion time will have higher compound concentrations in the blood. Because of the limited capacity of dogs to excrete 2,4-DB, higher blood levels are seen in the dog relative to those seen in the rat. Consequently, effects are seen at lower dose levels in the dog than in the rat. When comparing the plasma half-life of 2,4-DB among species, the Agency has determined that the rat is the most representative species to use in the risk assessment. Because of the similarities in metabolism and degradation in animals, plants, and the environment, 2,4-DB and 2,4-DB-DMAS were considered of equivalent toxicity in the risk assessment. Toxicity endpoints selected for 2,4-DB, both dietary and non-dietary, are presented in Tables 4 and 5 below.

Table 4. Toxicological Endpoints for 2,4-DB (Dietary)

Exposure Scenario	Dose for Risk Assessment and Uncertainty Factor	Special FQPA Safety Factor and Level of Concern	Study and Toxicological Effects (MRID #)
Acute Dietary (Females 13-49 years of age)	NOAEL = 62.5 mg/kg/day *UF = 100* **Acute RfD** = 0.6 mg/kg/day	FQPA SF = 1X **aPAD** = acute RfD / FQPA SF = 0.6 mg/kg/day	Rat developmental toxicity. LOAEL = 125 mg/kg/day based on skeletal variations/malformations, reduction is size of eyes, post-implantation loss. Endpoint based on a single dose. (41382701)
Acute Dietary (General population including infants and children)	**None**	N/A	No endpoint attributable to a single dose from oral toxicity studies.
Chronic Dietary (All populations)	NOAEL= 3 mg/kg/day *UF = 100* **Chronic RfD** = **0.03** mg/kg/day	FQPA SF = 1X **cPAD** = chronic RfD / FQPA SF = 0.03 mg/kg/day	Chronic/carcinogenicity study in rats. LOAEL = 30 mg/kg/day based on decreased body weight gain and food consumption in females. (40257501)

UF = uncertainty factor, FQPA SF = Special FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose, (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure, N/A = Not Applicable

No neurotoxicity studies were available for 2,4-DB or 2,4-DB-DMAS. Clinical signs suggestive of neurotoxicity occurred only at lethal doses. The Agency concluded that these effects were not indicative of neurotoxicity resulting from exposure to 2,4-DB and 2,4-DB-DMAS. There was no indication of toxicity to the central nervous system in developmental and/or reproductive studies.

There was no indication of prenatal susceptibility in the developmental rat studies with 2,4-DB and 2,4-DB-DMAS; with both chemicals, developmental effects occurred at doses two-fold higher than the doses that caused maternal toxicity. There was no prenatal susceptibility in the rabbit developmental toxicity study with 2,4-DB because no developmental toxicity occurred.

There was qualitative, but not quantitative susceptibility in the 2-generation reproduction study with 2,4-DB because offspring mortality occurred at a dose where parental toxicity was less severe (decreased food consumption and body weight, increased food conversion ratio, increased water consumption, organ weight changes, and macroscopic renal findings including kidney pallor and cortical scarring). The parental and offspring NOAELs were 30 mg/kg/day.

It was concluded that there was low concern for the qualitative susceptibility because the offspring toxicity was well characterized and was accompanied by maternal toxicity; there was a clear NOAEL/LOAEL for offspring toxicity; and the endpoint selected for long-term risk assessments (NOAEL = 3mg/kg/day in the chronic rat study) was considerably lower and would address the concerns for offspring toxicity seen in this study. Therefore, there were no residual uncertainties for pre- and/or post-natal toxicity.

General Toxicity Observations

In subchronic and chronic toxicity studies with 2,4-DB, some form of liver toxicity was noted. This included decreased liver function, increased liver weights, increased levels of liver enzymes, hepatocyte hypertrophy, icterus, and pale livers.

Kidney toxicity was noted in several studies. Effects included changes in kidney weight, kidney infarcts, tubular degeneration, and an increase in blood urea nitrogen concentrations.

Other toxicity included decreased hematological parameters, changes in heart weight, spots on the heart, and inflamed lacrimal glands (2,4-DB-DMAS).

No systemic toxicity was noted in 21-day dermal studies in rabbits with either 2,4-DB or 2,4-DB-DMAS, although local dermal irritation occurred in the dermal study with 2,4-DB-DMAS.

Short-term Dermal

An endpoint was not selected for short-term dermal exposures because there was no systemic toxicity observed in the subchronic dermal toxicity study and there were no developmental toxicity concerns.

Short-term Inhalation

For short-term inhalation scenarios an oral NOAEL of 31 mg/kg/day was selected from an oral rat developmental toxicity study during which decreased body weight, body weight gain, food consumption, and clinical signs (emaciation, few feces) were observed in the dams with a LOAEL of 62.5 mg/kg/day.

Intermediate-term Dermal and Inhalation

For intermediate-term dermal and inhalation scenarios an oral NOAEL of 15.8 mg/kg/day was selected from a subchronic oral toxicity study in rats during which decreased body weight gain, increased liver and kidney weight and microscopic changes were observed with a LOAEL of 50 mg/kg/day.

Dermal Absorption

A dermal absorption factor of 23% was selected for converting dermal exposures to oral equivalent doses. This value was derived from a dermal absorption study in rats.

Carcinogenicity Classification

The Agency has concluded that 2,4-DB is classified as “not likely to be a human carcinogen”; therefore, no carcinogenic dietary analysis is required.

Mutagenicity Potential

The Agency concluded that there is not a concern for mutagenicity resulting from exposure to 2,4-DB or 2,4-DB-DMAS.

Endocrine Disruption Potential

EPA is required under the Federal Food Drug and Cosmetic Act (FFDCA), as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) “may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate.” 2,4-DB has properties that could indicate Endocrine Disrupting Chemical

(EDC) properties. These include decreased body weights and altered liver function in mice exposed to 2,4-DB. When the appropriate screening and/or testing protocols being considered under the Agency's Endocrine Disrupting Screening Program (EDSP) have been developed, 2,4-DB may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

2. FQPA Safety Factor

The FQPA Safety Factor (as required by the Food Quality Protection Act of 1996) is intended to provide an additional 10-fold safety factor (10X), to protect for special sensitivity in infants and children to specific pesticide residues in food, drinking water, or residential exposures, or to compensate for an incomplete database. The FQPA Safety Factor has been removed (i.e., reduced to 1X) for 2,4-DB based on: (1) exposure databases are complete for 2,4-DB and 2,4-DB-DMAS and the risk assessment for each potential exposure scenario includes all metabolites and/or degradates of concern and, (2) the risk assessment does not underestimate the potential risk for infants and children. The FQPA Safety Factor assumes that the exposure databases (food, drinking water, and residential) are complete, the risk assessment for each potential exposure scenario includes all metabolites and/or degradates of concern, and does not underestimate the potential risk for infants and children. These criteria have been met for 2,4-DB and 2,4-DB-DMAS. Based on the analysis of submitted developmental toxicity studies, the Agency determined that no special FQPA Safety Factor was needed since there were no residual uncertainties for pre- and/or postnatal toxicity.

3. Population Adjusted Dose (PAD)

Dietary risk is characterized in terms of the Population Adjusted Dose (PAD), which reflects the reference dose (RfD), either acute or chronic, that has been adjusted to account for the FQPA Safety Factor (SF). This calculation is performed for each population subgroup. A risk estimate that is less than 100% of the acute or chronic PAD is not of concern.

a. Acute PAD

Acute dietary risk for 2,4-DB is assessed by comparing acute dietary exposure estimates (in mg/kg/day) to the acute Population Adjusted Dose (aPAD). Acute dietary risk is expressed as a percent of the aPAD. The aPAD is the acute reference dose (0.6 mg/kg/day) modified by the FQPA safety factor. The acute reference dose was derived from a developmental toxicity study in rats in which both the NOAEL (62.5 mg/kg/day) and the LOAEL (125 mg/kg/day) were determined. Acute dietary exposure was estimated only for females ages 13-49 because available studies did not show a toxicity endpoint attributable to a single exposure for the general population. The 2,4-DB aPAD is 0.6 mg/kg/day based on a reference dose of 0.6 mg/kg/day, and incorporating the FQPA safety factor of 1X.

b. Chronic PAD

Chronic dietary risk for 2,4-DB is assessed by comparing chronic dietary exposure estimates (in mg/kg/day) to the chronic Population Adjusted Dose (cPAD). Chronic dietary risk is expressed as a percent of the cPAD. The cPAD is the chronic reference dose (0.03 mg/kg/day)

modified by the FQPA safety factor. The cPAD was derived from a combined rat chronic/carcinogenicity study, in which 2,4-DB was administered to rats for 24 months to test the carcinogenic and chronic toxicity potential of the chemical. The chronic LOAEL was determined to be 30 mg/kg/day based on decreased body weight and food consumption in female rats. Consideration was given to using an endpoint from the chronic dog study. As previously discussed, because the dog is believed to be more sensitive to toxicity from 2,4-DB than the rat, the Agency has determined it is appropriate to use endpoints from available rat studies to assess potential risks in the risk assessment. The 2,4-DB cPAD is 0.03 mg/kg/day based on a reference dose of 0.03 mg/kg/day, which includes the incorporation of the FQPA safety factor (1X) for the overall U.S. population or any population subgroups.

4. Exposure Assumptions

Acute and chronic dietary exposure assessments were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), Version 1.3 and the Lifeline™ Model Version 2.0. Both models use food consumption data from the USDA's Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994-1996 and 1998. The CSFII data are based on the reported food consumption by more than 20,000 individuals over two non-consecutive survey days. For acute exposure estimates, individual one-day food consumption data are used on an individual-by-individual basis. For the chronic exposure assessment, consumption data are averaged for the entire U.S. population and within population subgroups.

5. Dietary (Food) Risk Assessment

a. Acute Dietary Risk

Generally, a dietary risk estimate that is less than 100% of the acute or chronic PAD does not exceed the Agency's risk concerns. A summary of acute and chronic risk estimates are shown in Tables 5 and 6.

A screening-level (tolerance level and 100% crop treated [% CT] were assessed) acute dietary risk assessment was conducted for all supported 2,4-DB food uses. Dietary risk estimates are provided for females 13-49 years old, the only population subgroup for which an endpoint was selected. The results using the DEEM-FCID™ and Lifeline™ models showed risk estimates at the 95th percentile of exposure to be <1% of the aPAD regardless of the model used and therefore were not of concern.

Table 5. Acute Dietary Exposure and Risk

Population Subgroup	Acute Dietary (95th Percentile)			
	DEEM-FCID™		LifelineTM	
	Dietary Exposure (mg/kg/day)	% aPAD	Dietary Exposure (mg/kg/day)	% aPAD
Females 13-49 years old	0.000467	0.08	0.000614	0.102

b. Chronic (Non-cancer) Dietary Risk

Tolerance level residues and 100% CT assumptions were also used to determine the screening-level chronic dietary exposure and risk estimates. This assessment concluded that for all included commodities, the chronic risk estimates are below the Agency's level of concern for the general U.S. population (<1% of the cPAD) and all population subgroups (<2.2% of the cPAD for infants less than 1 year old, the most highly exposed subgroup) when using DEEM-FCIDTM and Lifeline™ models.

Table 6. Chronic Dietary Exposure and Risk

Population Subgroup*	Chronic Dietary			
	DEEM-FCID™		LifelineTM	
	Dietary Exposure (mg/kg/day)	% cPAD	Dietary Exposure (mg/kg/day)	% cPAD
General U.S. Population	0.000242	0.8	0.000232	0.8
All Infants (< 1 year old)	**0.000661**	**2.2**	**0.000554**	**1.8**
Children 1-2 years old	0.000548	1.8	0.000539	1.8
Children 3-5 years old	0.000535	1.8	0.000505	1.7
Children 6-12 years old	0.000373	1.2	0.000346	1.2
Youth 13-19 years old	0.000238	0.8	0.000224	0.7
Adults 20-49 years old	0.000197	0.7	0.000198	0.7
Adults 50+ years old	0.000153	0.5	0.000191	0.6
Females 13-49 years old	0.000185	0.6	0.000228	0.8

**The values for the highest exposed population for each type of risk assessment are bolded.*

c. Dietary Risk from Drinking Water

Drinking water exposure to pesticides can occur through ground and surface water contamination. In assessing drinking water risks, EPA considers acute (one day), chronic (long-term) and, if applicable, cancer (overall) exposure, and uses either modeling or monitoring data, if available, to estimate those risks. To determine the maximum contribution from water allowed in the diet, EPA first looks at how much of the overall allowable risk is contributed by food and then calculates a "drinking water level of comparison" (DWLOC) to determine whether modeled or monitored exposure estimates exceed the allowable risk level. Estimated drinking water concentrations (EDWCs) that are above the corresponding DWLOC exceed the Agency's level of concern.

No degradation products of 2,4-DB were included in this assessment. The major degradate of 2,4-DB is 2,4-D. 2,4-D is a registered active ingredient. 2,4-D was found at a maximum of 5.0-15% of applied 2,4-DB in soil dissipation studies. The annual use of 2,4-DB is less than 1% of the annual use of 2,4-D (375,00 pounds vs. 46 million pounds). According to data from the U.S. Geographical Survey reported in the Environmental Fate and Effects Revised Risk Assessment for 2,4-DB dated July 20, 2004, 2,4-D is used throughout the entire country. The use of 2,4-DB is restricted to discrete areas of the country, which overlap areas of 2,4-D use. Therefore, drinking water exposure to 2,4-D will be addressed in the 2,4-D RED.

Because 2,4-DB-DMAS rapidly dissociates in water to form 2,4-DB, the Agency used environmental fate data for 2,4-DB as bridging data for 2,4-DB-DMAS. The mobility of 2,4-DB in mineral soils was classified as very mobile to moderately mobile**.**

i. Surface Water

Modeling: Estimated surface water (drinking water) concentrations are based on two models coupled together, PRZM and EXAMS. The PRZM/EXAMS modeling was performed with index reservoir scenarios and percent cropped area adjustment factors. The PRZM/EXAMS combined model provides a Tier II assessment that includes refined assumptions. The estimated drinking water concentrations (EDWCs) have been calculated for two types of dietary risk assessment: (1) acute or peak concentration; and (2) non-cancer chronic concentration. Modeling of surface water concentrations was performed using alfalfa, peanuts, and soybean application scenarios. Several scenarios for each crop were chosen to represent a geographically dispersed range of surface water concentrations in areas representative of where 2,4-DB is used. The Agency calculated 318.68 µg/L for the 1 in 10 year peak concentration (acute) and 72.40 µg/L for the 1 in 10 year annual daily average concentration (chronic non-cancer). These estimated concentrations were from the Texas alfalfa crop scenario. The acute DWLOC is 18,000 µg/L for women ages 13-49 (the only group with an endpoint of concern). The chronic DWLOC for the general population is 1,050 µg/L and 290 µg/L for infants less than one year of age. Since the EDWCs are less than the DWLOCs, both acute and chronic estimated concentrations of 2,4-DB in surface water are below the Agency's level of concern.

Monitoring: Monitoring data were available for 2,4-DB from the United States Geological Survey (USGS) National Water-Quality Assessment (NAWQA) Program, USEPA STOrage and RETrieval System for Water and Biological Monitoring Data (STORET), and from

the USGS Reservoir and Finished Water Pilot Monitoring Study. Frequency of these detections was not sufficient to calculate average concentrations of 2,4-DB.

The highest annual maximum concentration of 2,4-DB detected in surface water monitoring data was 0.83 µg/L from the NAWQA data at Reed Wash near Mack, Colorado, with the next highest being 0.81 µg/L from the STORET data at Big Limestone Creek near Limestone, Tennessee. Both monitored concentrations of 2,4-DB are below the Agency's level of concern.

ii. Ground Water

Modeling: The SCI-GROW model was used to estimate potential ground water concentrations. SCI-GROW is a screening tool, or Tier 1 model for ground water. It is based on a regression approach which relates the concentrations found in ground water in Prospective Ground Water studies to aerobic soil metabolism rate and soil-water partitioning properties of the chemical. The SCI-GROW model estimated the concentration of 2,4-DB in drinking water from shallow ground water sources to be 0.51 µg/L. Because the EDWC of 0.51 µg/L is less than the acute DWLOC for women 13-49 (18,000 µg/L), the chronic DWLOC for the general population (1,050 µg/L),and the chronic DWLOC for infants less than one year (209 µg/L); concentrations of 2,4-DB in ground water are not of concern to the Agency. This concentration can be used for both acute and chronic exposure estimates, and is below the Agency's level of concern.

Monitoring: 2,4-DB was reported once in the NAWQA ground water data at a concentration of 0.06 µg/L and was not detected in STORET data. This value is below the Agency's level of concern for both acute and chronic (non-cancer) risks.

For more information on drinking water risks and the calculations of the DWLOCs, see the Water Exposure section of the "Human Health Risk Assessment (Revised)," dated July 20, 2004.

6. Aggregate Risk

The Food Quality Protection Act amendments to the Federal Food, Drug, and Cosmetic Act (FFDCA, Section 408(b)(2)(A)(ii)) require "that there is a reasonable certainty that no harm will result from aggregate exposure to pesticide chemical residue, including all anticipated dietary exposures and other exposures for which there are reliable information." Aggregate exposure will typically include exposures from food, drinking water, residential uses of a pesticide, and other non-occupational sources of exposure. Since there are no residential uses for 2,4-DB, aggregate assessments included exposure to food and drinking water only.

a. Acute Aggregate Risk

An acute DWLOC was calculated only for females 13-49 years of age because this was the only population subgroup for which an acute dietary endpoint was selected. Results using the DEEM-FCIDTM and Lifeline^{TM} models showed risk estimates at the 95th percentile of exposure to be less than one percent of the aPAD for this population subgroup, and therefore were not of concern. As shown in Table 7, the DWLOC is 18,000 µg/L and the EDWC is 0.51

µg/L for ground water and 318 µg/L for surface water. Taking into consideration the two components of aggregate exposure discussed above, acute aggregate risk estimates are below the Agency's level of concern.

Table 7. Acute Aggregate Exposure

Population Subgroup	Acute PAD mg/kg/day	Food Exposure mg/kg/day	Target Max Water Exposure mg/kg/day	Ground Water EDWC µg/L	Surface Water EDWC µg/L	DWLOC µg/L
Females 13-49	0.6 mg/kg	0.000467	0.600	0.51	318.68	18,000

b. Chronic Aggregate Risk

Chronic aggregate risk was considered by aggregating chronic food and drinking water exposure. For chronic dietary risk, the most highly exposed population subgroup was all infants less than one year old. For this population subgroup, the chronic dietary exposure was less than 2.2% of the cPAD. As shown in Table 8, the DWLOC for this subgroup is 290 µg/L and the EDWC for ground water is 0.51 µg/L for ground water and is 72 µg/L for surface water. Because the EDWCs are below the DWLOC, aggregate dietary and drinking water exposure is below the Agency's level of concern.

