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Reregistration Eligibility Decision for Mefluidide

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Reregistration Eligibility Decision for Mefluidide

**Reregistration Eligibility Decision (RED) Document for
Mefluidide**

List B

Case Number 2370

Approved by: _____ Date: _____

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Glossary of Terms and Abbreviations

Ai	Active Ingredient
Ae	Acid Equivalent
aPAD	Acute Population Adjusted Dose
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formulation
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DNT	Developmental Neurotoxicity
EC	Emulsifiable Concentrate Formulation
EDWC	Estimated Drinking Water Concentration
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FQPA	Food Quality Protection Act
GLN	Guideline Number
LC ₅₀	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of a substance per weight or volume of water, air, or feed, e.g., mg/l, mg/kg, or ppm.
LD ₅₀	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern
LOAEL	Lowest Observed Adverse Effect Level
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligram Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification Number. EPA 's system for recording and tracking studies submitted.
MUP	Manufacturing-Use Product
NOAEL	No Observed Adverse Effect Level
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides, and Toxic Substances
PAD	Population Adjusted Dose
PHED	Pesticide Handler's Exposure Data
PHI	Pre-harvest Interval
Ppb	Parts Per Billion
PPE	Personal Protective Equipment
Ppm	Parts Per Million
PRZM/EXAMS	Tier II Surface Water Computer Model
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
ROW	Rights-of-way
RQ	Risk Quotient
TGAI	Technical Grade Active Ingredient
UV	Ultraviolet
WPS	Worker Protection Standard

Abstract

This document presents the Environmental Protection Agency's (hereafter referred to as EPA or the Agency) decision regarding the reregistration eligibility of the registered uses of mefluidide, mefluidide diethanolamine salt, and mefluidide potassium salt (the three active ingredients are collectively referred to as mefluidide). The Agency has determined that mefluidide-containing products are eligible for reregistration provided that: (1) the risk mitigation measures identified in this document are adopted; and (2) labels are amended to implement these measures. Additionally, EPA will issue a data call-in so that current data gaps are addressed.

Mefluidide is a plant growth regulator that is applied postemergence when needed. It is used to suppress seed heads and fruiting, as well as retarding growth to reduce mowing and trimming. It is also registered for growth control of low maintenance turf on rights-of ways, airports, public and industrial sites. Mefluidide products can also be used on residential lawns. As mefluidide has no food/feed uses and no U.S. tolerances associated with its use, it is not subject to the Food Quality Protection Act of 1996. The Agency has conducted human health and environmental fate and ecological effect risk assessments for mefluidide. The risk conclusions of these assessments are summarized below.

The Human Health risk assessment relies in part on studies in which adult human subjects were intentionally exposed to a pesticide or other chemical. These studies have been determined to require a review of their ethical conduct. These studies were reviewed by the independent Human Studies Review Board which concurred with the Agency's conclusions regarding both the ethical and scientific conduct of these studies, and that the studies are appropriate for use in the risk assessment.

Overall Risk Summary

There are no food-related pesticide uses of mefluidide. Therefore, no dietary exposure from food is expected. However, there is potential for drinking water exposure due to the outdoor uses of mefluidide. A drinking water assessment was conducted using Tier II (PRZM-EXAMS) modeling for surface water and Tier I (SCI-GROW) modeling for groundwater. The mefluidide concentrations in surface water are not expected to exceed 31 ug/L for the 1 in 10 year daily peak concentration, 9.5 ug/L for the 1 in 10 year annual concentration, and 5.3 ug/L for the 30 year annual average concentration. Mefluidide concentrations in ground water source drinking water are not expected to exceed 0.665ug/L.

The acute and chronic dietary (water only) assessments were conducted using the Dietary Exposure Evaluation Model (DEEM), and considered exposures from surface water only. The dietary risk is below the Agency's level of concern (LOC). The exposure for all infants, which is the most highly exposed reference subgroup, is 1% of the acute reference dose (aRfD), and 5 % of the chronic reference dose (cRfD). Therefore, no mitigation is needed for dietary exposure to mefluidide.

The residential handler and post-application risks for all use scenarios are below

the Agency's LOC.

Occupational handlers may be exposed to mefluidide while mixing, loading, and/or applying mefluidide products. The margins of exposure (MOEs) for occupational handler exposures were calculated for short/intermediate term scenarios. All of the MOEs are below the Agency's LOC with baseline personal protective equipment (PPE). Long term exposure was not assessed because there are no long term exposure scenarios for handlers based on the use patterns. Occupational post application risks were not assessed because there is not likely to be any occupational post-application exposure scenarios.

The Agency's ecological fate and effects assessment shows that risks from the use of mefluidide are below the Agency's level of concern for direct acute (listed and non-listed) and chronic exposure to aquatic freshwater and estuarine marine organisms and acute exposure to aquatic plants. However, the ecological fate and effects assessment identifies potential risks of concern for direct acute (listed and nonlisted) and chronic exposure to mammals and birds and acute (listed and nonlisted) exposure to terrestrial and semi-aquatic plants.

Risk Mitigation

To mitigate identified risk concerns from the use of mefluidide to mammals, birds and terrestrial and semi aquatic plants, the Agency is requiring and the registrant has agreed to amend labels to reflect the following spray drift and run-off language:

Wind Direction

Only apply this product if the wind direction favors on target deposition.

Wind Speed

Do not apply when the wind velocity exceeds 15 mph.

Temperature Inversions

Do not make ground spray applications into temperature inversions.

Inversions are characterized by stable air and increasing temperatures with height above the ground. Mist or fog may indicate the presence of an inversion in humid areas. The applicator may detect the presence of an inversion by producing a smoke layer near the ground surface.

Droplet Size

Use only Medium or coarser spray nozzle (ASABE S572).

Additional Requirements for Ground Applications

All ground boom application equipment must be properly maintained and calibrated using appropriate carriers or surrogates. Do not apply with a nozzle height greater than 4 feet above the ground or foliage canopy.

To Prevent Run-off

“To prevent product run-off, do not apply when raining or when rain is expected within 8 hours.”

“Do not irrigate for 8 hours after application.”

Next Steps

The Agency is issuing this Reregistration Eligibility Decision (RED) document for mefluidide as announced in a Notice of Availability published in the *Federal Register*. In the future, EPA will issue a generic Data Call-In (DCI) for additional data necessary to confirm the conclusions of this RED for the active ingredient mefluidide. EPA will also issue a product specific DCI for data necessary to complete product reregistration for products containing mefluidide.

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. 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 EPA. 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 risks 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.

This document summarizes the Agency's revised human health and ecological risk assessments and the reregistration eligibility decision for mefluidide. The document consists of six sections. Section I contains the regulatory framework for reregistration. Section II provides a profile of the use and usage of the chemical. Section III provides links to the mefluidide human health and ecological risk assessments. Section IV presents the Agency's reregistration eligibility and risk management decisions. Section V summarizes label changes necessary to implement the risk mitigation measures outlined in Section IV. Section VI provides information on how to access related documents and contains the appendices that list related information and supporting documents. The mefluidide risk assessments are available in the Public Docket, under docket number EPA-HQ-OPP-2007-0431 on the web page, <http://www.regulations.gov>.

II. Chemical Overview

Mefluidide is a plant growth regulator that is applied postemergence when needed, and is a member of the anilide class of compounds. It is used to suppress seed heads and fruiting, as well as retarding growth to reduce mowing and trimming. It is also registered for growth control of low maintenance turf on rights-of-ways, airports, public and industrial sites. Mefluidide products can also be used on residential lawns. There are no registered food/feed uses, and no food tolerances exist for mefluidide.

The acute toxicology profile of mefluidide and its salts is listed in Table 1.

Table 1. Acute Toxicity of Mefluidide and its salts (114001, 114002, 114003)			
Guideline No.	Study Type	Results (LD₅₀/LC₅₀) MRID	Toxicity Category
870.1100 (81-1)	Acute Oral (female rat) Mefluidide tech	>4000 mg/kg MRID 00047118	III
870.1100 (81-1)	Acute Oral (mouse) Mefluidide tech	1920.2 mg/kg MRID 00047117	III
870.1100 (81-1)	Acute Oral (mouse) Mefluidide tech	829.8 mg/kg MRID 00047116	III
870.1100 (81-1)	Acute Oral (dog) Mefluidide tech	Not established MRID 00049627; emesis precluded evaluation at 100, 500, 2000 mg/kg doses	III
870.1200 (81-2)	Acute Dermal (female rabbit) Mefluidide tech	>4000 mg/kg MRID 00047122 & 00049628 & 00083817	IV
870.1300 (81-3)	Acute inhalation – rat DEA salt of Mefluidide	>5.2 mg/L MRID 41888801	IV
870.1300 (81-3)	Acute inhalation – rat Mefluidide tech.	>5.4 mg/L MRID 41964601	IV
870.2400 (81-4)	Primary Eye Irritation (rabbit) Mefluidide tech	minimal irritation MRID 00047126, 00049630	III
870.2400 (81-4)	Primary Eye Irritation (rabbit) DEA Mefluidide	minimal irritation MRID43481203	III
870.2500 (81-5)	Primary Skin Irritation (rabbit), Mefluidide tech	Not a dermal irritant MRID 00047124, 00049629, 00083819	IV
87.2600 (81-6)	Dermal Sensitization (guinea pig), Mefluidide	Not a dermal sensitizer MRID 41887701	N/A
87.2600 (81-6)	Dermal Sensitization (guinea pig), Mefluidide	Not a dermal sensitizer MRID 00082076	N/A

A. Regulatory History

Mefluidide, mefluidide diethanolamine salt, and mefluidide potassium salt are collectively referred to as mefluidide. Mefluidide was first registered in October 1984, mefluidide diethanolamine salt was first registered in March 1973, and mefluidide potassium salt was first registered in December 1988.

B. Chemical Identification of Mefluidide

Based on the structural similarities of mefluidide (114001) and its diethanolamine (DEA) (114002) and potassium salts (114003), and the physical and chemical properties of the DEA and potassium salts, EPA has concluded that mefluidide DEA and potassium salts are biologically equivalent to mefluidide and thus they share the same toxicity as free mefluidide.

Tables 2-4 provide an overview of mefluidide's structure.

TABLE 2. Test Compound Nomenclature - Mefluidide (114001)	
Chemical Structure	
Empirical Formula	C ₁₁ H ₁₃ F ₃ N ₂ O ₃ S
Common name	Mefluidide
IUPAC name	5'-(1,1,1-trifluoromethanesulfonamido)acet-2',4'-xylidide
CAS name	<i>N</i> -[2,4-dimethyl-5-[[trifluoromethyl)sulfonyl]amino]phenyl]acetamide
CAS Registry Number	53780-34-0
End-use product/EP	St. Aug.GR w/Fertilizer (Reg. #538-181), Scotts Turf Manager (Reg.#538-200)
Chemical Class	Plant growth regulators
Known Impurities of Concern	None

TABLE 3. Test Compound Nomenclature - Diethanolamine Mefluidide (114002)	
Chemical Structure	
Empirical Formula	C ₁₅ H ₂₄ F ₃ N ₃ O ₅ S
Common name	Diethanolamine Mefluidide
IUPAC name	5'-(1,1,1-trifluoromethanesulfonylamino)acet-2',4'-xylylide - 2,2'-iminodiethanol (1:1)
CAS name	<i>N</i> -[2,4-dimethyl-5-[[trifluoromethyl)sulfonyl]amino]phenyl]acetamide compound with 2,2'-iminobis[ethanol] (1:1)
CAS Registry Number	53780-36-2 (This substance is a derivative of mefluidide [53780-34-0]).
End-use product/EP	EMBARK 2-S (Reg.# 2217-759), EMBARK 1-S (Reg.# 2217-763), EMBARK E-Z-TU-USE (Reg.# 2217-768), EH1135 PGR (Reg.# 2217-802), EMBARK R-T-U Northern (Reg.# 2217-787), EMBARK R-T-U Southern (Reg.# 2217-788), ER 721 (Reg.# 2217-809)
Chemical Class	Plant growth regulators
Known Impurities of Concern	None

TABLE 4. Test Compound Nomenclature - Potassium Mefluidide (114003)	
Chemical Structure	
Empirical Formula	C ₁₁ H ₁₂ F ₃ KN ₂ O ₃ S
Common name	Mefluidide
IUPAC name	Potassium (<i>EZ</i>)- <i>N</i> -[5-(1,1,1-trifluoromethanesulfonylamino)-2,4-dimethylphenyl]acetamide
CAS name	<i>N</i> -[2,4-dimethyl-5-[[trifluoromethyl)sulfonyl]amino]phenyl]acetamide monopotassium salt
CAS Registry Number	83601-83-6
End-use product/EP	EMBARK 1-L (Reg.# 2217-765), EMBARK 2-L (Reg.# 2217-766)
Chemical Class	Plant growth regulators
Known Impurities of Concern	None

C. Use Sites:

The uses that are included in the reregistration assessment are; agricultural/farm structures/buildings and equipment, agricultural/nonagricultural uncultivated areas/soils, airports/landing fields, commercial industrial lawns, commercial institutional/industrial premises/equipment, golf course turf, hospitals/medical institutions premises, household domestic dwellings outdoor premises, industrial areas (outdoor), nonagricultural outdoor buildings/structures, nonagricultural rights-of-way/fencerows/hedgerows, ornamental and or shade trees, ornamental ground cover, ornamental herbaceous plants, ornamental lawns and turf, ornamental nonflowering plants, ornamental woody shrubs and vines, paths/patios, paved area (private roads/sidewalks), recreational areas, and residential lawns.