Table 8. Chronic Aggregate Exposure

Population Subgroup	Chronic PAD mg/kg/day	Food Exposure mg/kg/day	Target Max Water Exposure mg/kg/day	Ground Water EDWC µg/L	Surface Water EDWC µg/L	DWLOC µg/L
U.S. Population (total)	0.03	0.000242	0.030	0.51	72.40	1050
All infants (< 1 year)	0.03	0.000661	0.029	0.51	72.40	290

7. Occupational Risk

Workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Occupational handlers of 2,4-DB and 2,4-DB-DMAS include workers in agricultural areas and workers in right-of-way areas. Occupational risk for all of these potentially exposed populations is measured by a Margin of Exposure (MOE) which determines how close the occupational exposure comes to a No Observed Adverse Effect Level (NOAEL) from toxicological studies. In the case of 2,4-DB, MOEs greater than 100 are not of concern to the Agency. This MOE includes the standard safety factors of 10X for intraspecies variability (i.e. differences among humans) and 10X for interspecies variability (differences between humans and animals). For workers entering a treated site, MOEs are calculated for each day after application to determine the minimum length of time required before workers can safely re-enter.

Occupational risk is assessed for exposure at the time of application (termed "handler" exposure) and is assessed for exposure following application, or post-application exposure. Application parameters are generally defined by the physical nature of the formulation (e.g., formula and packaging), by the equipment required to deliver the chemical to the use site, and by the application rate required to achieve an efficacious dose. Post-application risk is assessed for re-entry activities such as scouting, irrigating, pruning, and harvesting, and is based primarily on dermal exposure estimates. Occupational risks were assessed only for exposures from liquid formulations. Although there are several forms of 2,4-DB and 2,4-DB-DMAS products, all are considered liquids for the purpose of occupational exposure.

For more information on the assumptions and calculations of potential risk of 2,4-DB to workers, see the Occupational Exposure Assessment (Section 4.6) in the "Human Health Risk Assessment (Revised)," dated July 20, 2004 and the "Revised Occupational and Residential Exposure and Risk Assessment for the RED Document," dated July 19, 2004.

a. Occupational Toxicity

Because 2,4-DB and 2,4-DB-DMAS are very similar in their toxicity profiles, one set of endpoints can be used to evaluate occupational risks for both forms. Table 9 provides a listing of the toxicological endpoints used in the 2,4-DB occupational risk assessment.

Table 9: Toxicological Endpoints Used for Occupational Risk Assessment

Exposure Scenario	Dose or Factor Used in Risk Assessment	Study and Toxicological Effects (MRID #)
Dermal Short-term	None	Quantification not required. There is no systemic toxicity via the dermal route and there are no developmental toxicity concerns.
Dermal Intermediate-term	Oral NOAEL= 15.8 mg/kg/day*****	Subchronic rat toxicity. LOAEL = 50 mg/kg/day based on decreased body weight gain, increased relative liver/kidney weight and microscopic changes. (00104739)
Inhalation Short-term	NOAEL = 31 mg/kg/day+	Rat Developmental toxicity. LOAEL = 62.5 mg/kg/day based on decreased maternal body weight, body weight gain, and food consumption, and clinical signs (emaciation, few feces). (42536101, 4259201, 41382701)
Inhalation Intermediate-term	Oral NOAEL = 15.8 mg/kg/day	The same study and endpoint was used as for intermediate-term dermal exposure (see above).
Dermal Absorption Factor	23 percent of the oral dose	Dermal absorption study in rats with 2,4-DB DMAS (44729501).
* Since an oral NOAEL was selected, a dermal absorption factor should be used in route to route extrapolation. + Inhalation absorption is assumed to be equivalent to oral absorption (100 percent default value).		

b. Occupational Handler Exposure

Occupational handler risk estimates have been assessed for both short- and intermediate-term exposure durations. Because 2,4-DB is typically applied once or twice per season it is anticipated that 2,4-DB exposures would be primarily short-term. Because a toxicity endpoint for short-term dermal exposures was not determined, only short-term inhalation exposures to handlers were assessed. To address the limited possibility that intermediate exposures could occur, intermediate-term risks were assessed using the intermediate-term oral endpoint and dermal absorption factor of 23%.

The Agency has determined that there are potential exposures to individuals who mix, load, apply, and otherwise handle 2,4-DB during the usual use patterns associated with the pesticide's use. Based on the use patterns, the following exposure scenarios were assessed:

(1) mixing/loading liquid formulations;
(2) applying sprays by aerial application;
(3) applying sprays with ground boom equipment;
(4) flagger for aerial applications.

c. Occupational Handler Risk Summary

Occupational Handler Exposure Assumptions

Exposure analyses were performed using the Pesticide Handlers Exposure Database (PHED) as tabulated in the PHED Surrogate Exposure Guide of August 1998. A description of PHED is included in Appendix A of the "Revised Occupational and Residential Exposure and Risk Assessment for the Reregistration Eligibility Decision (RED) Document". Handler exposures are also calculated in Appendix A. Only inhalation exposures were assessed for short-term risks because there is no dermal endpoint for short-term exposures. Both inhalation and dermal exposures were assessed for intermediate-term risks and these exposures were combined because the endpoints were based on the same study. The target MOE is 100 for both short and intermediate-term exposures. Scenarios with an MOE less than 100 indicates a risk of concern.

The following assumptions and factors were used in order to complete the exposure and risk assessments for occupational handlers:

- The average work day is 8 hours;

- The daily acreage treated was taken from EPA Science Advisory Council for Exposure Standard Operating Procedure #9 "Standard Values for Daily Acres Treated in Agriculture," revised July 5, 2000. These values are listed in Table 7 of the Occupational and Residential Risk Assessment;

- The maximum label application rates are used to assess short-term risks because it is possible that these rates would be used for one to thirty consecutive days.

- The average application rates were used to assess intermediate-term risks because it is highly unlikely that maximum label rates would be used for more that thirty consecutive days;

• A body weight of 70 kg was assumed because the endpoint is not gender specific;

• The inhalation absorption rate is 100% and dermal absorption rate is 23%;

• Baseline PPE includes long sleeve shirts, long pants and no gloves or respirator;

• Single Layer PPE includes baseline PPE with chemical resistant gloves;

• Aerial applicators utilize closed cockpit aircraft and do not wear chemical resistant gloves; and

• All three formulations of 2,4-DB and 2,4-DB-DMAS are considered liquids when determining occupational exposure and risk.

Summary of Risk Estimates for Handlers

All of the short-term inhalation MOEs exceed 100 with baseline PPE. Respiratory protection is not needed. All of the intermediate-term mixer/loader combined MOEs exceed 100 if single layer PPE (i.e. baseline clothing with chemical resistant gloves) is worn. The intermediate-term MOEs for applicators also exceed 100 with baseline work clothing. Intermediate-term handler exposures are less likely to occur because 2,4-DB is applied only once or twice per season. Metabolism studies in rats also indicated that most of the 2,4-DB dose is excreted within 24 hours through the urine and feces. The MOEs for handlers are summarized in Tables 10 and 11.

Table 10. Occupational Handler Short-Term Risk Summary

Exposure Scenario	Crop	Label Application Rate (lb a.e./acre)	Acres/Day	Baseline Inhalation MOE
Mix/Load Liquids for Aerial	Alfalfa, Clover Mint Peanuts (SW), Soybeans Peanuts (SE)	1.5 0.75 0.4 0.25	1200 1200 1200 1200	1,000 2,000 3,800 6,000
Mix/Load Liquids for Ground boom	Alfalfa, Clover, CRPA Mint Peanuts (SW), Soybeans Peanuts (SE)	1.5 0.75 0.4 0.25	200 200 200 200	6,000 12,000 23,000 36,000
Aerial Application	Alfalfa, Clover Mint Peanuts (SW), Soybeans Peanuts (SE)	1.5 0.75 0.4 0.25	1200 1200 1200 1200	18,000 35,000 66,000 110,000
Ground boom Application	Alfalfa, Clover, CRPA Mint Peanuts (SW), Soybeans Peanuts (SE)	1.5 0.75 0.4 0.25	200 200 200 200	9,800 20,000 37,000 59,000

Exposure Scenario	Crop	Label Application Rate (lb a.e./acre)	Acres/Day	Baseline Inhalation MOE
Mix/Load Liquids for Aerial	Alfalfa, Clover Mint Peanuts (SW), Soybeans Peanuts (SE)	1.5 0.75 0.4 0.25	1200 1200 1200 1200	1,000 2,000 3,800 6,000
Flag Aerial Application	Alfalfa, Clover Mint Peanuts (SW), Soybeans Peanuts (SE)	1.5 0.75 0.4 0.25	1200 1200 1200 1200	3,400 6,900 13,000 21,000

Table 11. Occupational Handler Intermediate-Term Risk Summary

Exposure Scenario	Crop	Average Application Rate (lb a.e./acre)	Acres/ Day	Baseline Combined MOE	Single Layer Combined MOE[1]
Mix/Load Liquids for Aerial	Alfalfa, Clover Mint Peanuts Soybeans	0.55 0.75 0.24 0.13	1200 1200 1200 1200	**2.5** **1.8** **5.7** **11**	260 190 590 1100
Mix/Load Liquids for Ground boom	Alfalfa, Clover Mint Peanuts Soybeans	0.55 0.75 0.24 0.13	200 200 200 200	**15** **11** **34** **64**	1500 1100 3600 6600
Aerial Application	Alfalfa, Clover Mint Peanuts Soybeans	0.55 0.75 0.24 0.13	1200 1200 1200 1200	1400 1000 3200 5800	NA NA NA NA
Ground boom Application	Alfalfa, Clover Mint Peanuts Soybeans	0.55 0.75 0.24 0.13	200 200 200 200	2500 1900 5800 11000	2500 1900 5800 11000
Flag Aerial Application	Alfalfa, Clover Mint Peanuts Soybeans	0.55 0.75 0.24 0.13	1200 1200 1200 1200	580 430 1300 2500	540 400 1200 2300

[1]Baseline plus chemical resistant gloves
Values in bold are of concern to the Agency

d. Occupational Post-application Risk Summary

Post-application exposure to re-entry workers is possible because 2,4-DB can be applied foliarly, on the surface of the labeled crops. Post-application activities include irrigation and scouting, which can result in dermal exposures. The exposures were assessed using the intermediate-term dermal endpoint, standard assumptions and average daily rates. All of the post-application MOEs are above the target MOE of 100 on Day 0. It should be noted, however,

that 2,4-DB-DMAS is a Toxicity Category 1 eye irritant which requires a 48-hour REI according to the Worker Protection Standard (WPS).

e. Human Incident Data

In evaluating incidents to humans, the Agency reviewed reports from the National Poison Control Centers (PCC), the Agency's Office of Pesticide Program's Incident Data System (IDS), California Department of Pesticide Regulation, and the National Pesticide Telecommunications Network (NPTN).

There were a total of 7 reported incidents due to exposure to 2,4-DB. The majority of incidents resulted from misuse and exposure resulted in some form of dermal irritation.

The OPP Incident Data System reported 2 separate incidents. The first occurred in 1991, when 2,4-DB was misused on soybeans resulting in plant damage and health effects. No further information concerning the health effects was reported. The second incident occurred in 1993, when a hose broke and a worker was sprayed in the face. The worker was hospitalized the following day after experiencing unspecified symptoms. No further information concerning the case was reported.

Five exposure incidents were reported to Poison Control Centers from 1993-2001. Three of the five exposures reported some type of dermal reaction. The most serious case reportedly involved misuse with symptoms of flushed skin and blisters. One other case reported rash and another reported swelling and skin irritation. Two of the cases were seen in a health care facility and none were hospitalized.

B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment is presented below. 2,4-DB has several registered use sites: alfalfa, soybeans, peanuts, clover, peppermint, spearmint, and trefoil. The following risk characterization is intended to describe the magnitude of the estimated environmental risks for 2,4-DB use sites and any associated uncertainties.

For detailed discussions of all aspects of the environmental risk assessment, see the "Environmental Fate and Effects Division Revised Risk Assessment for 2,4-DB and 2,4-DB-DMAS Reregistration Eligibility Document (Revised)", dated December 13, 2004.

1. Environmental Fate and Transport

Available data indicate that 2,4-DB-DMAS rapidly dissociates in moist soils and aquatic environments, therefore, ecological risks were only assessed for 2,4-DB. Consequently, application rates are expressed in pounds of acid equivalents (a.e.) rather than pounds of active ingredient (a.i.) per acre. Bridging data were submitted by the registrant demonstrating that 2,4-DB-DMAS, a salt, rapidly dissociates when exposed to moisture to form 2,4-DB and dimethylamine. It is very important to note, however, that 2,4-DB-DMAS could persist under dry soil conditions. In soil environments 2,4-DB dissipation appears to be dependent on leaching and on oxidative microbial-mediated degradation to CO_2. In mineral soils 2,4-DB's metabolism

half-life is 24.5 days. Additionally, 2,4-DB was found to be stable to anaerobic metabolism in mineral soils, meaning 2,4-DB will not undergo biodegradation in anaerobic soils. The mobility of 2,4-DB in mineral soils was classified as very mobile to moderately mobile. The main path of dissipation in aquatic environments is photodegradation. The half-life for 2,4-DB in aquatic environments ranges from 6.3 to 17.2 days in different pH solutions.

The primary route of dissipation is transformation with the major transforming products being 2,4-D (with a maximum concentration of 5.0-15% of the applied) and 2,4-D Phenol (2,4-DP) (with a maximum concentration of 5.0-27.3 % applied). In the top soil layer (0-15 cm) 2,4-DB and its transformation products were detected.

Studies indicated the dissipation of 2,4-D depends on oxidative microbial-based mineralization, photodegradation in water, and leaching. 2,4-D has a low binding affinity in mineral soils and sediment. The major volatile degradate of 2,4-D in soil and aquatic environments was CO_2 . The mobility of 2,4-D in supplemental soil studies was classified as intermediately mobile to very mobile in "sieved" mineral soils. Aged radio labeled residues of 2,4-D appeared to be immobile in supplemental soil column studies. For a complete discussion of 2,4-D see the "Environmental Fate and Effects Division's Risk Assessment for the Reregistration Eligibility Document for 2,4-D", dated May 24, 2004. This document is available via the Internet at http://www.epa.gov/edockets.

2,4-DB has a vapor pressure of 6.37×10^{-5} Torr. 2,4-DB is not expected to be volatile under normal use conditions. Laboratory volatility studies are requested on a case by case basis for compounds with vapor pressure of 10^{-4} to 10^{-6} Torr. These data are reserved at this time.

2,4-DB is not expected to bioaccumulate because it is ionic (anion under most environmental conditions). The ionic nature of the compound will increase the water soluble nature of the compound and hence will lower the octanol to water coefficient. Octanol is an organic solvent that is used as a surrogate for natural organic matter. A low octanol to water coefficient means that 2,4-DB will not accumulate in the octanol, and, therefore, is not likely to bioaccumulate.

2. Ecological Risk

The Agency's ecological risk assessment compares toxicity endpoints from ecological toxicity studies to estimated environmental concentrations (EECs) based on environmental fate characteristics and pesticide use data. To evaluate the potential risk to non-target organisms from the use of 2,4-DB products, the Agency calculates a Risk Quotient (RQ), which is the ratio of the EEC to the most sensitive toxicity endpoint values, such as the median lethal dose (LD_{50}) or the median lethal concentration (LC_{50}). These RQ values are then compared to the Agency's levels of concern (LOCs) which indicate whether a chemical, when used as directed, has the potential to cause adverse effects on non-target organisms. When the RQ exceeds the LOC for a particular category, the Agency presumes a risk of concern to that category of organisms. The LOCs and the corresponding risk presumptions are presented in Table 12.

Table 12. LOCs and Associated Risk Presumptions

IF...	THEN the Agency presumes...
Mammals and Birds	
The acute RQ > LOC of 0.5	Acute risk
The acute RQ >LOC of 0.2	Risk that may be mitigated through restricted use
The acute RQ > LOC of 0.1	Acute effects may occur in Threatened and Endangered Species
The chronic RQ > LOC of 1	Chronic risk *and* Chronic effects may occur in Threatened and Endangered Species
Fish and Aquatic Invertebrates	
The acute RQ > LOC of 0.5	Acute risk
The acute RQ > LOC of 0.1	Risk that may be mitigated through restricted use
The acute RQ >LOC of 0.05	Acute effects may occur in Threatened and Endangered Species
The chronic RQ > LOC of 1	Chronic risk *and* Chronic effects may occur in Threatened and Endangered Species
Terrestrial and Aquatic Plants	
The acute RQ > LOC of 1	Acute risk *and* Acute effects may occur in Threatened and Endangered Species

For a more detailed explanation of the ecological risks posed by the use of 2,4-DB, please refer to the Revised Environmental Fate and Effects Risk Assessment for 2,4-DB dated December 13, 2004. This document is available on the internet at http://www.epa.gov.edockets.

The 2,4-DB risk assessment approach included an evaluation of available surface water and groundwater monitoring data as well as environmental modeling. The approach has relied on model predictions rather than monitoring data for EECs due to the non-targeting nature of the available 2,4-DB monitoring data. Specific uses chosen for modeling include alfalfa (grown in California, Minnesota, North Carolina, Pennsylvania, and Texas), soybeans (grown in Mississippi and Georgia) and peanuts (grown in North Carolina and Georgia). These crops were also chosen to represent a wide geographic area, thus encompassing a variety of environmental conditions. All application rates and ecotoxicity results were adjusted to acid equivalents accounting for molecular weight differences. Risks to aquatic organisms and terrestrial organisms are assessed based on modeled estimated environmental concentrations (EECs).

The Agency has concluded that 2,4-DB presents the greatest potential risks to (1) terrestrial non-target plants through spray-drift and runoff into adjacent areas where these plants are present; (2) small and medium size mammals through direct application to treated fields; (3) small and medium size birds through direct applications to treated fields; and (4) to threatened and endangered freshwater fish through spray drift and runoff from use on alfalfa. These findings are based solely on the Agency's screening level assessment and do not constitute "may affect" findings under the Endangered Species Act.

a. Risk to Birds

i. Toxicity (Hazard) Assessment

Based on the acute toxicity studies submitted for birds, there is a large differential between the acute toxicity when 2,4-DB is administered as a single gavage or when mixed in the feed. This disparity in mortality between the two types of studies suggests that the dietary matrix may reduce the toxicity of 2,4-DB. It is shown that when the chemical is mixed with the diet the test species will be exposed throughout the day despite the fact that nearly all of the chemical will be consumed early during the feeding period.