D. Formulations:

- Mefluidide formulations include granular, liquid ready-to-use, and soluble concentrate liquid.
- Multiple products that contain mefluidide also contain an additional plant growth regulator or herbicides such as paclobutrazol, imazapyr and imazethapyr.

E. Methods of Application:

- Mefluidide can be applied as a band treatment, broadcast, spot treatment, and spray. Mefluidide can be applied with several types of application equipment, including backpack sprayer, groundboom, hand held pump sprayer, handgun sprayer, hose-end sprayer, power sprayer, high pressure handwand, and spreader (push-type and belly grinder).

F. Use rates:

- The maximum application rate for mefluidide applied as ground sprays is 1.0 lb acid equivalents (ae)/acre (A). The maximum application rate for mefluidide, as a granular formulation, is 0.5 lb ae/A.

G. Annual usage:

- Annual use of mefluidide in the United States is generally less than 10,000 lb ae. The highest use areas for mefluidide include South Carolina, North Carolina, Virginia, West Virginia, California, Nevada, Arizona, and New Mexico.

H. Technical Registrant:

- PBI/Gordon Corporation is the technical registrant.

III. Links to the Mefluidide Risk Assessments

For details on the risks associated with the use of mefluidide, please refer to the Human Health and Ecological Risk Assessments for mefluidide located respectively in Appendices J and K. These documents are also available in the public docket EPA-HQ-OPP-2007-0431, located on-line in the Federal Docket Management System (FDMS) at <http://www.regulations.gov>.

IV. Risk Management and Reregistration Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether pesticides 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 mefluidide.

The Agency has completed its assessment of the dietary (water only), residential, occupational, and ecological risks associated with the use of pesticides containing the active ingredient mefluidide. Food risks are not assessed because there are no food/feed

uses of mefluidide. Based on a review of the mefluidide database and public comments on the Agency's assessments for the active ingredient mefluidide, the Agency has sufficient information on the human health and ecological effects of mefluidide to make decisions as part of the reregistration process under FIFRA. The Agency has determined that currently registered uses of mefluidide will not pose unreasonable adverse effects to humans or the environment provided that the risk mitigation measures and label changes outlined in this RED are implemented; therefore, products containing mefluidide are eligible for reregistration if the risk mitigation measures outlined in the document are adopted and label amendments are made to implement these measures. Label changes are described in Section V of this document. Appendix B identifies the generic data that the Agency reviewed as part of its determination of reregistration eligibility of mefluidide and lists the submitted studies that the Agency found acceptable. EPA will issue a data call-in to address data gaps identified in the risk assessments.

Based on its evaluation of mefluidide, the Agency has determined that mefluidide products, unless labeled and used as specified in this document, could result in unreasonable adverse effects on the environment. 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 mefluidide. If all changes outlined in this document are incorporated into the product labels, then current risks for mefluidide will be adequately mitigated for the purposes of this determination under FIFRA. Once a comprehensive endangered species assessment is completed, further changes to these registrations may be necessary.

B. Public Comments and Responses

The Agency solicited comments from the public regarding the reregistration of mefluidide through a 60-day comment period, which opened on June 20, 2007, and closed on August 21, 2007. During the public comment period, the Agency received only one set of comments which were from the technical registrant, PBI/Gordon Corporation, on the Environmental Fate and Effects Chapter and the Drinking Water Assessment.

To view the complete set of public comments and the Agency's responses to these comments, please refer to the public docket at <http://www.regulations.gov>, EPA-HQ-OPP-2007-0431.

C. Regulatory Position

1. Regulatory Rationale

The Agency has determined that mefluidide is eligible for reregistration provided the risk mitigation measures outlined in this document are adopted and label amendments are made to reflect these measures. This decision considers the risk assessments conducted by the Agency and the significance of the use of mefluidide.

The following is a summary of the rationale for managing risks associated with the use of mefluidide. Where labeling revisions are warranted, specific language is set

forth in the summary table in Section V of this document.

a. Human Health Risk Management

For additional details on the mefluidide human health risk assessment, please refer to the Human Health Risk Assessments for mefluidide located in Appendix J. This document is also available in the public docket EPA-HQ-OPP-2007-0431, located on-line in the Federal Docket Management System (FDMS) at <http://www.regulations.gov>.

1) Drinking Water Risk Mitigation

The Agency's human health assessment identifies a potential for drinking water exposure due to the outdoor uses of mefluidide. The drinking water assessment included surface water exposures only because estimated concentrations of mefluidide in groundwater were minimal. Drinking water risks are below the Agency's level of concern; therefore, no mitigation is needed.

2) Residential Handler Risk Mitigation

The Agency assessment considered several residential handler scenarios which include loading/applying granules with a belly grinder and with a broadcast spreader. It also assessed mixing/loading/applying with a hose-end sprayer and with a hand-held pump sprayer. The target Margin of Exposure (MOE) is 100 for residential assessments. This is based on 10X for intraspecies variation, and 10X interspecies extrapolation. The MOEs exceed 100 and the risks are below the Agency's level of concern. Therefore, no mitigation is needed.

3) Residential Post Application Risk Mitigation

The assessment considered residential post application scenarios for short term incidental oral exposure of toddlers playing on treated turf. All of the MOEs exceed 100, and the risks are therefore below the Agency's level of concern. Therefore, no mitigation is needed.

4) Occupational Handler Risk Mitigation

The risk assessment considered several scenarios for short/intermediate-term occupational handler risk which include mixing/loading liquid formulations. Long term exposure was not assessed because there are no long term exposure scenarios for handlers based on the use patterns. The target MOE is 100 for occupational assessments. This is based on 10X for intraspecies variation, and 10X interspecies extrapolation. All of the MOEs exceed 100 with baseline PPE, and the risks are below the Agency's level of concern. Therefore no, mitigation is needed.

5) Occupational Postapplication Risk Mitigation

Occupational postapplication risk was not assessed because there is not likely to be occupational post-application exposure. Therefore, no mitigation is needed.

b. Environmental Risk Management

For additional details on the mefluidide ecological fate and effects risk assessment, please refer to the Ecological Risk Assessment for mefluidide located in Appendix K. This document is also available in the public docket EPA-HQ-OPP-2007-0431, located on-line in the Federal Docket Management System (FDMS) at <http://www.regulations.gov>.

The results of the risk assessment suggest that typical use of mefluidide may result in exposures to nontarget plants and animals. The Agency's levels of concern (LOCs) are not exceeded for acute and chronic effects on freshwater and estuarine marine fish, aquatic invertebrates, and non-vascular and vascular aquatic plants in water bodies adjacent to areas treated with mefluidide. However, the Agency's assessment identifies potential for direct effects for acute and chronic exposure to mammals and birds, and for acute exposure to terrestrial and semi-aquatic plants.

For mammals, the acute LOC is not exceeded. However, acute listed species (hereafter referred to as "listed") and restricted use LOCs are exceeded for mammals (RQs ranging from 0.0 to 0.26) using upper bound Kenega residues resulting from maximum application rates of the liquid and granular formulations. The chronic LOC is only exceeded for 15g mammals (RQ of 1.02) that consume short grass using upper bound Kenega residues resulting from the maximum application rate for the liquid formulation. However, using mean Kenega residues resulting from the maximum application rates, no acute or chronic LOCs are exceeded for mammals, including the acute listed and restricted use LOCs. Given the conservative assumptions in the exposure scenarios, the Agency finds that the acute and chronic risks to mammals from exposure to mefluidide are not of concern.

For birds, the acute LOC is not exceeded. However, acute listed and restricted use LOCs are exceeded for small and medium sized birds (RQs ranging from <0.01 to <0.25) using upper bound Kenega residues resulting from maximum application rates for liquid and granular formulations. However, using mean Kenega residues resulting from the maximum application rate of the liquid, no acute LOCs are exceeded for birds, including the acute listed LOC. The chronic LOC for birds is also exceeded (RQs ranging from <0.4 to <6.32) using upper bound Kenega residues resulting from the maximum application rate for the liquid formulation. The chronic LOC using mean Kenega residues is also exceeded for birds (RQs ranging from <0.18 to <2.24).

The RQs for birds are reported as "less than" a certain value due to the fact that no mortality occurred at the highest level tested in the acute study used in the risk assessment. Therefore, for acute risks, RQs are calculated for birds based on the non-definitive LD50 value of >1500 mg ae/kg-bw, the highest value tested in the study. In fact, all available dietary toxicity studies on avian species failed to establish definitive acute LD50 values (i.e., the lethality values exceed the highest dose tested) including a bobwhite quail study in which birds were dosed at 5000 mg ae/kg-bw. If the LD50 value of 5000 mg ae/bw is used to assess acute risk to birds, no acute LOC exceedences would occur. Therefore, use of the 1500 mg ae/kg-bw value in the ecological risk assessment

adds uncertainty and may overestimate the acute risk to avian species.

No studies have been submitted to the Agency evaluating the chronic toxicity of mefluidide to birds. For the purposes of this risk assessment, it is assumed that birds are similar in toxicity responses to mammals in terms of the relative toxicity between acute and chronic toxicity endpoints. Acute to chronic ratios (ACRs) are derived from mefluidide laboratory rat and laboratory mouse data to determine the estimated chronic NOAEC of 38 mg ae/kg value for birds. The use of this value also adds uncertainty and may overestimate the chronic risk to avian species. Given the conservative assumptions in the hazard determinations as well as the exposure scenarios, the Agency finds that the acute and chronic risks to birds from exposure to mefluidide are not of concern.

For non-target terrestrial and semi-aquatic plants adjacent to treated sites, acute LOCs are exceeded at the maximum application rate for liquid and granular formulations. The RQs for non-endangered monocots due to exposure from spray drift and run-off following ground spray application range from 0.57 to 4.86. For granular applications, RQs for non-endangered monocots due to exposure from run-off alone range from 0.24 to 2.38. Dicots demonstrate more sensitivity than monocots with RQs ranging from 11.1 to 94.4 for ground spray application and 4.6 to 46.3 for granular application.

In assessing exposure to non-target terrestrial and semi-aquatic plants from spray drift, the Agency used very fine to fine droplet size as an input to the model because the mefluidide labels do not specify a droplet size. To reduce exposure due to spray drift, the Agency is requiring the spray drift language listed below which includes Medium or coarser droplet size for spray applications. The registrant will amend labels to reflect the following spray drift language:

Wind Direction

Only apply this product if the wind direction favors on target deposition.

Wind Speed

Do not apply when the wind velocity exceeds 15 mph.

Temperature Inversions

Do not make ground spray applications into temperature inversions.

Inversions are characterized by stable air and increasing temperatures with height above the ground. Mist or fog may indicate the presence of an inversion in humid areas. The applicator may detect the presence of an inversion by producing a smoke layer near the ground surface.

Droplet Size

Use only Medium or coarser spray nozzle (ASABE S572).

Additional Requirements for Groundboom Applications

All ground boom application equipment must be properly maintained and calibrated using appropriate carriers or surrogates. Do not apply with a nozzle height greater than 4

feet above the ground or foliage canopy.

Non-target terrestrial and semi-aquatic plants may also be exposed to mefluidide from runoff. The Agency's runoff exposure estimate assumes a 1-in-10 year rain event and is based on a pesticide's water solubility and the amount of pesticide present on the soil surface and its top one inch, characterized as "sheet runoff" (one treated acre to an adjacent acre) for dry areas and as "channelized runoff" (10 treated acres to a distant low-lying acre) for semiaquatic areas, and is based on percent runoff values of 0.01, 0.02, and 0.05 for water solubility of <10 ppm, 10-100 ppm, and >100 ppm, respectively. The modeled runoff exposure estimates likely overestimate actual exposures from runoff, given the conservative 1-in-10 year rain event assumption, and also given that practices, intended to minimize soil loss from runoff, are not taken into account. However, to reduce potential exposure to mefluidide from runoff, the Agency is requiring the following the label statement: "To prevent product runoff, do not apply when raining or when rain is expected within 8 hours. Do not irrigate for 8 hours after application."

2. 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 such endocrine effects as the Administrator may designate.*" Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there were scientific bases for including, as part of the program, androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. When the appropriate screening and/or testing protocols being considered under the Agency's Endocrine Disrupter Screening Program (EDSP) have been developed and vetted, mefluidide may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

3. Endangered Species Considerations

Based on the available screening level information, the patterns of mefluidide use are such that they coincide in time and space with areas frequented by avian and mammalian wildlife. These areas have been demonstrated to be used by wildlife as sources of food and cover. The potentially problematic wildlife food items identified by this risk assessment are likely to be present in and around the treated areas. In addition, there is potential for indirect effects to all taxonomic groups due to changes in habitat caused by vegetation changes. Some uses of mefluidide may not pose a threat for avian and mammalian wildlife, such as industrial sites that are not frequented by wildlife. These findings are based solely on EPA's screening level assessment and do not constitute "may effect" findings under the Endangered Species Act (ESA).

Table 5 summarizes the potential risk to listed species associated with the application of mefluidide for turf use.

Table 5. Potential Listed Species Risks Associated With Direct or Indirect Effects Due to Applications of Mefluidide Based on Screening-Level Assessment		
Listed Taxonomy	Direct Effects	Indirect Effects
Terrestrial and semi-aquatic plants – monocots	Yes	Yes ^c
Terrestrial and semi-aquatic plants – dicots	Yes	Yes ^c
Terrestrial invertebrates	None	Yes ^c
Birds	Yes	Yes ^{c,d,e}
Terrestrial phase amphibians	Yes ^b	Yes ^{c,e}
Reptiles	Yes	Yes ^{c,d,e}
Mammals	Yes	Yes ^{c,d,e}
Aquatic vascular plants	None	Yes ^c
Aquatic non-vascular plants ^a	None	Yes ^c
Freshwater fish	None	Yes ^c
Aquatic phase amphibians	None ^b	Yes ^c
Freshwater crustaceans	None	Yes ^c
Mollusks	None	Yes ^c
Marine/estuarine fish	None	Yes ^c
^a At the present time no aquatic non-vascular plants are included in Federal listings of threatened and listed species. The taxonomic group is included here for the purposes of evaluating potential contributions to indirect effects to other taxonomy and as a record of exceedances should future listings of non-vascular aquatic plants warrant additional evaluation of Federal actions		
^b Terrestrial phase amphibians and reptiles estimated using birds as surrogates. Aquatic amphibians estimated using freshwater fish as surrogates.		
^c Listed and Non-listed LOC exceeded for terrestrial and semi-aquatic plants.		
^d Listed, Restricted Use, and Acute LOC exceeded for some feeding guilds and size classes of birds.		
^e Listed, Restricted Use, and Chronic LOC exceeded for some feeding guilds and size classes of mammals.		

a. The Endangered Species Program

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.

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on threatened and endangered species, and to implement mitigation measures that address these impacts. To analyze the potential of registered pesticide uses that may affect any particular species, the Agency 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. When conducted, this species-specific analysis will also consider the risk mitigation measures that are being implemented as a result of this RED.

Following this future species-specific analysis, a determination that there is a likelihood of potential effects to a listed species may result in limitations on use of the pesticide, other measures to mitigate any potential effects, or consultations with the Fish and Wildlife Service and/or the National Marine Fisheries as appropriate. If the Agency determines use of mefluidide "may affect" listed species or their designated critical habitat, the Agency will employ the provisions in the Services' regulations (50 CFR Part 402). Until the species-specific analysis is completed, the risk mitigation measures being implemented through this RED will reduce the likelihood that endangered and threatened species may be exposed to mefluidide at levels of concern. The Agency is not requiring specific mefluidide label language at the present time relative to threatened and endangered species. If, in the future, specific measures are necessary for the protection of listed species, the Agency will implement them through the Endangered Species Program.

4. 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 mefluidide. For the specific labeling statements and a list of outstanding data, refer to Section V of this document.

V. What Registrants Need to Do

The Agency has determined that mefluidide is eligible for reregistration provided that the risk mitigation measures identified in this document are adopted and label amendments are made to reflect these measures. Additional data are required to fill data gaps identified and to confirm this decision. In the near future, the Agency intends to issue Data Call-In Notices (DCIs) requiring product specific data and generic (technical grade) data. Generally, registrants will have 90 days from receipt of a DCI to complete and submit response forms or request time extension and/or waiver requests with a full written justification. For product specific data, the registrant will have 8 months to submit data and amend labels. For generic data, due dates can vary depending on the specific studies being required. Below are tables of additional generic data that the Agency intends to require for mefluidide.

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic database supporting the reregistration of mefluidide has been reviewed and determined to be adequate for this reregistration decision. However, the following study in Table 6 would reduce the uncertainty in the ecological risk assessment and will be required by the generic DCI for mefluidide.

Table 6. Confirmatory Data Requirements for Reregistration

New Guideline Number	Old Guideline Number	Study/Requirements
850.2300	71-4	Avian Reproduction

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. In order to be eligible for reregistration, the technical registrants also must amend all product labels to incorporate the risk mitigation measures outlined in Section IV. The technical and MP labeling should also bear the labeling statements contained in Table 7, the 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 a pesticide after a determination of eligibility has been made. The registrant must review previous data submissions to ensure 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 Registrations Response Form provided for each product.

A product-specific data call-in, outlining specific data requirements will be issued in the near future.

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 the Label Changes Summary Table below.

a. Label Changes Summary Table

In order to be eligible for reregistration, registrants must 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.

Labeling 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 7: Summary of Labeling Changes for Mefluidide <i>For Manufacturing Products Only</i>		
Description	Amended Labeling Language	Placement on Label
For all Manufacturing Use Products	<p>“Only for formulation into a plant growth regulator for the following use(s) [fill blank only with those uses that are being supported by MP registrant].”</p> <p>Formulation into end-use products that list a range of percent active ingredient is prohibited.</p> <p>Not for formulation into an end use product that allows aerial application.</p>	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	<p>“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).”</p> <p>“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</p>	Directions for Use

formulator or user	of such use(s).”	
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		
Note to Product Registrants	End-use products that list a range of percent active ingredient are prohibited.	Ingredient Statement
PPE Requirements Established by the RED ¹ For Soluble Concentrate Liquid Formulations	<p>“Personal Protective Equipment (PPE)”</p> <p>“Some materials that are chemical-resistant to this product are” (<i>registrant inserts correct chemical-resistant material</i>). “If you want more options, follow the instructions for category” [<i>registrant inserts A,B,C,D,E,F,G,or H</i>] “on an EPA chemical-resistance category selection chart.”</p> <p>“All mixers, loaders, applications and other handlers must wear:</p> <ul style="list-style-type: none"> > Long-sleeved shirt, > Long pants and, > Shoes plus socks.” 	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
PPE Requirements Established by the RED ¹ For Liquid	<p>“Personal Protective Equipment (PPE)”</p> <p>“Some materials that are chemical-resistant to this product are”</p>	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

<p>ready-to-use and Granular Formulations</p>	<p>(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.”</p> <p>“All loaders, applicators and other handlers must wear:”</p> <ul style="list-style-type: none"> > Long-sleeved shirt, > Long pants and, > Shoes plus socks.” 	
<p>User Safety Requirements</p>	<p>“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 from other laundry.”</p> <p>“Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product’s concentrate. Do not reuse them.”</p>	<p>Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements</p>
<p>User Safety Recommendations</p>	<p>“User Safety Recommendations</p> <p>Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.</p> <p>Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.</p> <p>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.”</p>	<p>Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls</p> <p>(Must be placed in a box.)</p>
<p>Environmental Hazards</p>	<p>“Do not apply directly to water, or to areas where surface water is present</p>	<p>Precautionary Statements immediately</p>

	<p>or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate.”</p> <p>“This chemical has properties and characteristics associated with chemicals detected in ground water. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground water contamination”.</p>	<p>following the User Safety Recommendations</p>
<p>Restricted-Entry Interval for products with directions for use within scope of the Worker Protection Standard for Agricultural Pesticides (WPS)</p>	<p>Basic REI Statement</p> <p>“Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.”</p>	<p>Directions for Use, Under Agricultural Use Requirements Box</p>
<p>Entry Restrictions for products having occupational uses on the label not subject to the WPS</p>	<p>Entry Restriction for non-WPS uses applied as a spray:</p> <p>“Do not enter or allow others to enter until sprays have dried.”</p> <p>Entry Restriction for non-WPS uses applied dry:</p> <p>“Do not enter or allow others to enter until dusts have settled.”</p>	<p>If no WPS uses on the product label, place the appropriate statement in the Directions for Use Under General Precautions and Restrictions. If the product also contains WPS uses, then create a Non-Agricultural Use Requirements box as directed in PR Notice 93-7 and place the appropriate statement inside that box.</p>
<p>Early Entry Personal Protective Equipment for products with directions for use within the scope of the WPS</p>	<p>“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:</p> <ul style="list-style-type: none"> * coveralls, * shoes plus socks, * chemical-resistant gloves made of any waterproof material.” 	<p>Direction for Use Agricultural Use Requirements box</p>

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	Note to End-Use Product Registrant: Maximum application rate and maximum seasonal rates specified on the label must be listed as pounds or gallons of formulated product per unit area (i.e., acre, 1,000 square feet), not just as pounds active ingredient per unit area.	Directions for Use
Other Application Restrictions (Risk Mitigation)	<p>Do not contaminate food or feed. Do not contaminate water intended for irrigation or domestic purposes. Do not feed clippings to livestock. Do not graze livestock in treated areas. Keep out of lakes, streams, and ponds. Do not apply through any type of irrigation system.</p> <p>“To prevent product run-off, do not apply when raining or when rain is expected within 8 hours.”</p> <p>“Do not irrigate for 8 hours after application.”</p>	Directions for Use
Spray Drift for products applied as a spray	<p>“Spray Drift Requirements:</p> <p><i>Wind Direction</i> Only apply this product if the wind direction favors on target deposition.</p> <p><i>Wind Speed</i> Do not apply when the wind velocity exceeds 15 mph.</p>	Directions for Use

	<p><i>Temperature Inversions</i> Do not make ground spray applications into temperature inversions.</p> <p>Inversions are characterized by stable air and increasing temperatures with height above the ground. Mist or fog may indicate the presence of an inversion in humid areas. The applicator may detect the presence of an inversion by producing a smoke layer near the ground surface.</p> <p><i>Droplet Size</i> Use only Medium or coarser spray nozzle (ASABE S572)</p> <p><i>Additional Requirements for Groundboom Applications</i></p> <p>“All ground boom application equipment must be properly maintained and calibrated using appropriate carriers or surrogates. Do not apply with a nozzle height greater than 4 feet above the ground or foliage canopy.”</p>	
End Use Products Intended for Residential Use		
Application Restrictions	“Do not apply this product in a way that will contact any person, pet, either directly or through drift. Keep people and pets out of the area during application.”	Directions for Use under General Precautions and Restrictions
Entry Restrictions	Liquid: “Do not allow people or pets to enter the treated area until sprays have dried.”	Directions for use under General Precautions and Restrictions

	<p>Dry: “Do not allow people or pets to enter the treated area until dusts have settled.”</p>	
Other application restrictions	<p>Note to End-Use Product Registrant: Maximum application rate and maximum seasonal rates specified on the label must be listed as pounds or gallons of formulated product per unit area (i.e., acre, 1,000 square feet), not just as pounds active ingredient per unit area. Do not contaminate food or feed.</p> <p>Do not contaminate water intended for irrigation or domestic purposes. Do not feed clippings to livestock. Do not graze livestock in treated areas. Keep out of lakes, streams, and ponds. Do not apply through any type of irrigation system.</p> <p>“To prevent product run-off, do not apply when raining or when rain is expected within 8 hours.”</p> <p>“Do not irrigate for 8 hours after application.”</p>	Directions for Use
Environmental Hazards	<p>“Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate.”</p> <p>“This chemical has property and characteristics associated with chemical detected in ground water. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground water contamination”.</p>	Precautionary Statements immediately following the User Safety Recommendations

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.

VI. Appendices

Appendix A. Mefluidide Uses and Use-Patterns Eligible for Reregistration

NON-FOOD/NON-FEED USE PATTERNS SUMMARY FOR Mefluidide (CASE 2370)

SITE NAME	LIMITATIONS						
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate). Application Equipment (for any Reg.# at any rate).	Max. Single Appl. Rate to a Single Site	Form Code(s)	Max. Seasonal Rate	Max. # Apps/cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
ORNAMENTAL LAWNS AND TURF	Do not apply directly to water or wetlands. Do not apply when drift is likely to occur. Do not apply where runoff is likely to occur. Do not contaminate food or feed. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Do not contaminate water intended for irrigation or domestic purposes. Do not feed clippings to livestock. Do not graze treated areas.Keep children and domestic animals off treated areas until material is washed into soil. Keep out of lakes, streams, and ponds.						
Early fall Broadcast. Spreader.	.001248 lb 1K sq.ft	G	NS	NS NS	NS	NS	
Late summer Broadcast. Spreader.	.001248 lb 1K sq.ft	G	NS	NS NS	NS	NS	
Spring Broadcast. Spreader.	.001248 lb 1K sq.ft	G	NS	NS NS	NS	NS	

NON-FOOD/NON-FEED USE PATTERNS SUMMARY FOR Mefluidide, diethanolamine salt (CASE 2370)

Application rates calculated in terms of Active Ingredient.