For 2,4-DB and 2,4-DB-DMAS administered to birds at a test concentration in the diet of 5,000 ppm, no definitive LC_{50} values were determined for the two bird species tested, Bobwhite quail and Mallard duck. This indicates that it would take some undetermined value greater than 5,000 ppm to kill at least 50% of the birds tested. Since no definitive LC_{50} values for subacute dietary toxicity to birds were established, potential acute risks to birds from single and multiple aerial applications were determined based on the oral gavage results of 1536 mg/kg-bw.

Chronic bird studies are generally required when compounds are highly toxic in acute studies, are used repeatedly during a single season, have a long half-life in the soil and in the environment in general, have high residues in sprayed crops and seed, and have the potential to bioaccumulate in prey species. 2,4-DB and 2,4-DB-DMAS do not fulfill all of these criteria, and the Agency has decided to "reserve" chronic avian studies for 2,4-DB and 2,4-DB-DMAS for the following reasons: 2,4-DB and 2,4-DB-DMAS show medium toxicity to birds in acute studies; 2,4-DB and 2,4-DB-DMAS do not have excessively long half-lives in soil or aquatic environments; and, 2,4-DB and 2,4-DB-DMAS are not expected to biaccumulate in prey species.

ii. Exposure and Risk

Acute

Based on the acute oral gavage study using the technical grade material on Bobwhite quail (LD_{50} 1536 mg/kg-bw), acute LOCs were exceeded for small birds (i.e., 20 gram) feeding on short grass, categorizing 2,4-DB as slightly toxic. Effects observed in this study included reduction in body weight and feed consumption along with some depression and wing droopsy of the animals. Subacute dietary toxicity tests were conducted on waterfowl (Mallard duck) and upland game bird (Bobwhite quail). According to the toxicity studies conducted, the technical grade material is categorized as practically non-toxic to birds with non-definitive LC_{50} range of 1000 to >5000. Acute RQs are listed in Table 13.

Even though exceedances for birds trigger Restricted Use Classification for 2,4-DB and 2,4-DM-DMAS, these exceedances were the result of gavage studies which are not representative of exposure to birds in the field. These exceedances would, therefore, be inappropriate to use for regulatory purposes.

Table 13. Acute Avian Risk Quotients (RQs)

Food Type	Weight Class (mg)	Acute RQ
Short Grass	20	0.62
	100	0.28
Tall Grass	20	0.29
	100	0.13
Broadleaf forage, small insects	20	0.25
	100	0.11

RQs in this table were calculated for the maximum labeled application rate of 1.7 lbs a.e./acre twice per year. RQs for other application rates are a linear function of the listed RQs. For example, to calculate the RQ for a rate of 0.85 lb a.e./acre, multiply the listed RQs by ½ (since 0.85 lb a.e./acre is ½ the listed application rate of 1.7 lbs a.e./acre).

b. Risk to Mammals

i. Toxicity (Hazard) Assessment

Toxicity tests indicate 2,4-DB is "slightly toxic" to mammals exposed for short periods. To evaluate the acute risk to mammals, RQs were calculated using the minimum LD_{50} obtained from the acute oral studies (1,470-2,330 mg a.e./kg-bw, 2,4-DB-DMAS) and the maximum labeled rate (1.7 lbs a.e./acre). In contrast, sub-chronic toxic effects were observed in studies using dogs with dietary concentrations of 2,4-DB as low as 8 mg a.e./kg-diet. Effects observed included weight increase of selected organs, decreased body weight, and decreased hematology parameters. Other 2,4-DB mammalian sub-chronic studies had treatment related effects with NOAELs ranging from 30 to 700 mg a.e./kg-diet and LOAELs ranging from 50 to 2000 mg a.e./kg-diet.

Prenatal toxic effects were observed in prenatal developmental toxicity studies using rats and rabbits. Of these studies the lowest maternal NOAEL was 30 mg a.e./kg bw/day based on decreased body weight and food consumption. The lowest developmental NOAEL was 31.25 mg a.e./kg/day, based on litter resorption, decreased fetal weight, and altered growth.

Chronic toxic effects of 2,4-DB and 2,4-DB-DMAS were observed in a 2-generation reproduction study with rats where the NOAEL was determined to be 300 mg a.e./kg-day, for both the parental and reproductive endpoints. The parental NOAEL was based on increased water consumption (females), decreased food consumption, decreased body weight, increased food consumption ratio (females), organ weight changes and microscopic renal findings. The reproductive NOAEL was based on decreased pup weight and gain during lactation. No toxic effects were observed in the offspring, so an offspring NOAEL of 300 mg a.e./kg-diet was determined.

ii. Exposure and Risk

Acute

Predicted residues from the applications of 2,4-DB from all uses do not result in exceedance of the Acute LOC. However, exceedances of the restricted use and threatened and endangered species LOCs for small and medium size mammals do occur for certain food items when using the alfalfa application scenario (1.7 lb a.e./A, 2 times per year with a 30 day application interval).

For small and medium mammals, RQ exceedances which trigger Restricted Use Classification for 2,4-DB and 2,4-DB-DMAS were identified. The Agency has determined that these small exceedances result from a conservative assessment and are not representative of actual exposure. These RQ exceedances would, therefore, be inappropriate to use for regulatory purposes. In addition, exceedances for threatened and endangered species are based solely on the Agency's screening level assessment and do not constitute "may affect" findings under the Endangered Species Act. Therefore, regulatory action does not need to be taken for threatened and endangered mammals. Acute RQs are listed in Table 14.

Table 14. Acute RQs for Mammals Using Maximum and Mean EECs (LD_{50}=1470 mg/kg)

Site/Rate (in lbs a.i./A)	Weight Class	Herbivore/Insectivore Maximum Acute RQs Organized by Food Source			
		Short Grass	Tall Grass	Broadleaf plants/Insects	Fruits/Pods/Large insects
CA Alfalfa/ 1.7 lbs a.i./A 2 times per year 30-day application interval (Maximum EECs)	15	**0.41**	**0.19**	**0.23**	0.03
	35	**0.28**	**0.13**	**0.16**	0.02
	1000	0.06	0.03	0.02	<<0.01
CA Alfalfa/ 1.7 lbs a.i./A 2 times per year 10-day application interval (Mean EECs)	15	**0.14**	0.06	0.08	0.01
	35	**0.10**	0.04	0.05	0.01
	1000	0.02	0.01	0.01	<<0.01
Alfalfa/ 1.7 lbs a.i./A (Maximum EECs)	15	**0.26**	**0.12**	**0.15**	0.02
	35	**0.18**	0.08	**0.10**	0.01
	1000	0.04	0.02	0.02	<<0.01
Alfalfa/ 1.7 lbs a.i./A (Mean EECs)	15	0.09	0.04	0.05	0.01
	35	0.06	0.03	0.03	0.01
	1000	0.01	0.01	0.01	<<0.01
Peanuts/ 0.45 lbs a.i./A 2 times per year 21 day application interval (Maximum EECs)	15	**0.12**	0.05	0.07	0.01
	35	0.08	0.04	0.05	0.01
	1000	0.02	0.01	0.01	<<0.01
Peanuts/ 0.45 lbs a.i./A 2 times per year 21-day application interval (Mean EECs)	15	0.04	0.02	0.02	<<0.01
	35	0.03	0.01	0.02	<<0.01
	1000	0.01	<<0.01	<<0.01	<<0.01
Peanuts/ 0.45 lbs a.i./A (Maximum EECs)	15	0.07	0.03	0.04	<0.01
	35	0.05	0.02	0.03	<<0.01
	1000	0.01	0.01	0.01	<<0.01
Peanuts/ 0.45 lbs a.i./A (Mean EECs)	15	0.02	0.01	0.01	<0.01
	35	0.02	0.01	0.01	<<0.01
	1000	<<0.01	<<0.01	<<0.01	<<0.01
Soybean/ 0.4 lbs a.i./A 2 times per year 21-day application interval (Maximum EECs)	15	0.10	0.05	0.06	0.01
	35	0.07	0.03	0.04	<<0.01
	1000	0.02	0.01	0.01	<<0.01
Soybean/ 0.4 lbs a.i./A 2 times per year 21-day application interval (Mean EECs)	15	0.04	0.02	0.02	<<0.01
	35	0.03	0.01	0.01	<<0.01
	1000	0.01	<<0.01	<<0.01	<<0.01
Soybean/ 0.4 lbs a.i./A (Maximum EECs)	15	0.06	0.03	0.03	<<0.01
	35	0.04	0.02	0.02	<<0.01
	1000	0.01	<<0.01	0.01	<<0.01
Soybean/ 0.4 lbs a.i./A (Mean EECs)	15	0.02	0.01	0.01	<<0.01
	35	0.02	0.01	0.01	<<0.01
	1000	<<0.01	<<0.01	<<0.01	<<0.01

Acute Restricted and Threatened and Endangered Species Use LOC exceedances are in **bold**

Chronic

Chronic mammalian LOCs are exceeded for the maximum residues and two applications of 1.7 lbs a.e./A to alfalfa with a 30-day application interval for small mammals feeding on short grass (RQ = 2.1), tall grass (RQ = 1.0), and broadleaf plants and insects (RQ = 1.2), and, medium-size mammals feeding on short grass (RQ = 1.4). For a single application to alfalfa at the same rate and the maximum residues, the chronic LOC for small mammals feeding on short grass is exceeded (RQ = 1.36). All other scenarios examined resulted in RQs below the Agency's level of concern.

c. Risk to Fish and Aquatic Invertebrates

i. Toxicity (Hazard) Assessment for Freshwater Species

2,4-DB is classified as practically non-toxic to slightly toxic to freshwater fish under acute exposure with definitive LD_{50} values ranging from 2,000 ppb to 18,000 a.e. µg/L. Toxicity studies conducted using 2,4-DB-DMAS demonstrate that it is classified as slightly toxic to freshwater fish under acute exposure with a definitive LD_{50} value of 3,134 a.e. µg/L.

Two freshwater invertebrate toxicity studies were conducted using 2,4-DB. Based on the results of these studies, 2,4-DB is classified as slightly toxic to freshwater invertebrates on an acute basis, with LD_{50} values ranging from 15,000 ppb to 25,000 a.e. µg/L. For toxicity studies conducted using 2,4-DB-DMAS, this herbicide is categorized as slightly toxic to freshwater invertebrates with a definitive LC_{50} value of 2,321 a.e. µg/L.

Chronic early life-stage and life-stage toxicity studies were not conducted for freshwater fish and invertebrates. 2,4-DB and 2,4-DB-DMAS did not meet the Agency's criteria for conducting a chronic risk assessment. Based upon use patterns (one to two applications per year), a low acute toxicity profile, and rapid degradation to 2,4-D, chronic risks to freshwater fish and invertebrates are not likely to occur. In addition, any potential chronic exposures resulting from 2,4-D will be addressed in the 2,4-D RED.

Acute freshwater fish risk assessments using rainbow trout (LC_{50} = 2,000) for aerially applied 2,4-DB resulted in RQs below the Agency's level of concern for each crop scenario with the exception of the Texas Alfalfa scenario. Although this scenario was used in the risk assessment, the Agency feels that it provides a conservative assessment of the potential risks associated with 2,4-DB use on Texas alfalfa. For a complete discussion of the Texas Alfalfa scenario please read the environmental risk characterization section on page 36 of this document. In addition, all acute freshwater invertebrate RQs are below the Agency's level of concern. Table 15 summarizes toxicity endpoints used to assess risks to fish and aquatic invertebrates.

Table 15. Summary of Endpoints for 2,4-DB Acute Aquatic Toxicity Studies

2,4-DB		2,4-DB DMAS	
Organism	**Endpoint**	**Organism**	**Endpoint**
Freshwater Fish			
Rainbow Trout	LC_{50} = 2000 ppb	Rainbow trout	LC_{50} = 3134 ppb
Freshwater Invertebrate			
Stonefly (Pteronarcys sp.)	LC_{50} = 15,000 ppb	No data available	No data available

Full description of ecotoxicity studies available in Appendix C of EFED chapter
Toxicity value was converted to the "acid equivalents"

ii. Toxicity Assessment for Estuarine/Marine Species

2,4-DB did not meet the Agency's criteria for conducting a chronic risk assessment for estuarine and marine species. Based on the use patterns (one to two applications per year), a low acute toxicity profile for freshwater species, and rapid degradation to 2,4-D, chronic risks to marine and estuarine species are not likely to occur.

iii. Exposure and Risk

Aquatic estimated environmental concentrations for the aquatic ecological exposures were estimated using PRZM/EXAMS modeling that uses the standard field pond scenario and a Tier 2 screening model designed to estimate pesticide concentrations found in water at the edge of the field. Although 2,4-DB is classified as practically non-toxic to slightly toxic to freshwater fish, PRZM/EXAM simulations for the Texas alfalfa scenario indicate an exceedance (RQ = 0.09) of the acute threatened and endangered freshwater fish species LOC based on the 1 in 10 year peak EEC. This exceedance is likely caused by the high runoff vulnerability for the Texas alfalfa scenario coupled with the highest use rate for 2,4-DB (1.7 lbs a.e./A). 2,4-DB is expected to move off-site dissolved in runoff waters due to the low soil to water partitioning coefficients. The soil type of the Texas site is a sandy loam that is characterized by its high water table and slow hydraulic conductivity. Furthermore, the USDA runoff vulnerability for the region encompassing Milan County, TX is high. These findings are based solely on EPA's screening level assessment and do not constitute "may affect" findings under the Endangered Species Act. For a further discussion of the Texas Alfalfa scenario please see the environmental risk characterization section on page 36.

The 2,4-DB risk assessment assessed risks to aquatic organisms based on modeled Environmental Concentrations (EECs). The EECs used are presented in Table 16.

Table 16. PRZM /EXAMS Estimated Concentrations of 2,4-DB in Surface Water for Aquatic Exposure

Crop Scenario	Application rate (lb a.e./Acre) for 2 Applications	Interval Between Applications (Days)	Peak Conc. (ppb)	60 Day Conc. (ppb)
CA Alfalfa	1.7 lb a.e./A	30	20.19	17.44
MN Alfalfa	1.7 lb a.e./A	30	37.61	34.66
NC Alfalfa	1.7 lb a.e./A	30	81.12	72.97
PA Alfalfa	1.7 lb a.e./A	30	44.78	40.76
TX Alfalfa	1.7 lb a.e./A	30	182.6	156.9
MS Soybean	0.40 lb a.e./A	21	14.52	12.57
NC Peanut	0.45 lb a.e./A	21	23.36	18.07
GA Soybean	0.40 lb a.e./A	21	16.70	14.57
GA Peanut	0.45 lb a.e./A	21	16.18	14.79

d. Risk to Non-Target Insects

Guideline ecotoxicity tests indicate that 2,4-DB is "practically non-toxic" to honey bees. An acute toxicity study with 2,4-DB acid yielded a 48-hour LD_{50} = 14.5 µg a.e./bee.

e. Risk to Non-Target Terrestrial Plants

To assess risk to non-target terrestrial plants, several representative plant species were exposed to technical formulations of 2,4-DB and 2,4-DB-DMAS. Of the species tested, carrots (dicot) and onions (monocot) were chosen to be used in risk assessment because of their sensitivity to 2,4-DB. In order to assess risks to non-endangered plants, estimated environmental concentrations were compared to concentrations that would kill 25% of the test population (EC_{25}). To assess risks to threatened and endangered plants, estimated environmental conditions were compared to concentrations that would kill 5% of the test population (EC_{05}).

The greatest potential for risks is to terrestrial non-target plants from technical formulations of 2,4-DB from spray drift and runoff to areas adjacent to or near treated fields. Spray drift of 2,4-DB may potentially damage plants through direct contact (demonstrated through vegetative vigor studies) or through runoff and soil deposition during seedling emergence (demonstrated by seedling emergence studies). Runoff of 2,4-DB may potentially cause phytotoxicity to sprouting seeds and seedlings in areas receiving runoff downslope of application areas including wetlands. Potential risks to plants from exposures to the technical formulations outlined in this assessment may underestimate potential risks from the formulated product because formulations often include additives that enhance performance and thus potential for risks.

Potential effects on non-target terrestrial plants are most likely to occur as a result of spray drift from aerial and ground applications. 2,4-DB applied according to label directions as a liquid spray for ground or aerial applications may impact non-target plants for some distance

from the application site depending on droplet size, wind speed, direction, and other factors. Additionally, 2,4-DB product labels do not specify a required or recommended droplet size for spray applications. Based on the screening assessment of drift exposures, potential risks to non-target terrestrial plants from 2,4-DB exposures occur as either drift from ground spray at a distance of 25 ft from the edge of the field, or as an aerial exposure across a swath 175 feet from the edge of the field. This information is based on generalized spray drift modeling that assumes when chemicals are applied by ground equipment, the potential drift area will be 1% of the application rate. For aerial applications, the potential drift area is assumed to be 5% of the application rate.

Acute non-endangered terrestrial plant RQs and acute threatened and endangered species plant RQs are presented in Table 17 and 18.

Table 17. Acute Non -Endangered Terrestrial Plant RQs from 2,4-DB Exposure From Use on Alfalfa, Peanuts, and Soybeans at the Maximum and Average Rates Based on Seedling Emergence EC_{25} of 0.0059 lbs a.e./A for Carrots (dicot) and a Vegetative Vigor EC_{25} of 0.081 lbs a.e./A for Onions (monocot)

	Emergence Adjacent to Treated Sites		Emergence Semi-aquatic Sites		Vegetative Vigor	
Site/Rate in lbs a.e./A	**Ground Unincorporated**	**Aerial**	**Ground Unincorporated**	**Aerial**	**Ground Unincorporated**	**Aerial**
Alfalfa 1.7 lbs a.e./A	8.64	17.86	60.51	48.98	0.21	1.05
Alfalfa 0.55 lbs a.e./A	2.80	5.78	19.58	15.86	0.07	0.34
Peanuts 0.45 lbs a.e./A	2.29	4.73	16.02	12.97	0.06	0.28
Peanuts 0.13 lbs a.e./A	0.66	1.37	4.63	3.75	0.02	0.08
Soybeans 0.4 lbs a.e./A	2.03	4.20	14.24	11.53	0.05	0.25
Soybeans 0.29 lbs a.e./A	1.47	3.05	10.32	8.36	0.04	0.18

f. Risk to Non-Target Aquatic Plants

A study was submitted analyzing the ecotoxicity effects of 2,4-DB-DMAS on green algae. Because a NOAEL was not reported for aquatic plants, an EC_{25} value could not be established. Therefore, the LOAEL value was used for evaluating ecotoxicological effects of 2,4-DB-DMAS and 2,4-DB on this species of algae. The LOEL (lowest observable effect level) value was 0.932 mg a.e./L at which no adverse effects were observed. Using two annual

applications at labeled rates, acute levels of concern were not exceeded for aquatic non-vascular plants using green algae as the representative test species.

g. Food-Chain Effects

2,4-DB is not expected to bioaccumulate because of its ionic nature. Possible food-chain effects could occur as a result of damage to non-target terrestrial plants. Reproduction abnormalities are among the injuries that can occur after exposure to this herbicide. In the case of sterility and non-viable seed production, these cases may initiate a decrease in seed population and persist within the plant populations in subsequent years. Plant material serves as a primary food source for many species of animals. If the available plant material (including seeds) is reduced due to the effects of 2,4-DB, this may have negative effects through the food chain.

h. Risk to Threatened and Endangered Species

The risk assessment for threatened and endangered species indicates that 2,4-DB and 2,4-DB-DMAS exceed the threatened and endangered species LOCs for the use sites listed below.