SITE NAME	LIMITATIONS						
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate). Application Equipment (for any Reg.# at any rate).	Max. Single Appl. Rate to a Single Site	Form Code(s)	Max. Seasonal Rate	Max. # Apps/cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
AGRICULTURAL UNCULTIVATED AREAS	Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply through any type of irrigation system. Do not apply to any body of water. Do not apply when 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 graze treated areas.						
Foliar Spot treatment /Spray. Boom sprayer /Hand held sprayer /Handgun.	.03084 lb 1K sq.ft 1.316 lb A	SC/L	NS	NS NS	NS	NS	
AGRICULTURAL/FARM STRUCTURES/BUILDINGS AND EQUIPMENT	Do not apply directly to water or wetlands. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply through any type of irrigation system. Do not apply when drift is likely to occur. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Do not graze livestock in treated areas. Do not graze treated areas.						
Foliar Spray. Ground /Pressure sprayer.	.01365 lb/1 gal 1.344 lb/100 gal	SC/L	NS	NS NS	NS	NS	
When needed Spot treatment /Spray. Boom sprayer /Handgun /Hose-	.0112 lb 1K sq.ft 1.344 lb A	SC/L	NS	NS NS	NS	NS	

SITE NAME	LIMITATIONS						
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate). Application Equipment (for any Reg.# at any rate).	Max. Single Appl. Rate to a Single Site	Form Code(s)	Max. Seasonal Rate	Max. # Apps/cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
end sprayer /Power sprayer.							
AIRPORTS/LANDING FIELDS	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 directly to water. Do not apply through any type of irrigation system. Do not apply to any body of water. Do not apply when drift is likely to occur. Do not apply when wind velocity is 10 mph or greater. 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 or graze animals on treated areas. Do not graze treated areas.						
Foliar Spot treatment /Spray. Boom sprayer /Hand held sprayer /Handgun /Power sprayer.	.03084 lb 1K sq.ft 2.025 lb A	SC/L	NS	NS NS	NS	NS	
Postemergence Broadcast. Backpack sprayer /Sprayer.	.033 lb 1K sq.ft 1.32 lb A	SC/L	NS	NS NS	NS	NS	
COMMERCIAL/INDUSTRIAL LAWNS	Do not apply directly to water or wetlands. 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 directly to water. Do not apply through any type of irrigation system. Do not apply to any body of water. Do not apply when 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 graze treated areas.						
Foliar Spot treatment /Spray.	.0336 lb 1K sq.ft 1.344 lb A	SC/L	NS	NS NS	42	NS	

SITE NAME	LIMITATIONS						
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate). Application Equipment (for any Reg.# at any rate).	Max. Single Appl. Rate to a Single Site	Form Code(s)	Max. Seasonal Rate	Max. # Apps/cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
Boom sprayer /Hand held sprayer /Handgun /Hose-end sprayer /Power sprayer /Pressure sprayer.							
Postemergence Broadcast. Backpack sprayer /Sprayer.	.033 lb 1K sq.ft 1.32 lb A	SC/L	NS	NS NS	NS	NS	
COMMERCIAL/INSTITUTIONAL/INDUSTRIAL PREMISES/EQUIP. (INDOOR)	Do not apply directly to water or wetlands. 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 directly to water. Do not apply through any type of irrigation system. Do not apply to any body of water. Do not apply when 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 graze livestock in treated areas. Do not graze treated areas.						
Foliar Spot treatment /Spray. Boom sprayer /Ground /Hand held sprayer /Handgun /Power sprayer /Pressure sprayer.	.03084 lb 1K sq.ft 2.025 lb A .01365 lb/1 gal 1.344 lb/100 gal	SC/L	NS	NS NS	NS	NS	
Postemergence Broadcast. Backpack sprayer /Sprayer.	.033 lb 1K sq.ft 1.32 lb A	SC/L	NS	NS NS	NS	NS	
When needed Spot treatment /Spray. Boom sprayer /Handgun /Hose-end sprayer /Power sprayer.	.0112 lb 1K sq.ft 1.344 lb A	SC/L	NS	NS NS	NS	NS	

SITE NAME	LIMITATIONS						
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate). Application Equipment (for any Reg.# at any rate).	Max. Single Appl. Rate to a Single Site	Form Code(s)	Max. Seasonal Rate	Max. # Apps/cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
FENCEROWS/HEDGEROWS	Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply through any type of irrigation system. Do not apply to any body of water. Do not apply when drift is likely to occur. Do not apply when wind velocity is 10 mph or greater. 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 or graze animals on treated areas.						
Foliar Spray. Power sprayer.	.5788 lb A	SC/L	NS	NS NS	NS	NS	
GOLF COURSE TURF	Do not apply directly to water or wetlands. 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 directly to water. Do not apply through any type of irrigation system. Do not apply to any body of water. Do not apply when drift is likely to occur. Do not apply when wind velocity is 10 mph or greater. 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 or graze animals on treated areas. Do not graze treated areas.						
Foliar Spot treatment /Spray. Boom sprayer /Hand held sprayer /Handgun /Hose-end sprayer /Power sprayer /Pressure sprayer.	.0336 lb 1K sq.ft 1.344 lb A	SC/L	NS	NS NS	42	NS	
Postemergence Broadcast.	.033 lb 1K sq.ft 1.32 lb A	SC/L	NS	NS NS	NS	NS	

SITE NAME	LIMITATIONS						
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate). Application Equipment (for any Reg.# at any rate).	Max. Single Appl. Rate to a Single Site	Form Code(s)	Max. Seasonal Rate	Max. # Apps/cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
Backpack sprayer /Sprayer.							
HOSPITALS/MEDICAL INSTITUTIONS PREMISES (HUMAN/VETERINARY)	Do not apply directly to water or wetlands. 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 directly to water. Do not apply through any type of irrigation system. Do not apply to any body of water. Do not apply when 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 graze livestock in treated areas. Do not graze treated areas.						
Foliar Spot treatment /Spray. Boom sprayer /Ground /Hand held sprayer /Handgun /Power sprayer /Pressure sprayer.	.03084 lb 1K sq.ft 2.025 lb A .01365 lb/1 gal 1.344 lb/100 gal	SC/L	NS	NS NS	NS	NS	
Postemergence Broadcast. Backpack sprayer /Sprayer.	.033 lb 1K sq.ft 1.32 lb A	SC/L	NS	NS NS	NS	NS	
When needed Spot treatment /Spray. Boom sprayer /Handgun /Hose-end sprayer /Power sprayer.	.0112 lb 1K sq.ft 1.344 lb A	SC/L	NS	NS NS	NS	NS	
HOUSEHOLD/DOMESTIC DWELLINGS OUTDOOR PREMISES	Do not apply directly to water or wetlands. 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 directly to water. Do not apply through any type of irrigation system. Do not apply to any body of water.						

SITE NAME	LIMITATIONS						
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate). Application Equipment (for any Reg.# at any rate).	Max. Single Appl. Rate to a Single Site	Form Code(s)	Max. Seasonal Rate	Max. # Apps/cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
	Do not apply when 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. Do not graze livestock in treated areas. Do not graze treated areas.						
After mowing Band treatment. Sprayer.	1.003E-05 lb linear ft	RTU	NS	NS NS	NS	NS	
Foliar Spot treatment /Spray. Boom sprayer /Ground /Hand held sprayer /Handgun /Power sprayer /Pressure sprayer.	.03084 lb 1K sq.ft 2.025 lb A .01365 lb/1 gal 1.344 lb/100 gal	SC/L	NS	NS NS	NS	NS	
When needed Band treatment /Spot treatment /Spray. Boom sprayer /Handgun /Hose-end sprayer /Power sprayer /Sprayer.	.01281 lb 1K linear ft .0112 lb 1K sq.ft 1.344 lb A 1.037E-06 lb linear ft	RTU, SC/L	NS	NSNS	NS	NS	
INDUSTRIAL AREAS (OUTDOOR)	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 directly to water. Do not apply through any type of irrigation system. Do not apply to any body of water. Do not apply when drift is likely to occur. Do not apply when wind velocity is 10 mph or greater. 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.						

SITE NAME	LIMITATIONS						
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate). Application Equipment (for any Reg.# at any rate).	Max. Single Appl. Rate to a Single Site	Form Code(s)	Max. Seasonal Rate	Max. # Apps/cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
	Do not feed or graze animals on treated areas. Do not graze treated areas.						
After mowing Band treatment. Sprayer.	1.003E-05 lb linear ft	RTU	NS	NS NS	NS	NS	
Foliar Spot treatment /Spray. Boom sprayer /Hand held sprayer /Handgun /Power sprayer.	.03084 lb 1K sq.ft 2.025 lb A	SC/L	NS	NS NS	NS	NS	
When needed Band treatment. Sprayer.	.01281 lb 1K linear ft 1.037E-06 lb linear ft	RTU	NS	NS NS	NS	NS	
NONAGRICULTURAL OUTDOOR BUILDINGS/STRUCTURES	Do not apply directly to water or wetlands. 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 directly to water. Do not apply through any type of irrigation system. Do not apply to any body of water. Do not apply when 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. Do not graze livestock in treated areas. Do not graze treated areas.						
After mowing Band treatment. Sprayer.	1.003E-05 lb linear ft	RTU	NS	NS NS	NS	NS	

SITE NAME	LIMITATIONS						
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate). Application Equipment (for any Reg.# at any rate).	Max. Single Appl. Rate to a Single Site	Form Code(s)	Max. Seasonal Rate	Max. # Apps/cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
Foliar Spot treatment /Spray. Boom sprayer /Hand held sprayer /Handgun /Power sprayer.	.03084 lb 1K sq.ft 2.025 lb A	SC/L	NS	NS NS	NS	NS	
Postemergence Broadcast. Backpack sprayer /Sprayer.	.033 lb 1K sq.ft 1.32 lb A	SC/L	NS	NS NS	NS	NS	
When needed Band treatment /Spot treatment /Spray. Boom sprayer /Handgun /Hose-end sprayer /Power sprayer /Sprayer.	.01281 lb 1K linear ft .0112 lb 1K sq.ft 1.344 lb A 1.037E-06 lb linear ft	RTU, SC/L	NS	NS NS	NS	NS	
NONAGRICULTURAL RIGHTS-OF-WAY/FENCEROWS/HEDGEROWS	<p>Do not apply directly to water or wetlands. 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 directly to water. Do not apply through any type of irrigation system. Do not apply to any body of water. Do not apply when drift is likely to occur. Do not apply when wind velocity is 10 mph or greater. 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 or graze animals on treated areas. Do not graze livestock in treated areas. Do not graze treated areas.</p>						
After mowing Band treatment. Sprayer.	1.003E-05 lb linear ft	RTU	NS	NS NS	NS	NS	

SITE NAME	LIMITATIONS						
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate). Application Equipment (for any Reg.# at any rate).	Max. Single Appl. Rate to a Single Site	Form Code(s)	Max. Seasonal Rate	Max. # Apps/cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
Foliar Spot treatment /Spray. Boom sprayer /Ground /Hand held sprayer /Handgun /Power sprayer /Pressure sprayer.	.03084 lb 1K sq.ft 2.025 lb A .01365 lb/1 gal 1.344 lb/100 gal	SC/L	NS	NS NS	NS	NS	
Postemergence Broadcast. Backpack sprayer /Sprayer.	.033 lb 1K sq.ft 1.32 lb A	SC/L	NS	NS NS	NS	NS	
When needed Band treatment /Spot treatment /Spray. Boom sprayer /Handgun /Hose-end sprayer /Power sprayer /Sprayer.	.01281 lb 1K linear ft .0112 lb 1K sq.ft 1.344 lb A 1.037E-06 lb linear ft	RTU, SC/L	NS	NSNS	NS	NS	
NONAGRICULTURAL UNCULTIVATED AREAS/SOILS	Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply through any type of irrigation system. Do not apply to any body of water. Do not apply when drift is likely to occur. Do not apply when wind velocity is 10 mph or greater.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 or graze animals on treated areas.						
Foliar Spray. Power sprayer.	.5788 lb A	SC/L	NS	NS NS	NS	NS	
ORNAMENTAL AND/OR SHADE TREES	Do not apply directly to water or wetlands. 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 directly to water. Do not apply through any type of irrigation system.						

SITE NAME	LIMITATIONS						
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate). Application Equipment (for any Reg.# at any rate).	Max. Single Appl. Rate to a Single Site	Form Code(s)	Max. Seasonal Rate	Max. # Apps/cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
	Do not apply to any body of water. Do not apply when 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 graze livestock in treated areas. Do not graze treated areas.						
Foliar Broadcast /Spray. Hand held sprayer /Power sprayer /Sprayer.	.033 lb 1K sq.ft 2.025 lb A	SC/L	NS	NS NS	NS	NS	Geographic allowable: CA
Postemergence Broadcast. Backpack sprayer /Sprayer.	.033 lb 1K sq.ft 1.32 lb A	SC/L	NS	NS NS	NS	NS	
When needed Spot treatment /Spray. Boom sprayer /Handgun /Hose-end sprayer /Power sprayer.	.0112 lb 1K sq.ft 1.344 lb A	SC/L	NS	NS NS	NS	NS	
ORNAMENTAL GROUND COVER	Do not apply directly to water or wetlands. 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 directly to water. Do not apply through any type of irrigation system. Do not apply to any body of water. Do not apply when 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 graze treated areas.						
Foliar Broadcast /Spray.Ground /Hand	.033 lb 1K sq.ft 2.025 lb A.01365	SC/L	NS	NS NS	NS	NS	Geographic allowable: CA

SITE NAME	LIMITATIONS						
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate). Application Equipment (for any Reg.# at any rate).	Max. Single Appl. Rate to a Single Site	Form Code(s)	Max. Seasonal Rate	Max. # Apps/cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
Hand held sprayer /Power sprayer /Pressure sprayer /Sprayer.	lb/1 gal 1.344 lb/100 gal						
Postemergence Broadcast. Backpack sprayer /Sprayer.	.033 lb 1K sq.ft 1.32 lb A	SC/L	NS	NS NS	NS	NS	
ORNAMENTAL HERBACEOUS PLANTS	Do not apply directly to water or wetlands. 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 directly to water. Do not apply through any type of irrigation system. Do not apply to any body of water. Do not apply when 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 graze livestock in treated areas. Do not graze treated areas.						
Foliar Broadcast /Spray. Hand held sprayer /Power sprayer /Sprayer.	.033 lb 1K sq.ft 2.025 lb A	SC/L	NS	NS NS	NS	NS	Geographic allowable: CA
Postemergence Broadcast. Backpack sprayer /Sprayer.	.033 lb 1K sq.ft 1.32 lb A	SC/L	NS	NS NS	NS	NS	
When needed Spot treatment /Spray. Boom sprayer /Handgun /Hose-end sprayer /Power sprayer.	.0112 lb 1K sq.ft 1.344 lb A	SC/L	NS	NS NS	NS	NS	
ORNAMENTAL LAWNS AND TURF	Do not apply directly to water or wetlands. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark.						

SITE NAME	LIMITATIONS						
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate). Application Equipment (for any Reg.# at any rate).	Max. Single Appl. Rate to a Single Site	Form Code(s)	Max. Seasonal Rate	Max. # Apps/cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
	Do not apply directly to water. Do not apply through any type of irrigation system. Do not apply to any body of water. Do not apply when 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. Do not feed clippings to livestock. Do not graze treated areas.						
After mowing Band treatment. Sprayer.	1.003E-05 lb linear ft	RTU	NS	NS NS	NS	NS	
Foliar Broadcast /Spot treatment /Spray. Boom sprayer /Hand held sprayer /Handgun /Hose-end sprayer /Power sprayer /Pressure sprayer /Sprayer.	.0336 lb 1K sq.ft 1.344 lb A	SC/L	NS	NS NS	42	NS	Geographic allowable: CA
Postemergence Broadcast. Backpack sprayer /Sprayer /Spreader.	.033 lb 1K sq.ft 1.32 lb A	G, SC/L	NS	NS NS	NS	NS	
When needed Band treatment. Sprayer.	.01281 lb 1K linear ft 1.037E-06 lb linear ft	RTU	NS	NS NS	NS	NS	
ORNAMENTAL NONFLOWERING PLANTS	Do not apply directly to water or wetlands. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark.						

SITE NAME	LIMITATIONS						
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate). Application Equipment (for any Reg.# at any rate).	Max. Single Appl. Rate to a Single Site	Form Code(s)	Max. Seasonal Rate	Max. # Apps/cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
	Do not apply directly to water. Do not apply through any type of irrigation system. Do not apply to any body of water. Do not apply when 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 graze livestock in treated areas.Do not graze treated areas.						
Foliar Broadcast /Spray. Hand held sprayer /Power sprayer /Sprayer.	.033 lb 1K sq.ft 2.025 lb A	SC/L	NS	NS NS	NS	NS	Geographic allowable: CA
Postemergence Broadcast. Backpack sprayer /Sprayer.	.033 lb 1K sq.ft 1.32 lb A	SC/L	NS	NS NS	NS	NS	
When needed Spot treatment /Spray. Boom sprayer /Handgun /Hose-end sprayer /Power sprayer.	.0112 lb 1K sq.ft 1.344 lb A	SC/L	NS	NS NS	NS	NS	
ORNAMENTAL WOODY SHRUBS AND VINES	Do not apply directly to water or wetlands. 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 directly to water. Do not apply through any type of irrigation system. Do not apply to any body of water. Do not apply when 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 graze livestock in treated areas.Do not graze treated areas.						
Foliar	.033 lb 1K sq.ft	SC/L	NS	NS	NS	NS	Geographic allowable: CA

SITE NAME	LIMITATIONS						
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate). Application Equipment (for any Reg.# at any rate).	Max. Single Appl. Rate to a Single Site	Form Code(s)	Max. Seasonal Rate	Max. # Apps/ cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
Broadcast /Spray. Hand held sprayer /Power sprayer /Sprayer.	2.025 lb A			NS			
Postemergence Broadcast. Backpack sprayer /Sprayer.	.033 lb 1K sq.ft 1.32 lb A	SC/L	NS	NS NS	NS	NS	
When needed Spot treatment /Spray. Boom sprayer /Handgun /Hose-end sprayer /Power sprayer.	.0112 lb 1K sq.ft 1.344 lb A	SC/L	NS	NS NS	NS	NS	
PATHS/PATIOS	<p>Do not apply directly to water or wetlands. 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 directly to water. Do not apply through any type of irrigation system. Do not apply when 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. Do not graze livestock in treated areas.Do not graze treated areas.</p>						
After mowing Band treatment. Sprayer.	1.003E-05 lb linear ft	RTU	NS	NS NS	NS	NS	
Foliar Spray. Ground /Pressure sprayer.	.01365 lb/1 gal 1.344 lb/100 gal	SC/L	NS	NS NS	NS	NS	
Postemergence Broadcast.	.033 lb 1K sq.ft 1.32 lb A	SC/L	NS	NS NS	NS	NS	

SITE NAME	LIMITATIONS						
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate). Application Equipment (for any Reg.# at any rate).	Max. Single Appl. Rate to a Single Site	Form Code(s)	Max. Seasonal Rate	Max. # Apps/cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
Backpack sprayer /Sprayer.							
When needed Band treatment /Spot treatment /Spray. Boom sprayer /Handgun /Hose-end sprayer /Power sprayer /Sprayer.	.01281 lb 1K linear ft .0112 lb 1K sq.ft 1.344 lb A 1.037E-06 lb linear ft	RTU, SC/L	NS	NS NS	NS	NS	
PAVED AREAS (PRIVATE ROADS/SIDEWALKS)	Do not apply directly to water or wetlands.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 directly to water. Do not apply through any type of irrigation system. Do not apply to any body of water. Do not apply when 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. Do not graze livestock in treated areas. Do not graze treated areas.						
After mowing Band treatment. Sprayer.	1.003E-05 lb linear ft	RTU	NS	NS NS	NS	NS	
Foliar Spot treatment /Spray. Boom sprayer /Hand held sprayer /Handgun /Power sprayer.	.03084 lb 1K sq.ft 2.025 lb A	SC/L	NS	NS NS	NS	NS	
Postemergence Broadcast. Backpack sprayer /Sprayer.	.033 lb 1K sq.ft 1.32 lb A	SC/L	NS	NS NS	NS	NS	

SITE NAME	LIMITATIONS						
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate). Application Equipment (for any Reg.# at any rate).	Max. Single Appl. Rate to a Single Site	Form Code(s)	Max. Seasonal Rate	Max. # Apps/cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
When needed Band treatment /Spot treatment /Spray.Boom sprayer /Handgun /Hose-end sprayer /Power sprayer /Sprayer.	.01281 lb 1K linear ft .0112 lb 1K sq.ft 1.344 lb A 1.037E-06 lb linear ft	RTU, SC/L	NS	NS NS	NS	NS	
RECREATION AREA LAWNS	Do not apply directly to water or wetlands. 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 directly to water. Do not apply through any type of irrigation system. Do not apply to any body of water. Do not apply when drift is likely to occur. Do not apply when wind velocity is 10 mph or greater. 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 or graze animals on treated areas. Do not graze treated areas.						
Foliar Spot treatment /Spray. Boom sprayer /Hand held sprayer /Handgun /Hose-end sprayer /Power sprayer /Pressure sprayer.	.0336 lb 1K sq.ft 1.344 lb A	SC/L	NS	NS NS	42	NS	
Postemergence Broadcast. Backpack sprayer /Sprayer.	.033 lb 1K sq.ft 1.32 lb A	SC/L	NS	NS NS	NS	NS	
RESIDENTIAL LAWNS	Do not apply directly to water or wetlands. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply through any type of irrigation system. Do not apply when drift is likely to occur.						

SITE NAME	LIMITATIONS						
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate). Application Equipment (for any Reg.# at any rate).	Max. Single Appl. Rate to a Single Site	Form Code(s)	Max. Seasonal Rate	Max. # Apps/cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
Do not contaminate water by cleaning of equipment or disposal of equipment wash waters.Do not graze treated areas.							
Foliar Spot treatment /Spray. Boom sprayer /Handgun /Hose-end sprayer /Power sprayer /Pressure sprayer.	.0336 lb 1K sq.ft 1.344 lb A	SC/L	NS	NS NS	42	NS	

NON-FOOD/NON-FEED USE PATTERNS SUMMARY FOR Mefluidide, diethanolamine salt (CASE 2370)

Application rates calculated in terms of Acid Equivalent.

SITE NAME	LIMITATIONS						
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate). Application Equipment (for any Reg.# at any rate).	Max. Single Appl. Rate to a Single Site	Form Code(s)	Max. Seasonal Rate	Max. # Apps/cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
AGRICULTURAL UNCULTIVATED AREAS	Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply through any type of irrigation system. Do not apply to any body of water. Do not apply when 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 graze treated areas.						
Foliar Spot treatment /Spray.	.02344 lb (AE) 1K sq.ft	SC/L	NS	NS NS	NS	NS	

SITE NAME	LIMITATIONS						
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate). Application Equipment (for any Reg.# at any rate).	Max. Single Appl. Rate to a Single Site	Form Code(s)	Max. Seasonal Rate	Max. # Apps/cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
Boom sprayer /Hand held sprayer /Handgun.	1 lb (AE) A						
AGRICULTURAL/FARM STRUCTURES/BUILDINGS AND EQUIPMENT	Do not apply directly to water or wetlands. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply through any type of irrigation system. Do not apply when drift is likely to occur. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Do not graze livestock in treated areas. Do not graze treated areas.						
Foliar Spray. Ground /Pressure sprayer.	8.531E-04 lb (AE)/1 gal .084 lb (AE)/100 gal	SC/L	NS	NS NS	NS	NS	
When needed Spot treatment /Spray. Boom sprayer /Handgun /Hose-end sprayer /Power sprayer.	7.000E-04 lb (AE) 1K sq.ft .084 lb (AE) A	SC/L	NS	NS NS	NS	NS	
AIRPORTS/LANDING FIELDS	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 directly to water. Do not apply through any type of irrigation system. Do not apply to any body of water. Do not apply when drift is likely to occur. Do not apply when wind velocity is 10 mph or greater. 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 or graze animals on treated areas. Do not graze treated areas.						
Foliar Spot treatment /Spray. Boom sprayer /Hand held sprayer	(L) .02344 lb (AE) 1K sq.ft	SC/L	NS	NS NS	NS	NS	

SITE NAME	LIMITATIONS						
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate). Application Equipment (for any Reg.# at any rate).	Max. Single Appl. Rate to a Single Site	Form Code(s)	Max. Seasonal Rate	Max. # Apps/cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
Handgun /Power sprayer.	1.539 lb (AE) A						
Postemergence Broadcast. Backpack sprayer /Sprayer.	.025 lb (AE) 1K sq.ft 1 lb (AE) A	SC/L	NS	NS NS	NS	NS	
COMMERCIAL/INDUSTRIAL LAWNS	Do not apply directly to water or wetlands. 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 directly to water. Do not apply through any type of irrigation system. Do not apply to any body of water. Do not apply when 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 graze treated areas.						
Foliar Spot treatment /Spray. Boom sprayer /Hand held sprayer Handgun /Hose-end sprayer Power sprayer /Pressure sprayer.	.02344 lb (AE) 1K sq.ft 1 lb (AE) A	SC/L	NS	NS NS	42	NS	
Postemergence Broadcast. Backpack sprayer /Sprayer.	.025 lb (AE) 1K sq.ft 1 lb (AE) A	SC/L	NS	NS NS	NS	NS	
COMMERCIAL/INSTITUTIONAL/INDUSTRIAL PREMISES/EQUIP. (INDOOR)	Do not apply directly to water or wetlands. 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 directly to water. Do not apply through any type of irrigation system. Do not apply to any body of water. Do not apply when drift is likely to occur. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters.						

SITE NAME	LIMITATIONS						
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate). Application Equipment (for any Reg.# at any rate).	Max. Single Appl. Rate to a Single Site	Form Code(s)	Max. Seasonal Rate	Max. # Apps/cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
	Do not contaminate water, food, or feed by storage or disposal. Do not graze livestock in treated areas. Do not graze treated areas.						
Foliar Spot treatment /Spray. Boom sprayer /Ground /Hand held sprayer /Handgun /Power sprayer /Pressure sprayer.	.02344 lb (AE) 1K sq.ft 1.539 lb (AE) A 8.531E-04 lb (AE)/1 gal .084 lb (AE)/100 gal	SC/L	NS	NS NS	NS	NS	
Postemergence Broadcast. Backpack sprayer /Sprayer.	.025 lb (AE) 1K sq.ft 1 lb (AE) A	SC/L	NS	NS NS	NS	NS	
When needed Spot treatment /Spray. Boom sprayer /Handgun /Hose-end sprayer /Power sprayer.	7.000E-04 lb (AE) 1K sq.ft .084 lb (AE) A	SC/L	NS	NS NS	NS	NS	
FENCEROWS/HEDGEROWS	Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply through any type of irrigation system. Do not apply to any body of water. Do not apply when drift is likely to occur. Do not apply when wind velocity is 10 mph or greater. 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 or graze animals on treated areas.						
Foliar Spray. Power sprayer.	(L)	SC/L	NS	NS NS	NS	NS	

SITE NAME	LIMITATIONS						
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate). Application Equipment (for any Reg.# at any rate).	Max. Single Appl. Rate to a Single Site	Form Code(s)	Max. Seasonal Rate	Max. # Apps/cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
GOLF COURSE TURF	Do not apply directly to water or wetlands. 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 directly to water. Do not apply through any type of irrigation system. Do not apply to any body of water. Do not apply when drift is likely to occur. Do not apply when wind velocity is 10 mph or greater. 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 or graze animals on treated areas. Do not graze treated areas.						
Foliar Spot treatment /Spray. Boom sprayer /Hand held sprayer Handgun /Hose-end sprayer Power sprayer /Pressure sprayer.	(L) .02344 lb (AE) 1K sq.ft 1 lb (AE) A	SC/L	NS	NS NS	42	NS	
Postemergence Broadcast. Backpack sprayer /Sprayer.	.025 lb (AE) 1K sq.ft 1 lb (AE) A	SC/L	NS	NS NS	NS	NS	
HOSPITALS/MEDICAL INSTITUTIONS PREMISES (HUMAN/VETERINARY)	Do not apply directly to water or wetlands. 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 directly to water. Do not apply through any type of irrigation system. Do not apply to any body of water. Do not apply when 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 graze livestock in treated areas. Do not graze treated areas.						