Levels of concern for Freshwater fish were exceeded using the Texas alfalfa scenario by drift and runoff. These findings are based solely on the Agency's screening level assessment and do not constitute "may affect" findings under the Endangered Species Act.

Threatened and Endangered levels of concern were exceeded for small mammals feeding on short grass when using the soybean (0.40 lbs a.e./A, aerially applied two times per year with a 21-day application interval) and peanut (0.45 lbs a.e./A aerially applied two times per year with a 21-day application interval) application scenarios. These findings are based solely on the Agency's screening level assessment and do not constitute "may affect" findings under the Endangered Species Act.

Additional exceedances occurred for mammals for the following scenarios:

-Small mammals feeding on short grass, tall grass, and broadleaf plants/insects when single or multiple aerial applications are made to alfalfa;

-Medium-size mammals feeding on short grass, tall grass and broadleaf plants/insects when multiple aerial applications are made to alfalfa and short grass, and broadleaf plants/insects when a single application is made on alfalfa; and

-Small (15 grams) and medium (35 grams) mammals when using the alfalfa application scenario (1.7 lbs a.e./A, two times per year with a 30-day application interval).

The Agency has determined that no threatened and endangered mammals weighing less than 1000 grams inhabit alfalfa fields. Therefore, small mammals will not be affected by use of 2,4-DB and 2,4-DB-DMASin alfalfa related application scenarios.

Levels of concern were exceeded for small and medium size birds feeding on short grass, tall grass, and broadleaf plants/insects when multiple aerial applications are made to alfalfa. As discussed previously, it is highly unlikely that 2,4-DB or 2,4-DB-DMAS concentrations would

reach an effect level in the environment. Therefore, the Agency has determined that threatened and endangered birds will not be affected by use of 2,4-DB or 2,4-DB-DMAS.

Levels of concern were exceeded at the highest application rate for plants. Until a species specific assessment for endangered plants is conducted, the mitigation strategy articulated in this document will serve as an interim protection to reduce the likelihood that listed species will be exposed to 2,4-DB and 2,4-DB-DMAS. Additionally, these exceedances are based solely on the Agency's screening level assessment and do not constitute "may affect" findings under the Endangered Species Act.

Table 18. Acute Threatened and Endangered Terrestrial Plant RQs from 2,4-DB Exposure From Use on Alfalfa, Peanuts, and Soybeans at the Maximum and Average Rates Based on Seedling Emergence EC_{05} of 0.00045 lbs a.e./A for Carrots (dicot) and a Vegetative Vigor EC_{05} of 0.012 lbs a.e./A for Onions (monocot)

	Emergence Adjacent to Treated Sites		Emergence Semi-aquatic Sites		Vegetative Vigor	
Site/Rate in lbs a.e./A	**Ground Unincorporated**	**Aerial**	**Ground Unincorporated**	**Aerial**	**Ground Unincorporated**	**Aerial**
Alfalfa 1.7 lbs a.e./A	113.33	234.22	793.33	642.22	1.42	7.08
Alfalfa 0.55 lbs a.e./A	36.67	75.78	256.67	207.78	0.46	2.29
Peanuts 0.45 lbs a.e./A	30.00	62.00	210.00	170.00	0.38	1.88
Peanuts 0.13 lbs a.e./A	8.67	17.91	60.67	49.11	0.11	0.54
Soybeans 0.4 lbs a.e./A	26.67	55.11	186.67	151.11	0.33	1.67
Soybeans 0.29 lbs a.e./A	19.33	39.96	1135.33	109.56	0.24	1.21

i. Risk Characterization

To characterize ecological risks from applications to alfalfa in Texas, the Texas Alfalfa scenario, which was developed from studies in Milan County, TX, was used. This scenario used an application rate of 1.7 lbs a.e./A with two applications per season 30-days apart. The soil type of this area in Texas is a sandy loam that is highly susceptible to runoff. Alfalfa production is generally limited to well-drained soils due to a stand reduction or loss in wet soil conditions. In Texas, alfalfa is generally grown in the western panhandle area, where this type of soil is not common. Risk estimates using this scenario result in risk quotients that exceed the Agency's level of concern for freshwater fish, small and medium-size mammals, small and medium-size birds, and non-target terrestrial plants. This scenario results in a conservative estimate of risk because these findings are based solely on the Agency's screening level assessment and do not constitute "may affect" findings under the Endangered Species Act.

To evaluate acute risks to mammals, both mean and maximum estimated environmental concentrations (EECs) were used. Both the mean and the maximum (upper-bound) values are based on Kenaga degradation models for foliar pesticide residues. The upper-bound residues are based on the 90th percentile values of the maximum residues as observed on foliage. Likewise, the mean values are based on the mean residues observed. The application rate is multiplied by the upper-bound residue for a specific crop at time zero, and then a model is used to calculate the degradation over time to determine the existing residue. Generally the mean residue values are approximately 65% less than the upper bound values and there is roughly an equal decline in the RQs. Both values were used to characterize exceedances. For example, for the California alfalfa scenario, there are exceedances for both maximum and mean residues. This suggests that even a reduction in residue, possibly as a result from a reduction in application rate, RQs are still above the Agency's level of concern.

The greatest risk from 2,4-DB applications is to non-target terrestrial plants. 2,4-DB is a non-selective herbicide that can potentially harm plants that are not intended to come in contact with the chemical. Due to the nature of the chemical it is difficult to completely eliminate risks to plants without reducing the application rate to a level that would not be effective to control target weeds.

j. Ecological Incident Reports

There are presently no reported incidents in the Environmental Incident Information System (EIIS) database. The lack of reported incidents cannot be considered evidence of lack of hazard. Incident reporting is a voluntary process and no attempt has been made to actively investigate if mortality of wildlife and non-target plants is occurring on fields treated with 2,4-DB.

IV. Risk Management, Reregistration, and Tolerance Reassessment Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient 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 2,4-DB and 2,4-DB-DMAS as active ingredients. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all supported products containing 2,4-DB and 2,4-DB-DMAS.

The Agency has completed its assessment of the dietary, occupational, drinking water, and ecological risks associated with the use of pesticide products containing the active ingredients 2,4-DB and 2,4-DB-DMAS. Based on a review of these data and on public comments on the Agency's assessments for the active ingredients 2,4-DB and 2,4-DB-DMAS, the Agency has sufficient information on the human health and ecological effects of 2,4-DB to make decisions as part of the tolerance reassessment process under FFDCA and reregistration process under FIFRA, as amended by FQPA. The Agency has determined that 2,4-DB and 2,4-DB-DMAS containing products are eligible for reregistration provided that: (i) current data gaps and confirmatory data needs are addressed; (ii) the risk mitigation measures outlined in this document are adopted; and (iii) label amendments are made to reflect these measures. Label changes are described in Section V. Appendix A summarizes the uses of 2,4-DB and 2,4-DB-DMAS that are eligible for reregistration. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of 2,4-DB and 2,4-DB-DMAS, and lists the submitted studies that the Agency found acceptable. Data gaps are identified as generic data requirements that have not been satisfied with acceptable data.

Based on its evaluation of 2,4-DB and 2,4-DB-DMAS, the Agency has determined that 2,4-DB and 2,4-DB-DMAS products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA. Accordingly, should a registrant fail to implement any of the risk mitigation measures identified in this document, the Agency may take regulatory action to address the risk concerns from the use of 2,4-DB and 2,4-DB-DMAS. If all changes outlined in this document are incorporated into the product labels, then all current risks for 2,4-DB and 2,4-DB-DMAS will be substantially mitigated for the purposes of this determination.

B. Public Comments and Responses

Through the Agency's public participation process, EPA worked with stakeholders and the public to reach the regulatory decisions for 2,4-DB and 2,4-DB-DMAS. During the public comment period on the risk assessments, which closed on September 30, 2004, the Agency received comments from the California Regional Water Quality Control Board (CWQCB), San Francisco Bay Region. These comments in their entirety are available in the public docket, http://docket.epa.gov/edkpub/index.jsp, (OPP-2004-0220). The submitted letter was sent to the Office of Prevention, Pesticides, and Toxic Substances, divisions within the Office of Pesticide Programs, Office of Water, Office of Wetlands, Oceans, and Watersheds, as well as regional offices. In their comment, the CRWQCB suggested that the Agency perform a cumulative

ecological risk assessment for phenoxy herbicides. At this time the Agency has determined that 2,4-DB and 2,4-DB-DMAS do not have a common mode of action with other phenoxy herbicides and, therefore, a cumulative assessment was not performed. The CRWQCB also commented on the Agency's coordination with the Office of Water to develop water quality criteria in accordance with the Federal Clean Water Act. This comment has already been sent to the Office of Water and the Agency continues to coordinate on these efforts.

A task force consisting of some of the registrants also submitted comments to the Agency during Phase 1, the error only comment period. The Agency's responses to these comments are incorporated into the revised chapters and are available in the public docket.

C. Regulatory Position

1. Food Quality Protection Act Findings

a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with 2,4-DB and 2,4-DB-DMAS. The Agency has concluded that the tolerances for 2,4-DB and 2,4-DB-DMAS (expressed only as tolerances for 2,4-DB) meet the FQPA safety standards and that the risk from dietary (food sources only) exposure is within the "risk cup." An aggregate assessment was conducted for exposures through food and drinking water. A residential assessment was not conducted or included in the aggregate assessment because there are currently no registered residential uses for 2,4-DB or 2,4-DB-DMAS. The Agency has determined that the human health risks from these combined exposures are within acceptable levels. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children, as well as aggregate exposure from food and water.

b. Determination of Safety to U.S. Population

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with 2,4-DB and 2,4-DB-DMAS. The Agency has determined that the established tolerances for 2,4-DB, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, and that there is a reasonable certainty no harm will result to the general population or any subgroup from the use of 2,4-DB and 2,4-DB-DMAS. In reaching this conclusion, the Agency has considered all available information on the toxicity, use practices and exposure scenarios, and the environmental behavior of 2,4-DB and 2,4-DB-DMAS.

Acute risks from drinking water exposures are not of concern. Monitoring and modeling software have been used to estimate ground and surface water concentrations. An acute Drinking Water Level of Concern (DWLOC) was calculated only for females 13-49 years of age because this was the only population subgroup for which an endpoint was selected. The DWLOC calculated to assess the surface water contribution to acute (non-cancer) dietary exposure is 18,000 µg/L. The surface water estimated drinking water concentration (EDWC) (318.68 µg/L) is less than the acute DWLOC, indicating that acute exposure to 2,4-DB in drinking water from surface water sources is below the Agency's level of concern. The groundwater EDWC (0.51 µg/L) is also less than the acute DWLOC, indicating that acute

exposure to 2,4-DB in drinking water from groundwater sources is below the Agency's level of concern. Since the estimates for concentrations in surface water and groundwater are below the calculated acute DWLOC, the Agency concludes with reasonable certainty that exposure from water will not result in an unacceptable acute risk.

An acute aggregate assessment was only conducted for females 13-49 because this population subgroup was the only group for which an endpoint was selected. Since the EDWC is less then the acute DWLOC and acute dietary risk estimates are below 1% of the aPAD, acute aggregate risk is not a concern.

Chronic risks from drinking water exposures are not of concern. The DWLOC calculated to assess the surface water contribution to chronic (non-cancer) dietary exposure is a range from 1050 µg/L (for the U.S. general population) to 290 µg/L (infants <1 year). The surface water EDWC (72.40 µg/L) is less than the chronic DWLOC, indicating that chronic exposure to 2,4-DB in drinking water from surface water sources is below the Agency's level of concern. The groundwater EDWC (0.51 µg/L) is also less than the chronic DWLOC, indicating that chronic exposure to 2,4-DB in drinking water from groundwater sources is below the Agency's level of concern. Since the estimates for concentrations in surface water and groundwater are below the calculated chronic DWLOC, the Agency concludes with reasonable certainty that exposure to 2,4-DB from drinking water will not result in an unacceptable chronic risk.

A chronic aggregate risk assessment was conducted for infants less than one year of age. The chronic dietary exposure for this group, the most highly exposed population subgroup, was less than 2.2% of the cPAD from the DEEM model, and 1.8% of the cPAD from the Lifeline model. Both the surface water and ground water EDWCs for this subgroup are below the Agency's level of concern. Therefore, chronic aggregate risks are not of concern.

c. Determination of Safety to Infants and Children

EPA has determined that the established tolerances for 2,4-DB, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCA, that there is a reasonable certainty of no harm for infants and children. The safety determination for infants and children considers factors of the toxicity, use practices, and environmental behavior noted above for the general population, but also takes into account the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of 2,4-DB residues in this population subgroup.

No Special FQPA Safety Factor is necessary to protect the safety of infants and children. In determining whether or not infants and children are particularly susceptible to toxic effects from 2,4-DB residues, the Agency considered the completeness of the database for developmental and reproductive effects, the nature of the effects observed, and other information. The FQPA Safety Factor has been removed (i.e., reduced to 1X) for 2,4-DB based on: (1) exposure databases are complete for 2,4-DB and 2,4-DB-DMAS and the risk assessment for each potential exposure scenario includes all metabolites and/or degradates of concern and, (2) the risk assessment does not underestimate the potential risk for infants and children.

d. Endocrine Disruptor Effects

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that EPA include evaluations of potential effects in wildlife. For pesticides, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When the appropriate screening and/or testing protocols being considered under the EDSP have been developed, 2,4-DB and 2,4-DB-DMAS may be subject to additional screening and/or testing to better characterize effects related to endocrine disruption.

e. Cumulative Risks

Risks summarized in this document are those that result only from the use of 2,4-DB and 2,4-DB-DMAS. The Food Quality Protection Act (FQPA) requires that 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 reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the substances individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for 2,4-DB and 2,4-DB-DMAS. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

2. Tolerance Summary

Tolerances are currently established for residues of 2,4-DB and its metabolite 2,4-dichlorophenoxyacetic acid (2,4-D) that is also a registered active ingredient. Current tolerance levels are set at 0.2 ppm in or on the following raw agricultural commodities: alfalfa, clover, mint hay, peanut, soybean, soybean hay, and birdsfoot trefoil.

The Agency has concluded that the residue to be regulated in plant and livestock commodities is 2,4-DB *per se*, and that 2,4-D need not be included in the tolerance expression. 2,4-DB parent appears as the major compound in many of the plant and livestock matrices, and the 2,4-D metabolite is present only at low levels. Based on the Agency's decision and available

residue field trial data for 2,4-DB, the tolerance for residues of 2,4-DB in plant commodities should be expressed as follows "residues of 2,4-DB, both free and conjugated, determined as the acid". The reassessed tolerances for plants are as follows: alfalfa, forage (0.70 ppm); alfalfa, hay (2.0 ppm); clover, forage and clover, hay (to be determined due to insufficient data available); peppermint, tops and spearmint, tops (0.20 ppm); soybean, seed (0.50 ppm); soybean, forage (0.70 ppm); soybean, hay (2.0 ppm); peanut (0.05 ppm); trefoil, forage (0.70 ppm) and trefoil, hay (2.0 ppm).

As with plant tolerances, livestock tolerances should be expressed as residues of 2,4-DB, both free and conjugated, determined as the acid. The appropriate tolerance for 2,4-DB is 0.05 ppm (LOQ) in the meat byproducts of cattle, goats, hogs, horses, and sheep. There is no reasonable expectation of the transfer of residues of 2,4-DB from foodstuffs to livestock meat, fat, or milk based on adequate residue data; therefore the current use of 2,4-DB with respect to these commodities should be classified as 40 CFR 180.6(a)(3). Therefore, tolerances for residues of 2,4-DB in milk and in meat and fat of cattle, hogs, horses, and sheep are not required.

Sufficient data are available to determine that residues of 2,4-DB do not significantly concentrate in any peanut, soybean, or mint processed food/feed item; thus tolerances are not required for the processed commodities of these crops.

Adequate tolerance enforcement methods are currently available. 2,4-DB is completely recovered (>80%) by FDA MultiResidue Test Method 402 (PAM Vol I, updated 10/97). The Pesticide Analytical Manual (PAM) Vol. II, lists Method I for the enforcement of tolerances of 2,4-DB residues; this method is the PAM Vol. I method for chlorophenoxy acid residues in food.

2,4-DB Task Force submitted GC/ECD (gas chromatography with electron-capture detection) analytical methods that determine residues of 2,4-DB, 2,4-D, and 2,4-D phenol in several plant and livestock commodities. The methods were found to be adequate for data collection. If the submitted GC/ECD analytical method for plant commodities is proposed as a 2,4-DB tolerance enforcement method, then the method should be modified to include determination of both free and conjugated 2,4-DB and an independent laboratory validation (ILV) should be performed. If the GC/ECD method is proposed as the enforcement method for determining 2,4-DB in livestock commodities, independent laboratory validation of the method also should be performed. Adequate method radiovalidation data have been submitted for livestock commodities.

a. Tolerances Currently Listed Under 40 CFR §180.331 and Tolerance Reassessment

Table 19. Tolerance Reassessment Summary for 2,4-DB

Tolerances Listed Under 40 CFR § 180.331			
Commodity	**Current Tolerance (ppm)**	**Tolerance Reassessment (ppm)**	**Correct Commodity Definition/Comment**
Alfalfa	0.2 (N)	0.7	[*alfalfa, forage*] Residues of 2,4-DB in/on alfalfa forage at 30 and 60 days PHI ranged from non-detectable (<0.05) to 0.49 and non-detectable to 0.14 ppm. Based on the submitted field trials, the current tolerance of 0.2 (N) should be increased to 0.7 ppm.
		2.0	[*alfalfa, hay*] The residues of 2,4-DB in/on alfalfa hay treated at approximately 30 days PHI ranged from non-detectable (<0.05 ppm) to 1.7 ppm. Based on this study the tolerance for alfalfa hay should be increased to 2.0 ppm.
Clover	0.2 (N)	TBD[1]	[*clover, forage*] Data were submitted from four clover (crimson and ladino) field trials conducted in CA (2) and OR (2). Residues were non-detectable (<0.10 ppm) in 4 clover samples harvested 36-43 days following one post-emergent broadcast application of 0.84-1.68 lbs a.e./A 2,4-DB. Additional field trials on clover forage and hay are required at the maximum labeled rate with a 60 day PHI. Ten additional trials are recommended in the following regions: 1, 2, 4, 5 (3 studies), 6, 7, 8, and 9. Alternatively, if a crop group tolerance for Non-Grass Animal Feeds (Crop Group 18) is desired, eight additional trials are recommended in the following regions: 1, 2, 4, 5 (2 studies), 6, 7, and 8.
		TBD[1]	[*clover, hay*] See above comment for clover forage.
Mint, hay	0.2	0.2	[*peppermint, tops*] Residues were non-detectable (<0.01 ppm) in 12 peppermint hay samples harvested 133-212 days following one post-emergent application of 1 lb a.e./A 2,4-DB (1.6X the proposed maximum label rate of 0.64 lb a.e./A. A subsequent review of a SLN request concluded that residues would not exceed the established tolerance of 0.2 ppm in mint hay if a pre-harvest interval of 90 days is observed following early post-emergence application of the dimethylamine salt to mint at rates up to 0.75 lb a.i./A (0.64 lb a.e./A).