SITE NAME	LIMITATIONS						
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate). Application Equipment (for any Reg.# at any rate).	Max. Single Appl. Rate to a Single Site	Form Code(s)	Max. Seasonal Rate	Max. # Apps/cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
Foliar Spot treatment /Spray. Boom sprayer /Ground /Hand held sprayer /Handgun /Power sprayer /Pressure sprayer.	.02344 lb (AE) 1K sq.ft 1.539 lb (AE) A 8.531E-04 lb (AE)/1 gal .084 lb (AE)/100 gal	SC/L	NS	NS NS	NS	NS	
Postemergence Broadcast. Backpack sprayer /Sprayer.	.025 lb (AE) 1K sq.ft 1 lb (AE) A	SC/L	NS	NS NS	NS	NS	
When needed Spot treatment /Spray. Boom sprayer /Handgun /Hose-end sprayer /Power sprayer.	7.000E-04 lb (AE) 1K sq.ft .084 lb (AE) A	SC/L	NS	NS NS	NS	NS	
HOUSEHOLD/DOMESTIC DWELLINGS OUTDOOR PREMISES	Do not apply directly to water or wetlands. 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 directly to water. Do not apply through any type of irrigation system. Do not apply to any body of water. Do not apply when 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. Do not graze livestock in treated areas. Do not graze treated areas.						
After mowing Band treatment. Sprayer.	7.480E-06 lb (AE) linear ft	RTU	NS	NS NS	NS	NS	
Foliar	.02344 lb (AE) 1K	SC/L	NS	NS	NS	NS	

SITE NAME	LIMITATIONS						
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate). Application Equipment (for any Reg.# at any rate).	Max. Single Appl. Rate to a Single Site	Form Code(s)	Max. Seasonal Rate	Max. # Apps/cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
Spot treatment /Spray. Boom sprayer /Ground /Hand held sprayer /Handgun /Power sprayer /Pressure sprayer.	sq.ft 1.539 lb (AE) A 8.531E-04 lb (AE)/1 gal .084 lb (AE)/100 gal			NS			
When needed Band treatment /Spot treatment /Spray. Boom sprayer /Handgun /Hose-end sprayer /Power sprayer /Sprayer.	.009338 lb (AE) 1K linear ft 7.000E-04 lb (AE) 1K sq.ft .084 lb (AE) A 8.062E-07 lb (AE) linear ft	RTU, SC/L	NS	NSNS	NS	NS	
INDUSTRIAL AREAS (OUTDOOR)	<p>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 directly to water. Do not apply through any type of irrigation system. Do not apply to any body of water. Do not apply when drift is likely to occur. Do not apply when wind velocity is 10 mph or greater. 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 or graze animals on treated areas. Do not graze treated areas.</p>						
After mowing Band treatment. Sprayer.	7.480E-06 lb (AE) linear ft	RTU	NS	NS NS	NS	NS	
Foliar Spot treatment /Spray. Boom sprayer /Hand held sprayer	(L) .02344 lb (AE) 1K sq.ft 1.539 lb (AE) A	SC/L	NS	NS NS	NS	NS	

SITE NAME	LIMITATIONS						
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate). Application Equipment (for any Reg.# at any rate).	Max. Single Appl. Rate to a Single Site	Form Code(s)	Max. Seasonal Rate	Max. # Apps/cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
/Handgun /Power sprayer.							
When needed Band treatment. Sprayer.	.009338 lb (AE) 1K linear ft 8.062E-07 lb (AE) linear ft	RTU	NS	NS NS	NS	NS	
NONAGRICULTURAL OUTDOOR BUILDINGS/STRUCTURES	<p>Do not apply directly to water or wetlands. 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 directly to water. Do not apply through any type of irrigation system. Do not apply to any body of water. Do not apply when 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. Do not graze livestock in treated areas. Do not graze treated areas.</p>						
After mowing Band treatment. Sprayer.	7.480E-06 lb (AE) linear ft	RTU	NS	NS NS	NS	NS	
Foliar Spot treatment /Spray. Boom sprayer /Hand held sprayer /Handgun /Power sprayer.	.02344 lb (AE) 1K sq.ft 1.539 lb (AE) A	SC/L	NS	NS NS	NS	NS	
Postemergence Broadcast. Backpack sprayer /Sprayer.	.025 lb (AE) 1K sq.ft 1 lb (AE) A	SC/L	NS	NS NS	NS	NS	
When needed	.009338 lb (AE) 1K	RTU, SC/L	NS	NS	NS	NS	

SITE NAME	LIMITATIONS						
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate). Application Equipment (for any Reg.# at any rate).	Max. Single Appl. Rate to a Single Site	Form Code(s)	Max. Seasonal Rate	Max. # Apps/cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
Band treatment /Spot treatment /Spray. Boom sprayer /Handgun /Hose-end sprayer /Power sprayer /Sprayer.	linear ft 7.000E-04 lb (AE) 1K sq.ft .084 lb (AE) A 8.062E-07 lb (AE) linear ft			NS			
NONAGRICULTURAL RIGHTS-OF-WAY/FENCEROWS/HEDGEROWS	Do not apply directly to water or wetlands. 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 directly to water. Do not apply through any type of irrigation system. Do not apply to any body of water. Do not apply when drift is likely to occur. Do not apply when wind velocity is 10 mph or greater. 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 or graze animals on treated areas. Do not graze livestock in treated areas. Do not graze treated areas.						
After mowing Band treatment. Sprayer.	7.480E-06 lb (AE) linear ft	RTU	NS	NS NS	NS	NS	
Foliar Spot treatment /Spray. Boom sprayer /Ground /Hand held sprayer /Handgun /Power sprayer /Pressure sprayer.	(L) .02344 lb (AE) 1K sq.ft 1.539 lb (AE) A 8.531E-04 lb (AE)/1 gal .084 lb (AE)/100 gal	SC/L	NS	NS NS	NS	NS	

SITE NAME	LIMITATIONS						
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate). Application Equipment (for any Reg.# at any rate).	Max. Single Appl. Rate to a Single Site	Form Code(s)	Max. Seasonal Rate	Max. # Apps/cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
Postemergence Broadcast. Backpack sprayer /Sprayer.	.025 lb (AE) 1K sq.ft 1 lb (AE) A	SC/L	NS	NS NS	NS	NS	
When needed Band treatment /Spot treatment /Spray. Boom sprayer /Handgun /Hose-end sprayer /Power sprayer /Sprayer.	.009338 lb (AE) 1K linear ft 7.000E-04 lb (AE) 1K sq.ft .084 lb (AE) A 8.062E-07 lb (AE) linear ft	RTU, SC/L	NS	NSNS	NS	NS	
NONAGRICULTURAL UNCULTIVATED AREAS/SOILS	<p>Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply through any type of irrigation system. Do not apply to any body of water. Do not apply when drift is likely to occur. Do not apply when wind velocity is 10 mph or greater. 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 or graze animals on treated areas.</p>						
Foliar Spray. Power sprayer.	(L)	SC/L	NS	NS NS	NS	NS	
ORNAMENTAL AND/OR SHADE TREES	<p>Do not apply directly to water or wetlands. 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 directly to water. Do not apply through any type of irrigation system. Do not apply to any body of water. Do not apply when 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 graze livestock in treated areas.</p>						

SITE NAME	LIMITATIONS						
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate). Application Equipment (for any Reg.# at any rate).	Max. Single Appl. Rate to a Single Site	Form Code(s)	Max. Seasonal Rate	Max. # Apps/cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
	Do not graze treated areas.						
Foliar Broadcast /Spray. Hand held sprayer /Power sprayer /Sprayer.	.025 lb (AE) 1K sq.ft 1.539 lb (AE) A	SC/L	NS	NS NS	NS	NS	Geographic allowable: CA
Postemergence Broadcast. Backpack sprayer /Sprayer.	.025 lb (AE) 1K sq.ft 1 lb (AE) A	SC/L	NS	NS NS	NS	NS	
When needed Spot treatment /Spray. Boom sprayer /Handgun /Hose-end sprayer /Power sprayer.	7.000E-04 lb (AE) 1K sq.ft .084 lb (AE) A	SC/L	NS	NS NS	NS	NS	
ORNAMENTAL GROUND COVER	Do not apply directly to water or wetlands. 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 directly to water. Do not apply through any type of irrigation system. Do not apply to any body of water. Do not apply when 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 graze treated areas.						
Foliar Broadcast /Spray.Ground /Hand held sprayer /Power sprayer /Pressure sprayer /Sprayer.	.025 lb (AE) 1K sq.ft 1.539 lb (AE) A8.531E-04 lb (AE)/1 gal .084 lb (AE)/100 gal	SC/L	NS	NS NS	NS	NS	Geographic allowable: CA

SITE NAME	LIMITATIONS						
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate). Application Equipment (for any Reg.# at any rate).	Max. Single Appl. Rate to a Single Site	Form Code(s)	Max. Seasonal Rate	Max. # Apps/cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
Postemergence Broadcast. Backpack sprayer /Sprayer.	.025 lb (AE) 1K sq.ft 1 lb (AE) A	SC/L	NS	NS NS	NS	NS	
ORNAMENTAL HERBACEOUS PLANTS	Do not apply directly to water or wetlands. 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 directly to water. Do not apply through any type of irrigation system. Do not apply to any body of water. Do not apply when 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 graze livestock in treated areas. Do not graze treated areas.						
Foliar Broadcast /Spray. Hand held sprayer /Power sprayer /Sprayer.	.025 lb (AE) 1K sq.ft 1.539 lb (AE) A	SC/L	NS	NS NS	NS	NS	Geographic allowable: CA
Postemergence Broadcast. Backpack sprayer /Sprayer.	.025 lb (AE) 1K sq.ft 1 lb (AE) A	SC/L	NS	NSNS	NS	NS	
When needed Spot treatment /Spray. Boom sprayer /Handgun /Hose-end sprayer /Power sprayer.	7.000E-04 lb (AE) 1K sq.ft .084 lb (AE) A	SC/L	NS	NS NS	NS	NS	
ORNAMENTAL LAWNS AND TURF	Do not apply directly to water or wetlands. 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 directly to water. Do not apply through any type of irrigation system. Do not apply to any body of water.						

SITE NAME	LIMITATIONS						
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate). Application Equipment (for any Reg.# at any rate).	Max. Single Appl. Rate to a Single Site	Form Code(s)	Max. Seasonal Rate	Max. # Apps/cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
	Do not apply when 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. Do not feed clippings to livestock. Do not graze treated areas.						
After mowing Band treatment. Sprayer.	7.480E-06 lb (AE) linear ft	RTU	NS	NS NS	NS	NS	
Foliar Broadcast /Spot treatment /Spray. Boom sprayer /Hand held sprayer /Handgun /Hose-end sprayer /Power sprayer /Pressure sprayer /Sprayer.	.025 lb (AE) 1K sq.ft 1 lb (AE) A	SC/L	NS	NS NS	42	NS	Geographic allowable: CA
Postemergence Broadcast. Backpack sprayer /Sprayer /Spreader.	.025 lb (AE) 1K sq.ft 1 lb (AE) A (L)	G, SC/L	NS	NS NS	NS	NS	
When needed Band treatment. Sprayer.	.009338 lb (AE) 1K linear ft 8.062E-07 lb (AE) linear ft	RTU	NS	NS NS	NS	NS	
ORNAMENTAL NONFLOWERING PLANTS	Do not apply directly to water or wetlands. 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 directly to water. Do not apply through any type of irrigation system. Do not apply to any body of water.						

SITE NAME	LIMITATIONS						
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate). Application Equipment (for any Reg.# at any rate).	Max. Single Appl. Rate to a Single Site	Form Code(s)	Max. Seasonal Rate	Max. # Apps/cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
	Do not apply when 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 graze livestock in treated areas.Do not graze treated areas.						
Foliar Broadcast /Spray. Hand held sprayer /Power sprayer /Sprayer.	.025 lb (AE) 1K sq.ft 1.539 lb (AE) A	SC/L	NS	NS NS	NS	NS	Geographic allowable: CA
Postemergence Broadcast. Backpack sprayer /Sprayer.	.025 lb (AE) 1K sq.ft 1 lb (AE) A	SC/L	NS	NS NS	NS	NS	
When needed Spot treatment /Spray. Boom sprayer /Handgun /Hose-end sprayer /Power sprayer.	7.000E-04 lb (AE) 1K sq.ft .084 lb (AE) A	SC/L	NS	NS NS	NS	NS	
ORNAMENTAL WOODY SHRUBS AND VINES	Do not apply directly to water or wetlands. 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 directly to water. Do not apply through any type of irrigation system. Do not apply to any body of water. Do not apply when 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 graze livestock in treated areas.Do not graze treated areas.						
Foliar Broadcast /Spray. Hand held sprayer /Power sprayer /Sprayer.	.025 lb (AE) 1K sq.ft 1.539 lb (AE) A	SC/L	NS	NS NS	NS	NS	Geographic allowable: CA

SITE NAME	LIMITATIONS						
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate). Application Equipment (for any Reg.# at any rate).	Max. Single Appl. Rate to a Single Site	Form Code(s)	Max. Seasonal Rate	Max. # Apps/cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
Postemergence Broadcast. Backpack sprayer /Sprayer.	.025 lb (AE) 1K sq.ft 1 lb (AE) A	SC/L	NS	NS NS	NS	NS	
When needed Spot treatment /Spray. Boom sprayer /Handgun /Hose-end sprayer /Power sprayer.	7.000E-04 lb (AE) 1K sq.ft .084 lb (AE) A	SC/L	NS	NS NS	NS	NS	
PATHS/PATIOS	Do not apply directly to water or wetlands. 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 directly to water. Do not apply through any type of irrigation system. Do not apply when 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. Do not graze livestock in treated areas.Do not graze treated areas.						
After mowing Band treatment. Sprayer.	7.480E-06 lb (AE) linear ft	RTU	NS	NS NS	NS	NS	
Foliar Spray. Ground /Pressure sprayer.	8.531E-04 lb (AE)/1 gal .084 lb (AE)/100 gal	SC/L	NS	NS NS	NS	NS	
Postemergence Broadcast. Backpack sprayer /Sprayer.	.025 lb (AE) 1K sq.ft 1 lb (AE) A	SC/L	NS	NS NS	NS	NS	
When needed Band treatment /Spot treatment	.009338 lb (AE) 1K linear ft	RTU, SC/L	NS	NS NS	NS	NS	

SITE NAME	LIMITATIONS						
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate). Application Equipment (for any Reg.# at any rate).	Max. Single Appl. Rate to a Single Site	Form Code(s)	Max. Seasonal Rate	Max. # Apps/cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
/Spray. Boom sprayer /Handgun /Hose-end sprayer /Power sprayer /Sprayer.	7.000E-04 lb (AE) 1K sq.ft .084 lb (AE) A 8.062E-07 lb (AE) linear ft						
PAVED AREAS (PRIVATE ROADS/SIDEWALKS)	Do not apply directly to water or wetlands.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 directly to water. Do not apply through any type of irrigation system. Do not apply to any body of water. Do not apply when 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. Do not graze livestock in treated areas. Do not graze treated areas.						
After mowing Band treatment. Sprayer.	7.480E-06 lb (AE) linear ft	RTU	NS	NS NS	NS	NS	
Foliar Spot treatment /Spray. Boom sprayer /Hand held sprayer /Handgun /Power sprayer.	.02344 lb (AE) 1K sq.ft 1.539 lb (AE) A	SC/L	NS	NS NS	NS	NS	
Postemergence Broadcast. Backpack sprayer /Sprayer.	.025 lb (AE) 1K sq.ft 1 lb (AE) A	SC/L	NS	NS NS	NS	NS	
When needed Band treatment /Spot treatment	.009338 lb (AE) 1K linear ft	RTU, SC/L	NS	NS NS	NS	NS	

SITE NAME	LIMITATIONS						
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate). Application Equipment (for any Reg.# at any rate).	Max. Single Appl. Rate to a Single Site	Form Code(s)	Max. Seasonal Rate	Max. # Apps/cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
Spray.Boom sprayer /Handgun Hose-end sprayer /Power sprayer Sprayer.	7.000E-04 lb (AE) 1K sq.ft .084 lb (AE) A 8.062E-07 lb (AE) linear ft						
RECREATION AREA LAWNS	Do not apply directly to water or wetlands. 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 directly to water. Do not apply through any type of irrigation system. Do not apply to any body of water. Do not apply when drift is likely to occur. Do not apply when wind velocity is 10 mph or greater. 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 or graze animals on treated areas. Do not graze treated areas.						
Foliar Spot treatment /Spray. Boom sprayer /Hand held sprayer Handgun /Hose-end sprayer Power sprayer /Pressure sprayer.	(L) .02344 lb (AE) 1K sq.ft 1 lb (AE) A	SC/L	NS	NS NS	42	NS	
Postemergence Broadcast. Backpack sprayer /Sprayer.	.025 lb (AE) 1K sq.ft 1 lb (AE) A	SC/L	NS	NS NS	NS	NS	
RESIDENTIAL LAWNS	Do not apply directly to water or wetlands. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply through any type of irrigation system. Do not apply when drift is likely to occur. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters.Do not graze treated areas.						

Foliar Spot treatment /Spray. Boom sprayer /Handgun /Hose- end sprayer /Power sprayer /Pressure sprayer.	.0021 lb (AE) 1K sq.ft .084 lb (AE) A	SC/L	NS	NS NS	42	NS	
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NON-FOOD/NON-FEED USE PATTERNS SUMMARY FOR Potassium mefluidide (CASE 2370)

US EPA ARCHIVE DOCUMENT

SITE NAME	LIMITATIONS						
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate). Application Equipment (for any Reg.# at any rate).	Max. Single Appl. Rate to a Single Site	Form Code(s)	Max. Seasonal Rate	Max. # Apps/cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
AIRPORTS/LANDING FIELDS	Do not apply directly to water. Do not apply when drift is likely to occur. Do not contaminate water by cleaning of equipment or disposal of waste. Do not contaminate water, food, or feed by storage or disposal. Do not graze livestock in treated areas.						
When needed Broadcast. Backpack sprayer /Sprayer.	.025 lb 1K sq.ft 1 lb A	SC/L	NS	NS NS	NS	NS	
COMMERCIAL/INDUSTRIAL LAWNS	Do not apply directly to water. Do not apply when drift is likely to occur. Do not contaminate water by cleaning of equipment or disposal of waste. Do not contaminate water, food, or feed by storage or disposal. Do not graze livestock in treated areas.						
When needed Broadcast. Backpack sprayer /Sprayer.	.025 lb 1K sq.ft 1 lb A	SC/L	NS	NS NS	NS	NS	
COMMERCIAL/INSTITUTIONAL/INDUSTRIAL PREMISES/EQUIPMENT (OUTDOOR)	Do not apply directly to water. Do not apply when drift is likely to occur. Do not contaminate water by cleaning of equipment or disposal of waste. Do not contaminate water, food, or feed by storage or disposal. Do not graze livestock in treated areas.						
When needed Broadcast. Backpack sprayer /Sprayer.	.025 lb 1K sq.ft 1 lb A	SC/L	NS	NS NS	NS	NS	
GOLF COURSE TURF	Do not apply directly to water.						

SITE NAME	LIMITATIONS						
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate). Application Equipment (for any Reg.# at any rate).	Max. Single Appl. Rate to a Single Site	Form Code(s)	Max. Seasonal Rate	Max. # Apps/cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
	Do not apply when drift is likely to occur. Do not contaminate water by cleaning of equipment or disposal of waste. Do not contaminate water, food, or feed by storage or disposal. Do not graze livestock in treated areas.						
When needed Broadcast. Backpack sprayer /Sprayer.	.025 lb 1K sq.ft 1 lb A	SC/L	NS	NS NS	NS	NS	
HOSPITALS/MEDICAL INSTITUTIONS PREMISES (HUMAN/VETERINARY)	Do not apply directly to water. Do not apply when drift is likely to occur. Do not contaminate water by cleaning of equipment or disposal of waste. Do not contaminate water, food, or feed by storage or disposal. Do not graze livestock in treated areas.						
When needed Broadcast. Backpack sprayer /Sprayer.	.025 lb 1K sq.ft 1 lb A	SC/L	NS	NS NS	NS	NS	
INDUSTRIAL AREAS (OUTDOOR)	Do not apply directly to water. Do not apply when drift is likely to occur. Do not contaminate water by cleaning of equipment or disposal of waste. Do not contaminate water, food, or feed by storage or disposal. Do not graze livestock in treated areas.						
When needed Broadcast. Backpack sprayer /Sprayer.	.025 lb 1K sq.ft 1 lb A	SC/L	NS	NS NS	NS	NS	
NONAGRICULTURAL OUTDOOR BUILDINGS/STRUCTURES	Do not apply directly to water. Do not apply when drift is likely to occur. Do not contaminate water by cleaning of equipment or disposal of waste. Do not contaminate water, food, or feed by storage or disposal. Do not graze livestock in treated areas.						

SITE NAME	LIMITATIONS						
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate). Application Equipment (for any Reg.# at any rate).	Max. Single Appl. Rate to a Single Site	Form Code(s)	Max. Seasonal Rate	Max. # Apps/cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
When needed Broadcast. Backpack sprayer /Sprayer.	.025 lb 1K sq.ft 1 lb A	SC/L	NS	NS NS	NS	NS	
NONAGRICULTURAL RIGHTS-OF-WAY/FENCEROWS/HEDGEROWS	Do not apply directly to water. Do not apply when drift is likely to occur. Do not contaminate water by cleaning of equipment or disposal of waste. Do not contaminate water, food, or feed by storage or disposal. Do not graze livestock in treated areas.						
When needed Broadcast. Backpack sprayer /Sprayer.	.025 lb 1K sq.ft 1 lb A	SC/L	NS	NS NS	NS	NS	
PATHS/PATIOS	Do not apply directly to water. Do not apply when drift is likely to occur. Do not contaminate water by cleaning of equipment or disposal of waste. Do not contaminate water, food, or feed by storage or disposal. Do not graze livestock in treated areas.						
When needed Broadcast. Backpack sprayer /Sprayer.	.025 lb 1K sq.ft 1 lb A	SC/L	NS	NS NS	NS	NS	
PAVED AREAS (PRIVATE ROADS/SIDEWALKS)	Do not apply directly to water. Do not apply when drift is likely to occur. Do not contaminate water by cleaning of equipment or disposal of waste. Do not contaminate water, food, or feed by storage or disposal. Do not graze livestock in treated areas.						
When needed Broadcast. Backpack sprayer /Ground	.025 lb 1K sq.ft 1 lb A	SC/L	NS	NS NS	NS	NS	

SITE NAME	LIMITATIONS						
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate). Application Equipment (for any Reg.# at any rate).	Max. Single Appl. Rate to a Single Site	Form Code(s)	Max. Seasonal Rate	Max. # Apps/cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
/Sprayer.							
RECREATIONAL AREAS	Do not apply directly to water. Do not apply when drift is likely to occur. Do not contaminate water by cleaning of equipment or disposal of waste. Do not contaminate water, food, or feed by storage or disposal. Do not graze livestock in treated areas.						
When needed Broadcast. Backpack sprayer /Sprayer.	.025 lb 1K sq.ft 1 lb A	SC/L	NS	NS NS	NS	NS	

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

Guide to Appendix B

Appendix B contains the list of data requirements which support the reregistration for active ingredients within case #2073 (mefluidide) covered by this RED. It contains generic data requirements that apply to mefluidide 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 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns.
 - A. Terrestrial food
 - B. Terrestrial feed
 - C. Terrestrial non-food
 - D. Aquatic food
 - E. Aquatic non-food outdoor
 - F. Aquatic non-food industrial
 - G. Aquatic non-food residential
 - H. Greenhouse food
 - I. Greenhouse non-food
 - J. Forestry
 - K. Residential
 - L. Indoor food
 - M. Indoor non-food
 - N. Indoor medical
 - O. Indoor residential
3. Bibliographic Citation (Column 3). If the Agency has acceptable data in its files, this column 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 (Appendix D) for a complete citation of the study.

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Bibliographic Citation(s)
Product Chemistry				
830.7000	63-12	pH	C,J,K	259274. 41913301 and 02, 422513 01 through 04, 42309901, 42283301 through 03, 42331401 and 02, 42251401 through 05, 42282001, 42282002, 42302301, and 42323501.
830.7050	N/A	UV/Visible absorption	C,J,K	41913301 and 02, 422513 01 through 04, 42309901, 42283301 through 03, 42331401 and 02. 42251401 through 05, 42282001, 42282002, 42302301, and 42323501.
830.7200	63-5	Melting point/melting range	C,J,K	259274. 41913301 and 02, 422513 01 through 04, 42309901, 42283301 through 03, 42331401, and 02, 42251401 through 05, 42282001, 42282002, 42302301, and 42323501.
830.7300	63-7	Density	C,J,K	259274. 41913301 and 02, 422513 01 through 04, 42309901, 42283301 through 03, 42331401 and 02, 42251401 through 05, 42282001, 42282002, 42302301, and 42323501.
830.7370	63-10	Dissociation Constants in Water	C,J,K	41913301 and 02, 422513 01 through 04, 42309901, 42283301 through 03, 42331401 and 02, 42251401 through 05, 42282001, 42282002, 42302301, and 42323501.
830.7840	63-8	Water Solubility	C,J,K	259274. 41913301 and 02, 422513 01 through 04, 42309901, 42283301 through 03, 42331401 and 02, 42251401 through 05, 42282001, 42282002, 42302301, and 42323501.
830.7950	63-9	Vapor Pressure	C,J,K	42355501. 42251401 through 05, 42282001, 42282002, 42302301, and 42323501.
Environmental Fate				
35.2120	161-1	Hydrolysis	C,J,K	226846, 42935401
835.2240	161-2	Photodegradation Water	C,J,K	226851
835.2410	161-3	Photodegradation Soil and Air	C,J,K	43040801
835.4100	162-1	Aerobic Soil Metabolism	C,J,K	43162201
835.4300	162-3	Anaerobic Aquatic Metabolism	C,J,K	43120001
835.1240	163-1	Leaching/Adsorption/Desorption	C,J,K	43020801
835.6100	164-1	Terrestrial Field Dissipation	C,J,K	43276802, 43276801
850.1730	165-4	Fish Bioaccumulation	C,J,K	226851
Ecological Effects				
850.2100	71-1a	Avian Oral LD50 Quail/Duck	C,J,K	41601901