		0.2	[*spearmint, tops*] Residues were non-detectable (<0.01 ppm) in 6 spearmint hay samples harvested 133-212 days following one post-emergent application of 1 lb a.e./A 2,4-DB (1.6X the proposed maximum label rate of 0.64 lb a.e./A). A subsequent review of a SLN request concluded that residues would not exceed the established tolerance of 0.2 ppm in mint hay if a pre-harvest interval of 90 days is observed following early post-emergence application of the dimethylamine salt to mint at rates up to 0.75 lb a.i./A (0.64 lb a.e./A).
Peanut	0.2 (N)	0.05	The current tolerance (based on combined residues of 2,4-DB and 2,4-D for peanut nutmeat of 0.2 (N) ppm) can be lowered to 0.05 ppm. Products labeled for use on peanuts need to specify a minimum 60 day PHI.
Soybean	0.2 (N)	0.5	[*soybean, seed*]
Soybean, hay	0.2 (N)	2.0	Since only minimal data were provided for soybean hay at 60-day PHI, the Agency recommends that the tolerance be based on a forage-to-hay dry-down factor. Based on the 0.7 ppm tolerance for forage, %DM values of 35% and 85% for forage and hay, respectively, and a consequent dry-down factor of 2.4X, a tolerance of 2 ppm is appropriate for soybean hay.
Trefoil, birdsfoot	0.2 (N)	0.7	[*trefoil, forage*] The submitted field trial data for alfalfa was translated to trefoil.
		2.0	[*trefoil, hay*] The submitted field trial data for alfalfa was translated to trefoil.

Tolerances To Be Proposed Under 40 CFR § 180.331

Commodity	**Current Tolerance (ppm)**	**Tolerance Reassessment (ppm)**	**Correct Commodity Definition/Comment**
Soybean, forage	None	0.7	Residues in soybean forage following treatments at maximum label rates are unlikely to exceed 0.7 ppm (with a 60-day PGI)
Cattle, meat byproducts	None	0.05	The qualitative nature of residues in ruminants and poultry is adequately understood based on studies in dairy cows and laying hens.
Goat, meat byproducts	None	0.05	
Hog, meat byproducts	None	0.05	
Horse, meat byproducts	None	0.05	
Sheep, meet byproducts	None	0.05	

[1] TBD = To be determined, PGI = Pre-grazing Interval, PHI = Pre-harvesting Interval, N = Negligible

b. Codex Harmonization

Currently there are no Codex MRLs established for 2,4-DB or 2,4-DB-DMAS.

D. Regulatory Rationale

The Agency has determined that 2,4-DB and 2,4-DB-DMAS are eligible for reregistration provided that additional required data confirm this decision and that the risk mitigation measures outlined in this document are adopted, and label amendments are made to reflect these measures.

The following is a summary of the rationale for managing risks associated with the use of 2,4-DB and 2,4-DB-DMAS. Where labeling revisions are warranted, specific language is set forth in the summary tables of Section V of this document.

1. Human Health Risk Management

a. Dietary (Food) Risk Mitigation

For all supported commodities, the acute and chronic dietary exposure estimates are below the Agency's level of concern. Therefore, no risk mitigation measures are required to address exposure to 2,4-DB residues in food.

b. Drinking Water Risk Mitigation

Estimated EDWCs are below the Agency's DWLOC for acute and chronic aggregate risk. Therefore, no risk mitigation measures are required to address 2,4-DB and 2,4-DB-DMAS exposure from drinking water.

c. Residential Risk Mitigation

2,4-DB and 2,4-DB-DMAS do not have any registered residential uses or use patterns that would cause residential exposures.

d. Occupational Risk Mitigation

i. Handler Exposure

Occupational risks from handler and applicator exposures were calculated for short-term inhalation exposures and intermediate-term combined dermal and inhalation exposures. Standard assumptions and PHED unit exposure data were used. The maximum label rates were used for short-term exposures and average rates were used for intermediate-term exposures. All of the MOEs for short-term inhalation exceeded the target MOE of 100 with baseline respiratory protection (i.e. no respirators worn) and were not of concern. Intermediate-term handler exposures are unlikely to occur because 2,4-DB is applied only once or twice per season. All of the intermediate-term MOEs exceeded the target MOE with baseline PPE and chemical resistant gloves for mixer/loaders and baseline PPE for applicators.

Currently, 2,4-DB labels require water-proof gloves instead of chemical resistant gloves. Based on acute toxicity studies, the Agency is requiring that mixers and loaders wear gloves made of chemically resistant material when handling 2,4-DB.

Because the amine salt form of 2,4-DB is a severe eye irritant, protective eyewear should be worn by early re-entry workers and a re-entry interval of 48 hours will be established for 2,4-DB-DMAS products.

In summary, to reduce worker exposure, the Agency has determined that the following label changes for specific scenarios are appropriate and required for reregistration eligibility:

Mixers/Loaders/Applicators/Other Handlers (general): wear baseline (long-sleeve shirt, long pants, shoes, socks, no respirator), plus chemical resistant gloves for mixing, loading, and applying liquid formulations.

Flaggers: wear baseline (long-sleeve shirt, long pants, shoes, socks) for overhead exposure for flagging aerial applications.

ii. Post-Application Risk Mitigation

Post-application exposure to re-entry workers is possible because 2,4-DB can be applied foliarly to the top of most labeled crops. The exposures were assessed using the intermediate-term dermal endpoint, standard assumptions and average label rates. All of the MOEs are above the target MOE of 100 on Day 0. However, because the amine form of 2,4-DB is a Toxicity Category I eye irritant, a 48 hour REI is required to protect re-entry workers.

2. Environmental Risk Management

The Agency has concluded that 2,4-DB and 2,4-DB-DMAS present the greatest potential risks to: (1) terrestrial non-target plants through spray-drift and runoff into adjacent areas where these plants are present; (2) small and medium size mammals through direct application to treated fields; (3) small and medium size birds through direct application to treated fields; and (4) threatened and endangered freshwater fish through spray drift and runoff from use on alfalfa.

The major contributing factor of risk associated with 2,4-DB and 2,4-DB-DMAS is spray drift. To mitigate risk associated with spray drift, the registrant has agreed to include droplet size restrictions on 2,4-DB and 2,4-DB-DMAS labels. Labels must specify medium to coarse droplet size or a volume mean diameter of 300 microns or greater for spinning atomizer nozzles and prohibit fine sprays. Additionally, for aerial applications, the boom length must not exceed 75% of the wingspan or 90% of the rotor blade diameter to reduce spray drift.

3. Other Labeling Requirements

In order to be eligible for reregistration, various use and safety information will be included in the labeling of all end-use products containing 2,4-DB. For the specific labeling statements and a list of outstanding data, refer to Section V of this RED document.

4. Threatened and Endangered Species Considerations

a. The Endangered Species Program

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on threatened and endangered and threatened species, and to implement mitigation measures that address these impacts. The Endangered Species Act requires federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. To analyze the potential of registered pesticide uses that may affect any particular species, EPA uses basic toxicity and exposure data developed for the REDs and then considers ecological parameters, pesticide use information, geographic relationship between specific pesticide uses and species locations, and biological requirements and behavioral aspects of the particular species. This analysis will also consider the risk mitigation measures that are being implemented as a result of this RED.

A determination that there is a likelihood of potential impact to a listed species may result in limitations on use of the pesticide, other measures to mitigate any potential impact, or consultations with the Fish and Wildlife Service and/or the National Marine Fisheries Service as necessary.

b. General Risk Mitigation

2,4-DB end use products (EPs) may also contain other registered pesticides. Although the Agency is not proposing any mitigation measures for products containing 2,4-DB or 2,4-DB-DMAS specific to federally listed threatened and endangered species, the Agency needs to address potential risks from other end-use products. Therefore, the Agency requires that users adopt all threatened and endangered species risk mitigation measures for all active ingredients in the product. If a product contains multiple active ingredients with conflicting threatened and endangered species risk mitigation measures, the more stringent measure(s) should be adopted.

V. What Registrants Need to Do

The Agency has determined that 2,4-DB is eligible for reregistration provided that: (i) additional data that the Agency intends to require confirm this decision; and (ii) the risk mitigation measures outlined in this document are adopted, and (iii) label amendments are made to reflect these measures. To implement the risk mitigation measures, the registrants must amend their product labeling to incorporate the label statements set forth in the Label Changes Summary Table in Section B below (Table 23). The additional data requirements that the Agency intends to obtain will include, among other things, submission of the following:

For 2,4-DB technical grade active ingredient products, the registrant needs to submit the following items:

Within 90 days from receipt of the generic data call in (DCI):

1. completed response forms to the generic DCI (i.e., DCI response form and requirements status and registrant's response form); and

2. submit any time extension and/or waiver requests with a full written justification.

Within the time limit specified in the generic DCI:

1. cite any existing generic data which address data requirements or submit new generic data responding to the DCI.

Please contact Mika J. Hunter at (703) 308-0041 with questions regarding generic reregistration.

By US mail:
Document Processing Desk (DCI/SRRD)
Mika J. Hunter
US EPA (7508C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk (DCI/SRRD)
Mika J. Hunter
Office of Pesticide Programs (7508C)
Room 266A, Crystal Mall 2
1801 S. Bell Street
Arlington, VA 22202

For end use products containing the active ingredient 2,4-DB, the registrant needs to submit the following items for each product.

Within 90 days from the receipt of the product-specific data call-in (PDCI):

1. completed response forms to the PDCI (i.e., PDCI response form and requirements status and registrant's response form); and

2. submit any time extension or waiver requests with a full written justification.

Within eight months from the receipt of the PDCI:

1. two copies of the confidential statement of formula (EPA Form 8570-4);

2. a completed original application for reregistration (EPA Form 8570-1). Indicate on the form that it is an "application for reregistration";

3. five copies of the draft label incorporating all label amendments outlined in Table 23 of this document;

4. a completed form certifying compliance with data compensation requirements (EPA Form 8570-34); and

5. if applicable, a completed form certifying compliance with cost share offer requirements (EPA Form 8570-32); and

6. the product-specific data responding to the PDCI.

Please contact Venus Eagle at (703) 308-8045 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed as follows:

By US mail:
Document Processing Desk (PDCI/PRB)
Venus Eagle
US EPA (7508C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk (PDCI/PRB)
Venus Eagle
Office of Pesticide Programs (7508C)
Room 266A, Crystal Mall 2
1801 South Bell Street
Arlington, VA 22202

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic database supporting the reregistration of 2,4-DB has been reviewed and determined to be substantially complete. However, the following additional data requirements have been identified by the Agency as confirmatory and included in the generic DCI for this RED. Additionally, responses to outstanding data requirements (as required in a previous DCI) regarding spray drift and droplet size spectrum (guideline 201-1) are currently outstanding.

Table 20. Confirmatory Data Requirements for Reregistration

Guideline Study Name	New OPPTS Guideline No.	Old Guideline No.
Seedling Emergence: The Agency is requesting the entire seedling emergence and vegetative vigor toxicity studies be conducted using the TEP, in accordance with current policy. Toxicity tests conducted with the TEP would allow for the development of a more appropriate description of the actual risk to non-target terrestrial plants.	850.4100, 850.4150	122-1A, 122-1B
Estuarine/Marine Fish Acute Toxicity test using 2,4-DB or 2,4-DB-DMAS.	850.1075	72-3 A
Acute Estuarine/Marine Invertebrate test using 2,4-DB or 2,4-DB-DMAS	850.1025	72-3 B

2. Labeling for Technical and Manufacturing Use Products

To ensure compliance with FIFRA, technical and manufacturing use product (MP) labeling should be revised to comply with all current EPA regulations, PR Notices and applicable policies. The Technical and MP labeling should bear the labeling contained in Table 22 , Label Changes Summary Table.

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. The Registrant 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 the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

A product-specific data call-in, outlining specific data requirements, accompanies this RED.

2. Labeling for End-Use Products

Labeling changes are necessary to implement measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 21.

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 document. Persons other than the registrant may generally distribute or sell such products for 52 months from the approval of labels reflecting the mitigation described in 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.

a. Label Changes Summary Table

In order to be eligible for reregistration, amend all product labels to incorporate the risk mitigation measures outlined in Section IV. The following table describes how language on the labels should be amended.

Table 21. Labeling Changes Summary Table

Summary of Labeling Changes for 2,4-DB and 2,4-DB-DMAS		
Description	Amended Labeling Language	Placement on Label
For all Manufacturing Use Products	"Only for formulation into an herbicide for the following use(s) [fill blank only with those uses that are being supported by MP registrant]."	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formu lator or user group	"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)." "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)."	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	Precautionary Statements

End Use Products Intended for Occupational Use		
PPE Requirements Established by the RED[1] for Liquid Formulations	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are (*registrant inserts correct chemical-resistant material*). If you want more options, follow the instructions for category *[registrant inserts A,B,C,D,E,F,G, or H*] on an EPA chemical-resistance category selection chart." "All mixers, loaders, applicators and other handlers must wear : -long-sleeved shirt and long pants, - shoes and socks, plus -chemical-resistant gloves and chemical-resistant apron when mixing/loading, cleaning up spills, cleaning equipment, or otherwise exposed to concentrate." See Engineering Controls for additional requirements."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
Engineering Controls	"Pilots must use an enclosed cockpit in a manner that is consistent with the WPS for Agricultural Pesticides [40 CFR 170.240(d)(6)]. Pilots must wear the PPE required on this labeling for applicators."	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements)
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately fro m other laundry."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements

User Safety Recommendations	"User Safety Recommendations Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing/PPE 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."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)
Environmental Hazards	"This chemical is toxic to fish. Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring issues. Do not contaminate water when disposing of equipment washwaters. Do not contaminate water intended for irrigation or domestic purposes. Do not apply when weather conditions favor drift from target area." "Groundwater Contamination: Most cases of groundwater contamination involving phenoxy herbicides such as 2,4-DB have been associated with mixing/loading and disposal sites. Caution should be exercised when handling 2,4-DB pesticides at such sites to prevent contamination of groundwater supplies. Use of closed systems for mixing or transferring this pesticide will reduce the probability of spills. Placement of the mixing/loading equipment on an impervious pad to contain spill will help prevent groundwater contamination." "This chemical has properties and characteristics associated with chemicals detected in groundwater. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination. Application around a cistern or well may result in contamination of drinking water or groundwater."	Precautionary Statements immediately following the User Safety Recommendations
Restricted-Entry Interval (For 2,4-DB formulations)	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours."	Directions for Use, Under Agricultural Use Requirements Box
Restricted-Entry Interval (For 2,4-DB-DMAS formulations)	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 48 hours."	Directions for Use, Under Agricultural Use Requirements Box

Early Entry Personal Protective Equipment established by the RED. (For 2,4-DB formulations)	For early entry PPE use the following: "PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is: * coveralls, * shoes plus socks * chemical-resistant gloves made of any waterproof material."	Direction for Use Agricultural Use Requirements box
Early Entry Personal Protective Equipment established by the RED. (For 2,4-DB-DMAS formulations)	For early entry PPE use the following: "PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is: * coveralls, * shoes plus socks * chemical-resistant gloves made of any waterproof material * protective eyewear."	Direction for Use Agricultural Use Requirements box
General 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."	Place in the Direction for Use directly above the Agricultural Use Box.
Other Application Restrictions (Risk Mitigation)	"Do not apply this product through any type of irrigation system." "Do not use in or near greenhouse." "Do not feed/graze soybean forage or harvest hay for 60 days following any 2,4-DB application."	Directions for Use
Spray Drift	"SPRAY DRIFT MANAGEMENT" "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." "Apply only as a medium or coarser spray (ASAE standard 572) or a volume mean diameter of	Directions for Use

	300 microns or greater for spinning atomizer nozzles." "Apply only when the wind speed is 2-10 mph at the application site." *Additional requirements for aerial applications:* "The boom length must not exceed 75% of the wingspan or 90% or the rotor blade diameter." "Release spray at the lowest height consistent with efficacy and flight safety. Do not release spray at a height greater than 10 feet above the crop canopy." "When applications are made with a crosswind, the swath will be displaced downwind. The applicator must compensate for this displacement at the downwind edge of the application area by adjusting the path of the aircraft upwind." "Do not make applications into temperature inversions." *Additional requirements for ground boom application:* "Do not apply with a nozzle height greater than 4 feet above the crop canopy."	

[1] PPE that is established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.
[2] If the product contains oil or bears instructions that will allow application with an oil-containing material, the "N" designation must be dropped.

VI. APPENDICES

Appendix A. Table of Use Patterns for 2,4-DB

2,4-DB Acid

Site Application Timing	Formulation [EPA Reg. No.]	App. Type App. Equip-ment	Max. Single App. Rate (ai)	Max. Numb. App. Per Season/Crop Cycle	Max. Number App. Per Year	Max. Seasonal Rate (ai)	(PHI) (PGI) Pre-feeding Interval	Use Directions and Limitations
Alfalfa								
Foliar	75% EC [74530-15] [71368-49]	Spray Ground Low Volume Spray (Concentrate) Aerial	1.5 lbs ai/A	NS	NS	NS	30 day PGI 30 day Pre-feeding Interval.	Groundwater restriction. Do not apply through any type of irrigation system. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply when drift is likely to occur. Do not contaminate water by cleaning of equipment or disposal of equipment washwaters. Do not contaminate water, food, or feed by storage or disposal. Do not contaminate water intended for irrigation or domestic purposes.

Site Application Timing	Formulation [EPA Reg. No.]	App. Type App. Equip-ment	Max. Single App. Rate (ai)	Max. Numb. App. Per Season/Crop Cycle	Max. Number App. Per Year	Max. Seasonal Rate (ai)	(PHI) (PGI) Pre-feeding Interval	Use Directions and Limitations
Peanuts								
Post-emergence	75% EC [74530-15] [71368-49]	Low Volume Spray (Concentrate) Aircraft Spray Boom-sprayer	0.375 lbs ai/A	2	NS	NS	30 day PHI	See “alfalfa”. Do not feed treated hay or vines to livestock.
Soybeans								

Site Application Timing	Formulation [EPA Reg. No.]	App. Type App. Equip-ment	Max. Single App. Rate (ai)	Max. Numb. App. Per Season/Crop Cycle	Max. Number App. Per Year	Max. Seasonal Rate (ai)	(PHI) (PGI) Pre-feeding Interval	Use Directions and Limitations
Foliar	75% EC [74530-15] [71368-49]	Directed Spray Sprayer	0.375 lbs ai/A	1	NS	NS	60 day PHI	Groundwater restriction. Do not apply through any type of irrigation system. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply when drift is likely to occur. Do not apply to sandy soils. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Do not contaminate water, food, or feed by storage or disposal. Do not contaminate water intended for irrigation or domestic purposes. Do not feed treated forage or hay to livestock.
Pre-bloom through mid-bloom	75% EC [74530-15] [71368-49]	Low Volume Spray (concentrate) Aircraft Broadcast Boom-sprayer	0.2184 lbs ai/A	1	NS	NS	60 day PHI	Groundwater restriction. Do not apply through any type of irrigation system. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply when

Site Application Timing	Formulation [EPA Reg. No.]	App. Type App. Equip-ment	Max. Single App. Rate (ai)	Max. Numb. App. Per Season/Crop Cycle	Max. Number App. Per Year	Max. Seasonal Rate (ai)	(PHI) (PGI) Pre-feeding Interval	Use Directions and Limitations
Pre-bloom through mid-bloom	75% EC [74530-15] [71368-49]	Directed Spray Sprayer	0.375 lbs ai/A	1	NS	NS	60 day PHI	drift is likely to occur. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Do not contaminate water, food, or feed by storage or disposal. Do not contaminate water intended for irrigation or domestic purposes.

2,4-DB-DMA Salt (Acid Equivalents)

Site Application Timing	Formulation [EPA Reg. No.]	App. Type App. Equip-ment	Max. Single App. Rate (ae)	Max. Number App. Per Season/ Crop Cycle	Max. Number of App. Per Year	Max. Seasonal Rate (ae)	(PHI) (PGI) Pre-feeding Interval	Use Diretions and Limitations
Agricultural Fallow/Idle land								
Post-emergence	25.9% EC [51036-232]	Spray Aircraft, Boom Sprayer	1.5 lbs ae/A	NS	NS	NS	NS	Groundwater restriction. Do not apply through any type of irrigation system. Conservation Reserve Acres. For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. This product is toxic to fish. Do not graze treated areas or harvest for forage or hay.

Site Application Timing	Formulation [EPA Reg. No.]	App. Type App. Equip-ment	Max. Single App. Rate (ae)	Max. Number App. Per Season/ Crop Cycle	Max. Number of App. Per Year	Max. Seasonal Rate (ae)	(PHI) (PGI) Pre-feeding Interval	Use Diretions and Limitations
Post-emergence	25.9% SC/L [42570-38]	Spray Aircraft, Boom Sprayer	1.5 lbs ae/A	NS	NS	NS	NS	Groundwater restriction. Do not apply through any type of irrigation system. Conservation Reserve Acres. 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 by cleaning of equipment or disposal of equipment wash waters. This product is toxic to fish. Do not contaminate water, food, or feed by storage or disposal. Do not graze or harvest cover crops.

Site Application Timing	Formulation [EPA Reg. No.]	App. Type App. Equip-ment	Max. Single App. Rate (ae)	Max. Number App. Per Season/ Crop Cycle	Max. Number of App. Per Year	Max. Seasonal Rate (ae)	(PHI) (PGI) Pre-feeding Interval	Use Diretions and Limitations
Alfalfa								
Early Winter	23% SC/L [71368-48]	Spray Fixed-wing aircraft, Ground	1.422 lbs ae/A	NS	NS	NS	30-60 day PGI. 30-60 day Pre-feeding interval.	Groundwater restriction. Do not apply through any type of irrigation system. 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. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Do not contaminate water, food, or feed by storage or disposal.
Late Fall	23% SC/L [71368-48]	Spray Fixed-wind aircraft, Ground	1.422 lb ae/A	NS	NS	NS	30-60 day PGI. 30-60 day Pre-feeding interval.	See “early winter” alfalfa limitations.

Site Application Timing	Formulation [EPA Reg. No.]	App. Type App. Equip-ment	Max. Single App. Rate (ae)	Max. Number App. Per Season/ Crop Cycle	Max. Number of App. Per Year	Max. Seasonal Rate (ae)	(PHI) (PGI) Pre-feeding Interval	Use Diretions and Limitations
Post-emergence	23% SC/L [71368-48]	Spray Aircraft, Ground	1.422 lbs ae/A	NS	NS	NS	30-60 day PGI. 30-60 day Pre-feeding interval.	See "early winter" alfalfa limitations.
	25.9% EC [51036-232]	Spray Aircraft, Boom-sprayer	1.5 lbs ae/A	NS	NS	NS	30-60 day PGI. 30-60 day Pre-feeding interval.	Groundwater restriction. Do not apply through any type of irrigation system. For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. This product is toxic to fish.

Site Application Timing	Formulation [EPA Reg. No.]	App. Type App. Equip-ment	Max. Single App. Rate (ae)	Max. Number App. Per Season/ Crop Cycle	Max. Number of App. Per Year	Max. Seasonal Rate (ae)	(PHI) (PGI) Pre-feeding Interval	Use Diretions and Limitations
Post-emergence	25.9% SC/L [42750-38] [2749-516]	Spray Boom-sprayer, Aircraft	1.5 lbs ae/A	NS	NS	NS	30-60 day PGI. 30-60 day Pre-feeding interval.	See "early winter" alfalfa limitations. This product is toxic to fish.
		Spray Aircraft, Ground						
Post-emergence	26.2% EC [71368-46]	Spray Aircraft, Ground	1.5 lbs ae/A	NS	NS	NS	30-60 day PGI 30-60 day PHI	See "early winter" alfalfa limitations.

Site Application Timing	Formulation [EPA Reg. No.]	App. Type App. Equip-ment	Max. Single App. Rate (ae)	Max. Number App. Per Season/ Crop Cycle	Max. Number of App. Per Year	Max. Seasonal Rate (ae)	(PHI) (PGI) Pre-feeding Interval	Use Diretions and Limitations
	26.85% EC [15440-32]	Spray Ground, Aircraft	1.5 lbs ae/A	NS	NS	NS	30-60 day PGI. 30-60 day Pre-feeding interval.	Groundwater restriction. Do not apply through any type of irrigation system. 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 by cleaning of equipment or disposal of equipment wash waters. This product is toxic to fish. Do not contaminate water, food, or feed by storage or disposal.

Site Application Timing	Formulation [EPA Reg. No.]	App. Type App. Equip-ment	Max. Single App. Rate (ae)	Max. Number App. Per Season/ Crop Cycle	Max. Number of App. Per Year	Max. Seasonal Rate (ae)	(PHI) (PGI) Pre-feeding Interval	Use Diretions and Limitations
Post-emergence	26.85% EC [15440-34]	Spray Aircraft, Ground	1.7 lbs ae/A	NS	NS	NS	30-60 day PGI. 30-60 day Pre-feeding interval.	Groundwater restriction. Do not apply through any type of irrigation system. 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 by cleaning of equipment or disposal of equipment wash waters. This product is toxic to fish. Do not contaminate water, food, or feed by storage or disposal.
Clover								

Site Application Timing	Formulation [EPA Reg. No.]	App. Type App. Equip-ment	Max. Single App. Rate (ae)	Max. Number App. Per Season/ Crop Cycle	Max. Number of App. Per Year	Max. Seasonal Rate (ae)	(PHI) (PGI) Pre-feeding Interval	Use Diretions and Limitations
Post-emergence	25.9% EC [51036-232]	Spray Aircraft, Boom-sprayer	1.5 lbs ae/A	NS	NS	NS	60-day PGI 60-day Pre-feeding Interval	Groundwater restriction. Do not apply through any type of irrigation system. For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. This product is toxic to fish.

Site Application Timing	Formulation [EPA Reg. No.]	App. Type App. Equip-ment	Max. Single App. Rate (ae)	Max. Number App. Per Season/ Crop Cycle	Max. Number of App. Per Year	Max. Seasonal Rate (ae)	(PHI) (PGI) Pre-feeding Interval	Use Diretions and Limitations
Post-emergence	25.9% SC/L [42750-38]	Spray Aircraft, Boom-sprayer	1.5 lbs ae/A	NS	NS	NS	60-day PGI 60-day Pre-feeding Interval	Groundwater restriction. Do not apply through any type of irrigation system. 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 by cleaning of equipment or disposal of equipment wash waters. This product is toxic to fish. Do not contaminate water, food, or feed by storage or disposal.
Peanuts								

Site Application Timing	Formulation [EPA Reg. No.]	App. Type App. Equip-ment	Max. Single App. Rate (ae)	Max. Number App. Per Season/ Crop Cycle	Max. Number of App. Per Year	Max. Seasonal Rate (ae)	(PHI) (PGI) Pre-feeding Interval	Use Diretions and Limitations
Post-plant	23% FlC [51036-00231]	Broadcast Aircraft, Boom-sprayer	0.3938 lbs ae/A	NS	2	NS	30-45 day PHI	Groundwater restriction. Do not apply through any type of irrigation system. For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. This product is toxic to fish. Do not contaminate water, food, or feed by storage or disposal. Do not feed hay or vines to livestock.
		Spray Aircraft, Boom-sprayer	0.2406 lbs ae/A	NS	2	NS	45 day PHI	

Site Application Timing	Formulation [EPA Reg. No.]	App. Type App. Equip-ment	Max. Single App. Rate (ae)	Max. Number App. Per Season/ Crop Cycle	Max. Number of App. Per Year	Max. Seasonal Rate (ae)	(PHI) (PGI) Pre-feeding Interval	Use Diretions and Limitations
Post-plant	23% SC/L [42750-39]	Spray Boom-sprayer, Aircraft	0.2406 lbs ae/A	NS	2	NS	45 day PHI	Groundwater restriction. Do not apply through any type of irrigation system. For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or to disposal or equipment wash waters. This product is toxic to fish. Do not contaminate water, food, or feed by storage or disposal. Do not feed treated hay or vines to livestock. 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.

Site Application Timing	Formulation [EPA Reg. No.]	App. Type App. Equip-ment	Max. Single App. Rate (ae)	Max. Number App. Per Season/ Crop Cycle	Max. Number of App. Per Year	Max. Seasonal Rate (ae)	(PHI) (PGI) Pre-feeding Interval	Use Diretions and Limitations
Post-plant	23% SC/L [42750-39]	Broadcast Aircraft, Boom-sprayer	0.3938 lbs ae/A	NS	2	NS	30-45 day PHI	Groundwater restriction. Do not apply through any type of irrigation system. For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or to disposal or equipment wash waters. This product is toxic to fish. Do not contaminate water, food, or feed by storage or disposal. Do not feed treated hay or vines to livestock. 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.
	23% SC/L [2749-126]	Broadcast Aircraft, Ground	0.2406 lb ae/A	NS	2	NS	45 day PHI	
		Spray Aircraft, Ground	0.3938 lbs ae/A	NS	2	NS	30 day PHI	

Site Application Timing	Formulation [EPA Reg. No.]	App. Type App. Equip-ment	Max. Single App. Rate (ae)	Max. Number App. Per Season/ Crop Cycle	Max. Number of App. Per Year	Max. Seasonal Rate (ae)	(PHI) (PGI) Pre-feeding Interval	Use Diretions and Limitations
Post-plant	25.9% EC [51036-232]	Spray Aircraft, Boom-sprayer	0.25 lbs ae/A	NS	2	NS	30-45 day PHI	Groundwater restriction. Do not apply through any type of irrigation system. For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. This product is toxic to fish. Do not feed hay or vines to livestock.
		Broadcast Aircraft, Boom-sprayer	0.4 lbs ae/A	NS	2	NS	30-45 day PHI	

Site Application Timing	Formulation [EPA Reg. No.]	App. Type App. Equip-ment	Max. Single App. Rate (ae)	Max. Number App. Per Season/ Crop Cycle	Max. Number of App. Per Year	Max. Seasonal Rate (ae)	(PHI) (PGI) Pre-feeding Interval	Use Diretions and Limitations
	25.9% SC/L [42750-38]	Spray Aircraft Broadcast Aircraft, Boom-sprayer	0.4 lbs ae/A	NS	2	NS	30 -45 day PHI	Groundwater restriction. Do not apply through any type of irrigation system. 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 by cleaning of equipment or disposal of equipment wash waters. This product is toxic to fish. Do not contaminate water, food, or feed by storage or disposal. Do not feed treated hay or vines to livestock.
		Spray Boom-sprayer	0.25 lbs ae/A	NS	2	NS	45 day PHI	

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	26.85% EC [15440-34]	Spray Aircraft, Ground	0.275 lbs ae/A	NS	2	NS	45 day PHI	Groundwater restriction. Do not apply through any type of irrigation system. 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 by cleaning of equipment or disposal of equipment wash waters. This product is toxic to fish. Do not contaminate water, food, or feed by storage or disposal. Do not feed treated hay or vines to livestock.
		Broadcast Aircraft, Ground	0.45 lbs/A	NS	2	NS	30-45 day PHI	

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	26.85% EC [15440-32]	Broadcast Aircraft, Ground	0.4 lbs ae/A	NS	3	NS	30-45 day PHI	Groundwater restriction. Do not apply through any type of irrigation system. 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 by cleaning of equipment or disposal of equipment wash waters. This product is toxic to fish. Do not contaminate water, food, or feed by storage or disposal. Do not feed treated hay or vines to livestock.
		Spray Aircraft, Ground	0.25 lbs ae/A	NS	2	NS	45 day PHI	

Site Application Timing	Formulation [EPA Reg. No.]	App. Type App. Equip-ment	Max. Single App. Rate (ae)	Max. Number App. Per Season/ Crop Cycle	Max. Number of App. Per Year	Max. Seasonal Rate (ae)	(PHI) (PGI) Pre-feeding Interval	Use Diretions and Limitations
Ground-crack	25.9% EC [51036-232]	Spray Aircraft, Boom-sprayer	0.25 lbs ae/A	NS	2	NS		Groundwater restriction. Do not apply through any type of irrigation system. For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. This product is toxic to fish. Do not feed hay or vines to livestock.

Site Application Timing	Formulation [EPA Reg. No.]	App. Type App. Equip-ment	Max. Single App. Rate (ae)	Max. Number App. Per Season/ Crop Cycle	Max. Number of App. Per Year	Max. Seasonal Rate (ae)	(PHI) (PGI) Pre-feeding Interval	Use Diretions and Limitations
	25.9% SC/L [42750-38]	Spray Aircraft, Boom-sprayer	0.25 lbs ae/A	NS	2	NS		Groundwater restriction. Do not apply through any type of irrigation system. 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 by cleaning of equipment or disposal of equipment wash waters. This product is toxic to fish. Do not contaminate water, food, or feed by storage or disposal. Do not feed treated hay or vines to livestock.

Site Application Timing	Formulation [EPA Reg. No.]	App. Type App. Equip-ment	Max. Single App. Rate (ae)	Max. Number App. Per Season/ Crop Cycle	Max. Number of App. Per Year	Max. Seasonal Rate (ae)	(PHI) (PGI) Pre-feeding Interval	Use Diretions and Limitations
Post-emergence	23% SC/L [71368-47] [71368-48]	Spray Aircraft, Fixed-wing aircraft, Boom-sprayer	0.3828 lb/A	NS	2	NS	30 day PHI	Groundwater restriction. Do not apply through any type of irrigation system. 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 by cleaning of equipment or disposal of equipment wash waters. Do not contaminate water, food, or feed by storage or disposal. Do not contaminate water. Do not feed treated hay or vines to livestock.

Site Application Timing	Formulation [EPA Reg. No.]	App. Type App. Equip-ment	Max. Single App. Rate (ae)	Max. Number App. Per Season/ Crop Cycle	Max. Number of App. Per Year	Max. Seasonal Rate (ae)	(PHI) (PGI) Pre-feeding Interval	Use Diretions and Limitations
	25.9% EC [51036-232]	Broadcast Aircraft, Boom-sprayer Spray Aircraft, Boom-sprayer	0.25 lbs ae/A	NS	NS	NS	30-45 day PHI	Groundwater restriction. Do not apply through any type of irrigation system. For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. This product is toxic to fish. Do not feed hay or vines to livestock.

Site Application Timing	Formulation [EPA Reg. No.]	App. Type App. Equip-ment	Max. Single App. Rate (ae)	Max. Number App. Per Season/ Crop Cycle	Max. Number of App. Per Year	Max. Seasonal Rate (ae)	(PHI) (PGI) Pre-feeding Interval	Use Diretions and Limitations
	25.9% SC/L [2749-516]	Broadcast Aircraft, Boom-sprayer	0.4 lbs ae/A	NS	2	NS	30 day PHI	Groundwater restriction. Do not apply through any type of irrigation system. 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 by cleaning of equipment or disposal of equipment wash waters. This product is toxic to fish. Do not contaminate water, food, or feed by storage or disposal. Do not feed treated hay or vines to livestock. Do not contaminate water.
	25.9% SC/L [42750-38]	Spray Aircraft, Boom-sprayer	0.4 lbs ae/A	NS	2	NS	30-45 day PHI	

Site Application Timing	Formulation [EPA Reg. No.]	App. Type App. Equip-ment	Max. Single App. Rate (ae)	Max. Number App. Per Season/ Crop Cycle	Max. Number of App. Per Year	Max. Seasonal Rate (ae)	(PHI) (PGI) Pre-feeding Interval	Use Diretions and Limitations
	26.2% EC [71368-46]	Broadcast Aircraft, Boom-sprayer	0.4 lbs ae/A	NS	2	NS	30 day PHI	Groundwater restriction. Do not apply through any type of irrigation system. 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. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Do not contaminate water, food, or feed by storage or disposal. Do not feed treated hay or vines to livestock.

Site Application Timing	Formulation [EPA Reg. No.]	App. Type App. Equip-ment	Max. Single App. Rate (ae)	Max. Number App. Per Season/ Crop Cycle	Max. Number of App. Per Year	Max. Seasonal Rate (ae)	(PHI) (PGI) Pre-feeding Interval	Use Diretions and Limitations
Peppermint								
Early post-emergence	26.2% SC/L [ID94001000]	Spray Sprayer	0.75 lbs ae/A	NS	NS	NS	90 day PHI	Groundwater restriction. Do not apply through any type of irrigation system. 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. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Do not contaminate water, food, or feed by storage or disposal.
Soybeans								

Site Application Timing	Formulation [EPA Reg. No.]	App. Type App. Equip-ment	Max. Single App. Rate (ae)	Max. Number App. Per Season/ Crop Cycle	Max. Number of App. Per Year	Max. Seasonal Rate (ae)	(PHI) (PGI) Pre-feeding Interval	Use Diretions and Limitations
Pre-emergence	23% FlC [51036-231]	Spray Aircraft, Boom-sprayer	0.2188	NS	NS	NS	60 day PGI 60 day PHI 60 day Pre-feeding Interval	Groundwater restriction. Do not apply through any type of irrigation system. For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. This product is toxic to fish. Do not contaminate water, food, or feed by storage or disposal.

Site Application Timing	Formulation [EPA Reg. No.]	App. Type App. Equip-ment	Max. Single App. Rate (ae)	Max. Number App. Per Season/ Crop Cycle	Max. Number of App. Per Year	Max. Seasonal Rate (ae)	(PHI) (PGI) Pre-feeding Interval	Use Diretions and Limitations
Pre-emergence	23% SC/L [42750-39]	Spray Aircraft, Boom-sprayer	0.2188	NS	NS	NS	60 day PGI 60 day PHI 60 day Pre-feeding Interval	Groundwater restriction. Do not apply through any type of irrigation system. For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. This product is toxic to fish. Do not contaminate water, food, or feed by storage or disposal.

Site Application Timing	Formulation [EPA Reg. No.]	App. Type App. Equip-ment	Max. Single App. Rate (ae)	Max. Number App. Per Season/ Crop Cycle	Max. Number of App. Per Year	Max. Seasonal Rate (ae)	(PHI) (PGI) Pre-feeding Interval	Use Diretions and Limitations
Pre-emergence	25.9% EC [51036-232]	Spray Aircraft, Boom Sprayer	0.225 lbs ae/A	NS	NS	NS	60 day PGI 60 day PHI 60 day Pre-feeding Interval	Groundwater restriction. Do not apply through any type of irrigation system. For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. This product is toxic to fish.

Site Application Timing	Formulation [EPA Reg. No.]	App. Type App. Equip-ment	Max. Single App. Rate (ae)	Max. Number App. Per Season/ Crop Cycle	Max. Number of App. Per Year	Max. Seasonal Rate (ae)	(PHI) (PGI) Pre-feeding Interval	Use Diretions and Limitations
Pre-emergence	25.9% SC/L [42750-38]	Spray Aircraft, Boom-sprayer	0.225 lbs ae/A	NS	NS	NS	60 day PGI 60 day PHI 60 day Pre-feeding Interval	Groundwater restriction. Do not apply through any type of irrigation system. For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. This product is toxic to fish. Do not contaminate water, food, or feed by storage or disposal.

Site Application Timing	Formulation [EPA Reg. No.]	App. Type App. Equip-ment	Max. Single App. Rate (ae)	Max. Number App. Per Season/ Crop Cycle	Max. Number of App. Per Year	Max. Seasonal Rate (ae)	(PHI) (PGI) Pre-feeding Interval	Use Diretions and Limitations
Pre-emergence	26.2% EC [71368-46]	Broadcast Aircraft, Boom-sprayer	0.225 lbs ae/A	NS	NS	NS	60 day PHI	Groundwater restriction. Do not apply through any type of irrigation system. 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. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Do not contaminate water, food, or feed by storage or disposal.

Site Application Timing	Formulation [EPA Reg. No.]	App. Type App. Equip-ment	Max. Single App. Rate (ae)	Max. Number App. Per Season/ Crop Cycle	Max. Number of App. Per Year	Max. Seasonal Rate (ae)	(PHI) (PGI) Pre-feeding Interval	Use Diretions and Limitations
Pre-emergence	26.85 % EC [15440-32]	Spray Aircraft, Ground	0.225 lbs ae/A	NS	NS	NS	60 day PGI 60 day PHI 60 day Pre-feeding Interval	Groundwater restriction. Do not apply through any type of irrigation system. For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. This product is toxic to fish. Do not contaminate water, food, or feed by storage or disposal.
Pre-emergence	26.85% EC [15440-34]	Spray Aircraft, Ground	0.25 lbs ae/A	NS	NS	NS		

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Pre-bloom	23% SC/L [71368-47] [71368-48]	Broadcast Aircraft, Boom-sprayer, Fixed-wing Aircraft	0.175 lbs ae/A	NS	NS	NS	60 day PHI	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. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Do not contaminate water, food, or feed by storage or disposal. Groundwater restriction. Do not apply through any type of irrigation system.
Pre-bloom	23% SC/L [2749-126]	Broadcast Boom-sprayer	0.2188 lbs ae/A	NS	NS	NS		
Pre-bloom	25.9% SC/L [2749-516]	Broadcast Aircraft, Boom-sprayer	0.182 lbs ae/A	NS	NS	NS		

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Pre-bloom	26.2% EC [71368-46]	Broadcast Aircraft, Boom-sprayer	0.182 lbs ae/A	NS	NS	NS		
Bloom	23% SC/L [71368-46]	Broadcast Aircraft, boom-sprayer	0.2188 lbs ae/A	NS	NS	NS	60 day PHI	Groundwater restriction. Do not apply through any type of irrigation system. Do not apply directly to water, or to areas where surface water is present or to areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Do not contaminate water, food, or feed by storage or disposal. Do not contaminate water.
	23% SC/L [2749-126]	Broadcast Boom-sprayer						
	23% SC/L	Broadcast Boom-sprayer, Fixed-wing aircraft						

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Bloom	25.9% SC/L [2749-516]	Broadcast Aircraft, Boom-sprayer	0.222 lbs ae/A	NS	NS	NS	60 day PHI	Groundwater restriction. Do not apply through any type of irrigation system. Do not apply directly to water, or to areas were surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Do not contaminate water, food, or feed by storage or disposal. Do not contaminate water.
	26.2% EC [71368-46]							

Site Application Timing	Formulation [EPA Reg. No.]	App. Type App. Equip-ment	Max. Single App. Rate (ae)	Max. Number App. Per Season/ Crop Cycle	Max. Number of App. Per Year	Max. Seasonal Rate (ae)	(PHI) (PGI) Pre-feeding Interval	Use Diretions and Limitations
Post-emergence	23% FlC [51036-231]	Broadcast Aircraft, Boom-sprayer	0.2188 lbs ae/A	NS	2	NS	60 day PGI 60 day PHI 60 day Pre-feeding Interval	Groundwater restriction. Do not apply through any type of irrigation system. For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. This prodct is toxic to fish. Do not contaminate water, food or feed by storage or disposal.
Post-emergence	23% FlC [51036-231]	Directed Spray Band Sprayer	0.3938 lbs ae/A					

Site Application Timing	Formulation [EPA Reg. No.]	App. Type App. Equip-ment	Max. Single App. Rate (ae)	Max. Number App. Per Season/ Crop Cycle	Max. Number of App. Per Year	Max. Seasonal Rate (ae)	(PHI) (PGI) Pre-feeding Interval	Use Diretions and Limitations
Post-emergence	23% SC/L [71368-47] [71368-48]	Directed Spray Low Pressure Ground Sprayer	0.3828 lbs ae/A	NS	2	NS	60 day PHI	Groundwater restriction. Do not apply through any type of irrigation system. For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by

Site Application Timing	Formulation [EPA Reg. No.]	App. Type App. Equip-ment	Max. Single App. Rate (ae)	Max. Number App. Per Season/ Crop Cycle	Max. Number of App. Per Year	Max. Seasonal Rate (ae)	(PHI) (PGI) Pre-feeding Interval	Use Diretions and Limitations
Post-emergence	23% SC/L [42750-39] [71368-47] [71368-48]	Broadcast Boom-sprayer (only 42750-39) Broadcast Aircraft Directed Spray Band Sprayer	0.2188 lbs ae/A				60 day PHI 60 day PGI 60 day Pre-feeding Interval	
	23% SC/L [42750-39]	Directed Spray Low Pressure Ground Sprayer	0.3938 lbs ae/A					
	25.9% EC [51036-232]	Directed Spray Band Sprayer	0.4 lbs ae/A	NS	2	NS	60 day PHI 60 day PGI	Groundwater restriction. Do not apply through any type of irrigation system. For

Site Application Timing	Formulation [EPA Reg. No.]	App. Type App. Equip-ment	Max. Single App. Rate (ae)	Max. Number App. Per Season/ Crop Cycle	Max. Number of App. Per Year	Max. Seasonal Rate (ae)	(PHI) (PGI) Pre-feeding Interval	Use Diretions and Limitations
Post-emergence	25.9% EC [51036-232]	Band Treatment Sprayer	0.225 lbs ae/A				60 day Pree-feeding Interval	terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. This product is toxic to fish.
	25.9% SC/L [2749-516]	Band Treatment Sprayer	0.225 lbs ae/A	NS	2	NS	60 day PHI 60 day PGI* 60 day Pre-	Groundwater restriction. Do not apply through any type of irrigation system. Do not apply directly to water, or to areas where surface water
Post-emergence	25.9% SC/L [42750-38]	Broadcast Aircraft, Boom Sprayer	0.225 lbs ae/A					

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	25.9% SC/L [42750-38] [2749-516]	Directed Spray Low Pressure Ground Sprayer	0.4 lbs ae/A					
Post-emergence	26.2% EC [71368-46]	Directed Spray Low Pressure Ground Sprayer	0.4 lbs ae/A	NS	2	NS	60 day PHI	Groundwater restriction. Do not apply through any type of irrigation system. Do not apply directly to

Site Application Timing	Formulation [EPA Reg. No.]	App. Type App. Equip-ment	Max. Single App. Rate (ae)	Max. Number App. Per Season/ Crop Cycle	Max. Number of App. Per Year	Max. Seasonal Rate (ae)	(PHI) (PGI) Pre-feeding Interval	Use Diretions and Limitations
	26.2% EC [71368-46]	Band Treatment Sprayer	0.225 lbs ae/A					water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Do not contaminate water, food, or feed by storage or disposal. Do not apply to sandy soils. Do not feed treated forage or hay to livestock.
	26.85% EC [15440-32]	Directed Spray Band Sprayer	0.4 lbs ae/A	NS	2	NS	60 day PGI 60 day PHI 60 day Pre-feeding	Groundwater restriction. Do not apply through any type of irrigation system. Do not apply directly to water, or to areas where surface water is present or to
	26.85% EC [15440-34]	Directed Spray Band Sprayer	0.45 lbs ae/A					

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Post-emergence	26.85% EC [15440-32]	Broadcast Aircraft, Ground	0.225 lbs ae/A					
	26.85% EC [15440-34]	Broadcast Aircraft, Ground	0.25 lbs ae/A					
Foliar	23% SC/L [2749-126]	Directed Spray Low Pressure Ground Sprayer	0.3938 lbs ae/A	NS	2	NS	60 day PHI	Do not apply to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water. Do not apply to sandy soils. Do not contaminate water by cleaning of equipment or disposal of equipments wash waters. Do not contaminate water, food, or feed by storage or disposal. Do not feed treated forage or hay to

Site Application Timing	Formulation [EPA Reg. No.]	App. Type App. Equip-ment	Max. Single App. Rate (ae)	Max. Number App. Per Season/ Crop Cycle	Max. Number of App. Per Year	Max. Seasonal Rate (ae)	(PHI) (PGI) Pre-feeding Interval	Use Diretions and Limitations
								livestock.
Spearmint								

Site Application Timing	Formulation [EPA Reg. No.]	App. Type App. Equip-ment	Max. Single App. Rate (ae)	Max. Number App. Per Season/ Crop Cycle	Max. Number of App. Per Year	Max. Seasonal Rate (ae)	(PHI) (PGI) Pre-feeding Interval	Use Diretions and Limitations
Early Post-emergence	26.2% SC/L [ID940010000]	0.75 lbs ae/A	Spray Sprayer	NS	NS	NS	90 day PHI	Groundwater restriction. Do not apply through any type of irrigation system. 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 by cleaning of equipment or disposal of equipment wash waters. Do not contaminate water, food, or feed by storage or disposal.
Trefoil								

Site Application Timing	Formulation [EPA Reg. No.]	App. Type App. Equip-ment	Max. Single App. Rate (ae)	Max. Number App. Per Season/ Crop Cycle	Max. Number of App. Per Year	Max. Seasonal Rate (ae)	(PHI) (PGI) Pre-feeding Interval	Use Diretions and Limitations
Post-emergence	25.9% EC [51036-232]	Spray Aircraft, Boom Sprayer	1.5 lbs ae/A	NS	NS	NS	NS	Groundwater restriction. Do not apply through any type of irrigation system. For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. This product is toxic to fish.

Site Application Timing	Formulation [EPA Reg. No.]	App. Type App. Equip-ment	Max. Single App. Rate (ae)	Max. Number App. Per Season/ Crop Cycle	Max. Number of App. Per Year	Max. Seasonal Rate (ae)	(PHI) (PGI) Pre-feeding Interval	Use Diretions and Limitations
Post-emergence	25.9%SC/L [42750-38]	Spray Aircraft, Boom Sprayer	1.5 lbs ae/A	NS	NS	NS	60 day PGI 60 day Pre-feeding Interval	Groundwater restriction. Do not apply through any type of irrigation system. 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 by cleaning of equipment or disposal of equipment wash waters. This product is toxic to fish. Do not contaminate water, food, or feed by storage or disposal.

Appendix B. Table of Generic Data Requirements and Studies Used to Make the Reregistration Decision

Guide to Appendix B

Appendix B contains listing of data requirements which support the reregistration for active ingredients within case #0196 (2,4-DB) covered by this RED. It contains generic data requirements that apply to 2,4-DB in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following formats:

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 Guidance, which are available from the National technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. Use Pattern (Column 4). 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 list the identify 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.

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Bibliographic Citation(s)
PRODUCT CHEMISTRY				
830.1550	61-1	Product Identity and Composition	A, B	45770101, 45996901, 43119201, 43969501 (DMAS)
830.1600	61-2 A	Description of Starting Material	A, B	431192001, 45770101, 45996901, 431192, 43969501
830.1620	61-2 B	Description of Production Process	A, B	45770102, 45996901, 431192, 43969501
830.1670	61-2 B	Discussion of Formation of Impurities	A, B	45770103, 45996901, 431192, 43969501
830.1700	62-1	Preliminary Analysis	A, B	45770105, 45996901, 431192, 43969505
830.1750	62-2	Certified Limits	A, B	45770104, 45770105, 45996901, 43969501
830.1800	62-3	Enforcement of Analytical Method	A, B	45770105, 45996901, 431192, 43969505
830.6302	63-2	Color	A, B	45996904
830.6303	63-3	Physical State	A, B	45996904, 431192, 43969504
830.7100	63-18	Viscosity	A, B	43969504,
830.6314	63-14	Oxidation/Reduction	A, B	431192, 43969504
830.6304	63-4	Odor	A, B	45996904
830.6313	63-13	Stability	A, B	45996904, 431192
830.7000	63-12	pH	A, B	45996904, 431192
830.7200	63-5	Melting Point	A, B	45996904, 431192
830.7300	63-7	Density	A, B	45996904, 431192, 43969504
830.7550/ 7560/757 0	63-11	Partition Coefficient	A, B	45996904, 431192
830.6316	63-16	Explodability	A, B	431192, 43969504
830.6317	63-17	Storage Stability	A, B	431192
830.7370	63-10	Dissociation Constant	A, B	431192
830.7840/ 7860	63-8	Water Solubility	A, B	45996904, 431192
830.7950	63-9	Vapor Pressure	A, B	45996904, 431192
830.6320	63-20	Corrosion Characteristics	A, B	431192, 43969504
830.7050	None	UV/Visible Absorption	A, B	45996904, 431192
ECOLOGICAL EFFECTS				

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Bibliographic Citation(s)
850.4100	122-1A	Seedling Emergence	A, B	41605401 (DMAS), 43359001 (DMAS) Additional Data Required (see Tables 20 and 21)
850.4150	122-1B	Vegetative Vigor	A, B	41605401 (DMAS), 43359001 Additional Data Required (see Tables 20 and 21)
850.4230	123-1	Early Seedling Growth Toxicity	A, B	43054001 (DMAS)
850.2100	71-2	Avian Acute Dietary Toxicity - Bobwhite Quail	A, B	108367 (DMAS), 126694 (DMAS), 41370103 (DMAS), 41370102
850.2200	71-2B	Avian Acute Dietary Toxicity - Mallard Duck	A, B	108368 (DMAS), 126695 (DMAS), Accession # 22923
850.2100	71-1	Avian Acute Dietary Toxicity - Peking Duck	A, B	92162
850.2200	None	Avian Acute Dietary Toxicity - Pheasant	A, B	Accession # 22923
850.2200	None	Avian Acute Dietary Toxicity - Japanese Quail	A, B	Accession # 36935
850.2300	71-4	Chronic Reproductive Toxicity Study in Birds	A, B	Waiver submitted (Reserved)
850.3020	141-1	Honey Bee Acute Contact Toxicity	A, B	Accession # 18842
850.1075	72-1A	Fish Toxicity Bluegill	A, B	40762602, 41407802 (DMAS)
850.1075	72-1C	Fish Toxicity Rainbow Trout	A, B	40762601, 92168 (DMAS), 116347 (DMAS), 41370104 (DMAS)
850.1010	72-2A	Invertebrate Toxicity Daphnid	A, B	41407801, 41642701 (DMAS)
850.1075	72-3 A	Estuarine/Marine Fish Acute Toxicity Test	A, B	Outstanding Study
850.1025	72-3B	Estuarine/Marine Toxicity - Mollusk	A, B	Outstanding Study
		Stonefly Acute Toxicity	A, B	40094602

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Bibliographic Citation(s)
850.1075	72-1A	Fish Acute Toxicity-Bluegill	A, B	Accession #s 50682, 03503, and RP24DB0;
850.1400	72-4	Fish Early Life-stage Toxicity Test	A, B	MRID 54668 (DMAS)
850.1075	72-1C	Fish Acute Toxicity-Rainbow Trout	A, B	Accession #s 50682, 03503, and RP24DB023
850.1075	72-1	Fish Acute Toxicity-Fathead Minnow	A, B	Accession # 03503
850.5400	122-2	Algal Toxicity	A, B	41407803 (DMAS)
850.3020	141-1	Honey Bee Acute Contact Toxicity	A, B	Accession # 18842
850.4400	122-2	Aquatic Plant Toxicity Test using *Lemna spp*.	A, B	In Review
OCCUPATIONAL/RESIDUE EXPOSURE				
NONE	201-1	Droplet Size Spectrum	A, B	Data Gap
NONE	202-1	Drift Field Evaluation	A, B	Data Gap
TOXICOLOGY				
870.1100	81-1	Acute Oral Toxicity-Rat	A, B	00128854, 0092159, 41224401 (DMAS)
870.1200	81-2	Acute Dermal Toxicity-Rabbit/Rat	A, B	0128854, 41224402 (DMAS)
870.1300	81-3	Acute Inhalation Toxicity-Rat	A, B	41774001, 41370101 (DMAS),
870.2400	81-4	Primary Eye Irritation-Rabbit	A, B	0128854, 00092160, 41958001 (DMAS)
870.2500	81-5	Primary Skin Irritation	A, B	0128854, 0250871 (DMAS)
870.2600	81-6	Dermal Sensitization	A, B	43593904 (Under Review), 43968911 (DMAS) (Under Review)
870.3100	82-1A	90-Day Feeding - Rodent	A, B	00104739, 41775401 (DMAS)
870.3150	82-1B	90-Day Feeding - Non-rodent	A, B	00092165
870.3200	82-2	21-Day Dermal - Rabbit/Rat	A, B	44729501 (DMAS), 41551301, 41529901 (DMAS)
870.3465	82-4	90-day Subchronic Inhalation Toxicity Test-Rat	A, B	Study Waived

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Bibliographic Citation(s)
870.7600	85-3	Dermal Penetration	A, B	44729501 (DMAS)
870.4100	83-1B	Chronic Feeding Toxicity - Non-Rodent	A, B	42006301, 42384001
870.4200	83-2B	Oncogenicity - Mouse	A, B	42387301, 40257502, 41936201
870.3700	83-3A	Developmental Toxicity - Rat	A, B	41382701, 41382702, 42536101 (DMAS), 42595201 (DMAS)
870.3700	83-3B	Developmental Toxicity - Rabbit	A, B	41529902, 41529903
870.3800	83-4	2-Generation Reproduction - Rat	A, B	40257503
870.4300	83-5	Combined Chronic Toxicity/ Carcinogenicity	A, B	40257501
870.5140	84-2A	Gene Mutation (Ames Test)	A, B	40257504, 41256101 (DMAS)
870.5375	84-2B	Structural Chromosomal Aberration	A, B	40257506, 41224403 (DMAS)
870.5550	84-2	Unscheduled DNA Synthesis in Mammalian Cells in Culture	A, B	40257507, 41358901 (DMAS)
	84-4	Other Genotoxic Effects	A, B	41810701 (DMAS), 40257505
870.7485	85-1	General Metabolism	A, B	41981601, 44774101, 43830101 (DMAS)
		Characterization of 2,4-DB	A, B	44774102, 44774103, 44334701, 44334702, 44334703
ENVIRONMENTAL FATE				
Non-guideline		Non-guideline	A, B	37080
835.2120	161-1	Hydrolysis	A, B	43991801, 41101101, 45512401, 41888001
835.2410	161-3	Photodegradation - Soil	A, B	41101103, 41101104, 42678401
835.2370	161-4	Photodegradation - Air	A, B	41479702
835.4100	162-1	Aerobic Soil Metabolism	A, B	41325501
835.4200	162-2	Anaerobic Soil Metabolism	A, B	41325501
835.4400	162-3	Anaerobic Aquatic Metabolism	A, B	43908301

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Bibliographic Citation(s)
835.4300	162-4	Aerobic Aquatic Metabolism	A, B	41325501, 43779601
835.2240	161-2	Aqueous Photolysis	A, B	41101102, 42067801
835.1230	163-1	Sediment and Soil Adsorption/Desorption for Parent and Degradates	A, B	41101105, 41617201, 143294
835.1410	163-2	Volatility-Lab	A, B	Reserved
835.6100	164-1	Terrestrial Field Dissipation	A, B	41325502, 44660502 (peanuts), 44660503 (soybeans), 44680701 (alfalfa)
NONE	165-4	Bioconcentration in Fish	A, B	Waived
RESIDUE CHEMISTRY				
860.1000	170-1	Background	A, B	44997903
860.1300	171-4A	Nature of Residue - Plants	A, B	42965901 (alfalfa), 43033901 (peanut), 43033803 (soybean), 42965901, 43033801, 43033803
860.1300	171-4B	Nature of Residue - Livestock	A, B	43009801(hen), 43033802 (goat)
860.1340	171-4C	Residue Analytical Method -plants	A, B	43033801, 43358601, 43201701 (soybean), 43121801 (alfalfa), 43393301 (peanuts) Additional Data in Review
860.1340	171-4D	Residue Analytical Method-Animal	A, B	44334704, 44546301, 44997901 Outstanding Study
860.1850	165-1	Confined Rotational Crop	A, B	43004301
860.1380	171-4E	Storage Stability	A, B	44334705, 44997902, 43607001, 43607002
860.1480	171-4J	Meat, Milk, Poultry, Eggs Milk and the Fat, Meat, and Meat Byproducts of Cattle, Goats, Hogs, Horses and Sheep Eggs and the Fat, Meat, and Meat Byproducts of Poultry	A, B	44997902, 44334705

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Bibliographic Citation(s)
860.1500	171-4K	Crop Field Trials	A, B	43620301 (alfalfa), 00116018 (clover), 00102943 (mint), 43631201 (peanut), 43607001 (soybean) Additional Data in Review
860.1650	171-13	Analytical Reference Standards		Outstanding Study
Processed Food/Feed				
860.1520	171-4L	Processed Food	A, B	00102943, 00161196 (mint), 43621201 (peanut), 43607002 (soybean)

Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in room 119, Crystal Mall #2, 1801 Bell St., Arlington, VA 22202. It is open Monday through Friday, excluding legal holidays, from 8:30 AM to 4:00 PM.

The docket initially contained preliminary risk assessments and related documents as of April 28, 2004. Sixty days later the first public comment period closed. The EPA then considered comments and revised the risk assessments.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site: http://www.epa.gov/edockets

These documents include:

1. 2,4-DB and 2,4-DB-DMA - Report of the Hazard Identification Assessment Review Committee, June 13, 2003

2. 2,4-DB [4-(2,4-dichlorophenoxy) butyric acid] and 2,4-DB dimethylamine salt: REVISED Product Chemistry and Residue Chemistry Summary Documents for the Reregistration Eligibility Decision Document (RED), July 19, 2004

3. 2,4-DB and 2,4-DB-DMA Toxicology Chapter for RED, July 20, 2004

4. 2,4-DB Acute and Chronic Dietary Exposure Assessments for the Reregistration Eligibility Decision, July 13, 2004

5. 2,4-DB and 2,4-DB-DMA Human Health Risk Assessment, July 20, 2004

6. HED's Response to Error Only Comments from 2,4-DB Task Force, July 20, 2004

7. 2,4-DB: Revised Occupational and Residential Exposure and Risk Assessment for the Reregistration Eligibility Decision (RED) Document, July 19, 2004

8. Environmental Fate and Effects Division Revised Risk Assessment for 4-(2,4-dichlorophenoxy) Butyric Acid (2,4-DB) and Dimethylamine 4-(2,4-dichlorophenoxy) Butyrate (2,4-DB-DMAS) Reregistration Eligibility Document, December 13, 2004

9. Review of 2,4-DB Incident Reports, May 11, 2004

Appendix D. Citations Considered to be Part of the Data Base Supporting the Reregistration Decision (Bibliography)

GUIDE TO APPENDIX D

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 (1999), 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.

2,4-DB Bibliography

MRID	Citation Reference
00002865	Osborne, W.W.; Rud, O.E.; Harris, C.; Hameed, K.M.; Pristou, R.; Lambe, R.C.; Fox, J.A.; Sill, L. (1976) Evaluation of Certain Herbicide-Nematicide Treatments on the Incidence of Peanut Pod Rot. (Unpublished study received Sep 28, 1976 under 400-130; prepared by Virginia Polytechnic Institute and State Univ., Dept. of Plant Pathology and Physiology, submitted by Uniroyal Chemical, Bethany, Conn.; CDL:230405-W)
00004463	National Weed Committee, Western Section, Canada (1967) 1967 Report of the Research Appraisal Committee for Western Canada. (Unpublished study received Nov 6, 1967 under 464-398; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:003622-H)
00004484	Leng, M.L. (1970) Summary Statement on Residue Studies with Phenoxy Herbicides in Forage

Grasses and Legumes. (Unpublished study received Jan 11, 1971 under 9F0761; prepared by Dow Chemical Co., submitted by National Agricultural Chemicals Association, Industry Task Force on Phenoxy Herbicide Tolerances, Washington, D.C.; CDL:091313-A)

00004488 Leng, M.L. (1968) Metabolism in Animals. (pp. 35-38 only; unpublished study received Jan 11, 1971 under 9F0761; prepared by Dow Chemical Co., submitted by National Agricultural Chemicals Association, Industry Task Force on Phenoxy Herbicide Tolerances, Washington, D.C.; CDL:091313-F)

00004570 Ball, R.W.E.; Soundy, M. (1958) 2,4-DB and MCPB in Lucerne: Part I. The Effect of 2,4-DB and MCPB on the Development of the Lucerne Plant. (Preprint, British Weed Control Conference, November, 1958; unpublished study received Dec 5, 1960 under 359-400; prepared by May & Baker, Ltd., Agricultural and Horticultural Research Station, Eng., submitted by Rhone-Poulenc, Inc., Monmouth Junction, N.J.; CDL:023310-C)

00004571 Ball, R.W.E.; Wilson, C.W. (1958) 2,4-DB and MCPB in Lucerne-Part III-The Effects of MCPB and 2,4-DB on Established Lucerne. (Preprint, British Weed Control Conference, November, 1958; unpublished study received Dec 5, 1960 under 359-400; prepared by May & Baker, Ltd., Agricultural and Horticultural Research Station, Eng., submitted by Rhone-Poulenc, Inc., Monmouth Junction, N.J.; CDL:023310-D)

00004661 Leng, M.L. (1968) Review on the Metabolism of Phenoxy Compounds in Plants and Animals. Summary of studies 092090-B through 092090- AF. (Unpublished study received Sep 16, 1968 under 8F0676; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:092090-A)

00004662 Shaw, W.C.; Hilton, J.L.; Moreland, D.E.; Jansen, L.L. (1960) Herbicides in plants. Pages 119-125,130-133, In The Nature and Fate of Chemicals Applied to Soils, Plants, and Animals. Washington, D.C.: U.S. Agricultural Research Service. (ARS 20-9; also in unpublished submission received Sep 16, 1968 under 8F0676; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL: 092090-B)

00004664 Swanson, C.R. (1965) Chlorinated phenoxyacetic and phenoxypropionic acids. Pages 9-16,26-36, In Metabolic Fate of Herbicides in Plants. Washington, D.C.: U.S. Agricultural Research Service. (Crops Research, ARS 34-66; also in unpublished submission received Sep 16, 1968 under 8F0676; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:092090-D)

00004685 Linscott, D.L. (1964) Degradation of 4-(2,4-Dichlorophenoxy)-butyric acid 4-

(2,4-DB) in plants. Journal of Agricultural and Food Chemistry 12(1):7-10. (Also in unpublished submission received Sep 16, 1968 under 8F0676; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:092090-AD)

00004701 Bache, C.A.; Hardee, D.D.; Holland, R.F.; Lisk, D.J. (1964) Absence of Phenoxyacid herbicide residues in the milk of dairy cows at high feeding levels. Journal of Dairy Science XLVII(3):298-299. (Also in unpublished submission received Sep 12, 1968 under 8F0676; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL: 092980-O)

00004702 Bache, C.A.; Lisk, D.J.; Wagner, D.G.; Wagner, R.G. (1964) Elimination of 2-

Methyl-4-chlorophenoxyacetic acid and 4-(2-Methyl-4- chlorophenoxybutyric) acid in the urine from cows. Journal of Dairy Science XLVII(1):93-95. (Also in unpublished submission received Sep 12, 1968 under 8F0676; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:092980-P)

00004706 Gutenmann, W.H.; Hardee, D.D.; Holland, R.F.; Lisk, D.J. (1963) Disappearance of 4-(2,4-Dichlorophenoxybutyric) acid herbicide in the dairy cow. Journal of Dairy Science XLVI(9):991-992. (Also in unpublished submission received Sep 12, 1968 under 8F0676; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL: 092980-U)

00004710 Lisk, D.J.; Gutenmann, W.H.; Bache, C.A.; Warner, R.G.; Warner, D. G. (1963) Elimination of 2,4-D in the urine of steers fed 4- (2,4-DB) or 2,4-D. Journal of Dairy Science XLVI(12):1435-1437. (Also In unpublished submission received Sep 12, 1968 under 8F0676; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL: 092980-Y)

00004717 Gutenmann, W.H.; Lisk, D.J. (1963) Rapid determination of 4(2,4-DB) and a metabolite, 2,4-D, in treated forage by electron affinity spectroscopy. Journal of Agricultural and Food Chemistry 11(4): 304-306. (Also in unpublished submission received Sep 12, 1968 under 8F0676; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:092980-AI)

00004718 Hagin, R.D.; Linscott, D.L. (1965) Determination of 4-(2,4-Dichlorophenoxy)-butyric acid (2,4-DB) and 2,4-Dichlorophenoxyacetic acid (2,4-D) in forage plants. Journal of Agricultural and Food Chemistry 13(2):123-125. (Also in unpublished submission received Sep 12, 1968 under 8F0676; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:092980-AJ)

00004725 Stanley, C.W. (1966) Derivatization of pesticide-related acids and phenols for gas chromatographic determination. Journal of Agricultural and Food Chemistry 14(3):321-323. (Also in unpublished submission received Sep 12, 1968 under 8F0676; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:092980-AQ)

00004772 Menzie, C.M. (1966) Metabolism of pesticides. Pages 61-69, In Special Scientific Report–Wildlife No. 96. By U.S. Fish and Wildlife Service. U.S. Dept. of the Interior. (Also in unpublished submission received Oct 19, 1971 under 8F0676; submitted by National Agricultural Chemicals Association, Industry Task Force on Phenoxy Herbicide Tolerances, Washington, D.C.; CDL:091183-N)

00004784 Chipman Chemical Company, Incorporated. (1967) Summary of Available Acute Toxicity Data on a Bromoxynil octanoate/MCPA Isoocty Ester Formulation as Compared with Bromoxynil and MCPA: SR/3/67. (Unpublished study received Mar 10, 1967 under 359-601; submitted by Rhone-Poulenc, Inc., Monmouth Junction, N.J.; CDL:023320-D)

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41402215 Pesselman, R. (1989) pH Value Determination of 2,4-DB Dimethylamine Salt: Lab Project Number: HLA 6001-401. Unpublished study prepared by Hazleton Laboratories America, Inc. 25 p.

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Appendix E. Generic Data Call-In

Appendix F. Product Specific Data Call-In

Appendix G. Batching of 2,4-DB and 2,4-DB-DMAS Products for Meeting Acute Toxicity Data Requirements for Reregistration

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing 2,4-DB as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Not with-standing the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the

choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Twenty one products were found which contain 2,4-DB as the active ingredient. These products have been placed into eight batches and a "No Batch" category in accordance with the active and inert ingredients and type of formulation.

$ No Batch: Each product in this Batch should generate their own data.

NOTE: The technical acute toxicity values included in this document are for informational purposes only. The data supporting these values may or may not meet the current acceptance criteria.

Batch 1	EPA Reg. No.	% Active Ingredient
	2749-93	98.0
	15440-20	96.0
	19713-124	98.0
	46146-01	97.0

Batch 2	EPA Reg. No.	% Active Ingredient
	71368-49	75.0
	74530-15	75.0

Batch 3	EPA Reg. No.	% Active Ingredient
	15440-32	26.85
	15440-34	26.85

Batch 4	EPA Reg. No.	% Active Ingredient
	71368-46	26.2
	71368-48	26.2

Batch 5	EPA Reg. No.	% Active Ingredient
	42750-38	25.9
	51036-232	25.9

Batch 6	EPA Reg. No.	% Active Ingredient
	2749-516	25.9
	71368-33	25.9

Batch 7	EPA Reg. No.	% Active Ingredient
	42750-39	23.0
	51036-231	23.0
	74530-17	23.0

Batch 8	EPA Reg. No.	% Active Ingredient
	2749-126	23.0
	71368-32	23.0

No Batch	EPA Reg. No.	% Active Ingredient
	15440-33	49.2
	71368-47	23.0

Appendix H. List of All Registrants Sent the Data Call-In

Appendix I. List of Available Related Documents and Electronically Available Forms

Pesticide Registration Forms are available at the following EPA internet site: http://www.epa.gov/opprd001/forms/ .

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)

2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.

3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.'

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@epamail.epa.gov.

The following Agency Pesticide Registration Forms are currently available via the internet at the following locations:

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf
8570-34	Certification with Respect to Citations of Data (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf

8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf

Pesticide Registration Kit
www.epa.gov/pesticides/registrationkit/.

Dear Registrant:

For your convenience, we have assembled an online registration kit that contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.

2. Pesticide Registration (PR) Notices

   a. 83-3 Label Improvement Program—Storage and Disposal Statements

   b. 84-1 Clarification of Label Improvement Program

   c. 86-5 Standard Format for Data Submitted under FIFRA

   d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)

   e. 87-6 Inert Ingredients in Pesticide Products Policy Statement

   f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement

   g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments

   h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_Notices.

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader.)

   a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment

   b. EPA Form No. 8570-4, Confidential Statement of Formula

   c. EPA Form No. 8570-27, Formulator's Exemption Statement

   d. EPA Form No. 8570-34, Certification with Respect to Citations of Data

e. EPA Form No. 8570-35, Data Matrix

4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader.)

   a. Registration Division Personnel Contact List

   b. Biopesticides and Pollution Prevention Division (BPPD) Contacts

   c. Antimicrobials Division Organizational Structure/Contact List

   d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)

   e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)

   f. 40 CFR Part 158, Data Requirements for Registration (PDF format)

   g. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information. These include:

1. The Office of Pesticide Programs' Web Site

2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) at the following address:

   National Technical Information Service (NTIS)
   5285 Port Royal Road
   Springfield, VA 22161

The telephone number for NTIS is (703) 605-6000. Please note that EPA is currently in the process of updating this booklet to reflect the changes in the registration program resulting from the passage of the FQPA and the reorganization of the Office of Pesticide Programs. We anticipate that this publication will become available during the Fall of 1998.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their Web site.

4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at (800) 858-7378 or through their Web site: ace.orst.edu/info/nptn.

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner

encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

Date of receipt
EPA identifying number
Product Manager assignment

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying File Symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a CAS number if one has been assigned.