850.2200	71-2	Avian Dietary LC50 Quail	C,J,K	41601902, 41601903
850.2300	71-4	Avian Reproduction	C,J,K	Data Gap
850.1075	72-1	Freshwater Fish LC50	C,J,K	41893701, 41893702
850.1010	72-2	Freshwater Invertebrate LC50	C,J,K	41893703
850.1045	72-3a	Estuarine/Marine Fish LC50	C,J,K	42562303
850.1025	72-3b	Estuarine/Marine Mollusk EC50	C,J,K	42562401
850.1400	72-4a	Fish Early Life-Stage (freshwater)	C,J,K	Data Gap
850.1400	72-4a	Fish Early Life-Stage (estuarine/marine)	C,J,K	Data Gap
850.1300	72-4b	Aquatic Invertebrate Life-Cycle (freshwater)	C,J,K	Data Gap
850.1350	72-4c	Aquatic Invertebrate Life-Cycle (estuarine/marine)	C,J,K	Data Gap
850.1500	72-5	Fish Full Life-Cycle	C,J,K	Data Gap
850.4225	123-1a	Seedling Emergence (Tier II)	C,J,K	47190701
850.4250	123-1b	Vegetative Vigor (Tier II)	C,J,K	Data Gap
850.4400	123-2	Aquatic Plant Growth (Tier II)	C,J,K	43526605
850.5400	123-2	Algal Toxicity (Tiers I and II)	C,J,K	43526601
850.3020	141-1	Honey Bee Acute Contact LD50	C,J,K	42562801
850.3030	141-2	Honey Bee Residue on Foliage	C,J,K	425628-01
Toxicology				
870.1100	81-1	Acute Oral Toxicity Rat	C,J,K	00047118
870.1100	81-1	Acute Oral Toxicity Mouse	C,J,K	00047117, 00047116
870.1100	81-1	Acute Oral Dog	C,J,K	00049627
870.1200	81-2	Acute Dermal Toxicity Rabbit	C,J,K	00047122, 00049628, 00083817
870.1300	81-3	Acute Inhalation Toxicity Rat	C,J,K	41888801
870.2400	81-4	Primary Eye Irritation Rabbit	C,J,K	00047126, 00049630, 43481203
870.2500	81-5	Primary Skin Irritation Rabbit	C,J,K	00047124, 00049629, 00083819
870.2600	81-6	Dermal Sensitization Guinea pig	C,J,K	41887701, 00082076
870.3100	82-1a	90-Day Oral Toxicity SD Rat	C,J,K	00047136
870.3100	82-1a	90-Day Oral Toxicity Wistar rat	C,J,K	00047136
870.3150	82-1b	90-Day Oral Toxicity Dog	C,J,K	00047141
870.3150	82-1b	21-Day Dermal Toxicity Rabbit	C,J,K	00082073
870.3200	82-2	21-Day Dermal Toxicity	C,J,K	00082073, 42029601, 41972901

870.3700b	N/A	Developmental Toxicity NZW Rabbit	C,J,K	00132992, 00047138, 00047139
870.3800	N/A	3-Generation Reproduction Charles River Rat	C,J,K	00082748
870.4100b	83-1	Chronic Toxicity Dog	C,J,K	00132995
870.4200b	83-2	Carcinogenicity Mouse	C,J,K	00082747
870.4300a	83-3a	Prenatal Developmental Toxicity Study – Rat	C,J,K	00061930, 42097201, 42097701, 42026102
870.5100	N/A	Ames, <i>S typhimurium</i>	C,J,K	00132996, 41888804
870-5300	N/A	<i>In vitro</i> Cell (CHO) Chromosomal Aberration	C,J,K	00132996
870.5300	84-2	<i>In vitro</i> Mammalian Cell HGPRT Test	C,J,K	41888803
870.5550	84-2	Unscheduled DNA Synthesis	C,J,K	41888802, 00132996
N/A	N/A	Non GDL Metabolism & Pharmacokinetics Unacceptable/NG	C,J,K	
N/A	N/A	Non GDL Carcinogenicity Rats	C,J,K	000610307, 00082737

Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket EPA-HQ-OPP-2006-0874. This docket may be accessed in the OPP docket room located at Room S-4900, One Potomac Yard, 2777 S. Crystal Drive, Arlington, VA. It is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m. All documents may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site: <http://www.regulations.gov>.

The docket initially contained preliminary risk assessments, supporting documents, and technical (or manufacturing-use) registrant error comments for chlorflurenol as of June 20, 2007. After a sixty-day public comment period, EPA considered the public comments that were submitted to the docket and revised the risk assessments as necessary. The revised risk assessments, any supporting documents that needed to be revised, and memos describing the Health Effects Division (HED), the Ecological Fate and Effects Division (EFED), and the Biological and Economic Assessment Division (BEAD) response to public comments will be added to the docket in September 2007.

The Agency documents in the docket include:

1. Federal Register Notice: Mefluidide Risk Assessment; Notice of Availability (Phase 3 of 4-Phase Process)
2. Reader's Guide to the Mefluidide E-docket # EPA-HQ-OPP-2007-0431
3. Mefluidide Use Closure Memo
4. Table A3. Non-Food/Non-Feed Use Patterns Summary for Mefluidide (Case 2370)
5. Table A3. Non-Food-Feed Use Patterns Summary for Mefluidide, diethanolamine salt (CASE 2370)
6. Table A3. Non-Food/Non-Feed Use Patterns Summary for Potassium mefluidide (CASE 2370)
7. Table A3. Non-Food/Non-Feed Use Patterns Summary for Mefluidide, diethanolamine salt by Acid Equivalent (CASE 2370)
8. Mefluidide; Diethanolamine Mefluidide, and Potassium Mefluidide- Phase 2, (30-Day Error only Correction), HED Chapter of the Re-registration Eligibility Decision Document (RED).

9. Mefluidide - Toxicology Section for the Reregistration Eligibility Decision Document (RED)
10. Mefluidide – Occupational and Residential Exposure and Risk Assessment for the Reregistration Eligibility Decision (RED)
11. Appendix A 1-3 Standard Formulas Used for Calculating Occupational and Residential Exposures to Mefluidide; Occupational Handler Exposure Data and; Risk Calculations for Mefluidide; Residential Handler Exposure Data and Risk Calculations for Mefluidide
12. Appendix B – Mefluidide Occupational Handler Risks
13. Appendix C – Residential Handler Risks
14. Appendix D – Residential Turf Post Application Risk Assessment for Mefluidide
15. Mefluidide Incident Report
16. Error Corrections First Phase for Reregistration of Mefluidide acid, Mefluidide-DEA and Mefluidide-K
17. Re-registration Eligibility Document Environmental Fate and Effects Science Chapter
18. Drinking Water Assessment for N-[2,4-dimethyl-5-[[trifluoromethyl)sulfonyl]amino]phenyl]acetamide (Mefluidide), N-{2,4-dimethyl-5-[[trifluoromethyl)sulfonyl]amino]phenyl}acetamide monopotassium salt (Potassium Mefluidide), and N-[2,4-dimethyl-5[[trifluoromethyl)sulfonyl]amino]phenyl]actamide Compound with 2,2-iminobis[ethanol] (1:1)
19. Response to comments Phase III for Reregistration of Mefluidide acid, Mefluidide-DEA and Mefluidide-K
20. Re-registration Eligibility Document Environmental Fate and Effects Science Chapter (dated 9/13/07)
21. Alternative Assessment of Mefluidide

Appendix D. Citations Considered to be Part of the Database 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 Entry. 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.

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12064	Monaco, T. (1974) Weed Control in Blueberries: Ideal Tract. (Un- published study received Dec 19, 1975 under 6E1719; prepared by North Carolina State Univ., submitted by Interregional Research Project No. 4, New Brunswick, N.J.; CDL:095364-AH)
12098	Talbert, R.E.; Howell, S.L.; Kennedy, J.M.; et al. (1974) Field Evaluation of Herbicides in Small Fruit and Nut Crops, 1974. (Unpublished study received Mar 14, 1977 under 7E1936; prepared by Univ. of Arkansas, Dept. of Agronomy and Dept. of Horticul- ture and Forestry, submitted by Interregional Research Project No. 4, New Brunswick, N.J.; CDL:097354-C)
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32574	Osgood, ?; Teshime, ? (19??) Supporting Efficacy Data for Ethrel Use on Sugarcane. (Unpublished study received May 15, 1980 un- der 264-EX-59; submitted by Union Carbide Agricultural Products Co., Ambler, Pa.; CDL:099426-B)
47115	3M Company (1976) Synopsis. Summary of studies 226850-B through 26850-AB. (Unpublished study received Nov 9, 1976 under 7182- 7; CDL:226850-A)
47116	Sibinski, L.J.; Saunders, D.R.; Nelson, R.A. (1975) Acute Oral Tox- icity Study in Mice with Technical MBR 12325 (Lot No. 2) Test No. AT2-59. (Unpublished study received Nov 9, 1976 under 7182- 7; submitted by 3M Co., St. Paul, Minn.; CDL:226850-B)
47117	Sibinski, L.J.; Saunders, D.R.; Nelson, R.A. (1975) Acute Oral Tox- icity Study in Mice with Technical MBR 12325 (Lot No. 6): Test No. AT 3-77. (Unpublished study received Nov 9, 1976 under 7182-7; submitted by 3M Co., St. Paul, Minn.; CDL:226850-C)

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- 47121 Steffen, G.R.; Saunders, D.R.; Nelson, R.A. (1975) Acute Oral Toxicity Study in Dogs with Technical MBR 12325 (Lot No. 8): Test No. AT4-18. (Unpublished study received Nov 9, 1976 under 7182-7; submitted by 3M Co., St. Paul, Minn.; CDL:226850-G)
- 47122 Steffen, G.R.; Saunders, D.R.; Nelson, R.A. (1975) Acute Dermal Toxicity Study in Rabbits with Technical MBR 12325 (Lot No. 6): Test No. AT3-64. (Unpublished study received Nov 9, 1976 under 7182-7; submitted by 3M Co., St. Paul, Minn.; CDL:226850-H)
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- 47133 O'Malley, K.D.; Ebbens, K.L.; Nelson, R.A. (1976) Acute Oral Toxicity Study with S-15017 in Albino Rats: Test No. 475A0283. (Unpublished study received Nov 9, 1976 under 7182-7; submitted by 3M Co., St. Paul, Minn.; CDL:226850-S)
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- 47136 Goldenthal, E.I.; Wazeter, F.X.; Geil, R.G.; et al. (1975) Three Month Subacute Toxicity Study in Rats: IRDC No. 102-025. (Unpublished study received Nov 9, 1976 under 7182-7; prepared by International Research and Development Corp., submitted by 3M Co., St. Paul, Minn.; CDL:226850-V)
- 47137 Steffen, G.R.; Saunders, D.R.; Nelson, R.A. (1975) A 21 Day Dose Range Finding Feeding Study in Dogs with Technical MBR 12325, Lot No. 9: Test No. 175R0002. (Unpublished study received Nov 9, 1976 under 7182-7; submitted by 3M Co., St. Paul, Minn.; CDL: 226850-W)
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- 92089005 Wilson, R. (1990) Pbi/gordon Corporation Phase 3 Summary of MRID 00047123 and Related MRIDs 00056003. Acute Dermal Toxicity Study in Rabbits with the Diethanolamine Salt Formulation of MBR12325 (Lot No. XG-2-1-16): Test No. 475A0115. 7 p.
- 92089006 Wilson, R. (1990) Pbi/gordon Corporation Phase 3 Summary of MRID 00047127. Acute Ocular Irritation Study in Rabbits with the Diethanolamine Salt Formulation of MBR 12325 (Lot No. XG-2-1-16): Test No. 475E0093.: 6 p.
- 92089007 Wilson, R. (1990) Pbi/gordon Corporation Phase 3 Summary of MRID 00047132. Acute Ocular Irritation Test with Embark 2s (Lot XH-68 7/15) Diethanolamine Salt Formulation in Albino Rabbits: Test No. 475E0093.: 6 p.
- 92089008 Wilson, R. (1990) Pbi/gordon Corporation Phase 3 Summary of MRID 00047125. Primary Skin Irritation Study in Rabbits with the Diethanolamine Salt Formulation of MBR 12325 (Lot No. XG-2-1-16): Test No. 475E0020.: 6 p.
- 92089009 Wilson, R. (1990) Pbi/gordon Corporation Phase 3 Summary of MRID 00047131. Primary Skin Irritation with Embark 2s Diethanolamine Salt Formulation in Albino Rabbits: Test No. 476E0221.: 6 p.
- 92089010 Wilson, R. (1990) PBI/Gordon Corporation Phase 3 Summary of MRID 00082077. Sensitization Study with MBR 12325-2S in Albino Guinea Pigs: Report #201.: 7 p
- 92089011 Wilson, R. (1990) Pbi/gordon Corporation Phase 3 Summary of MRID 00082073. Three Week Dermal Toxicity Study in Rabbits: 102029; Report No. 170. 7 p.

92089999 Pbi/gordon Corporation (1990) Reregistration Phase 3 Response: Diethanolamine mefluidide (N-(2,4-dimethyl-5-(((trifluoromet. Correspondence and Supporting Material.

MRID	Citation Reference for Mefluidide Potassium Salt (114003)
74605	Green, C.D. (1981) Formulated MBR 12325-K 2S Herbicide/Plant Growth Regulator: (Product Chemistry): Report No. 514. (Unpublished study received May 22, 1981 under 7182-12; submitted by 3M Co., St. Paul, Minn.; CDL: 245250-A)
74606	Green, C.D. (1981) Gas Chromatographic Analysis of MBR 12325-K Salt Formulations: Report No. 125. Method dated Apr 1981. (Unpublished study received May 22, 1981 under 7182-12; submitted by 3M Co., St. Paul, Minn.; CDL:245250-B)
74607	Burke, R.D. (1981) Letter sent to C.D. Green dated Mar 9, 1981: Corrosion test on Mefluoride 2S: Report No. 515. (Unpublished study received May 22, 1981 under 7182-12; submitted by 3M Co., St. Paul, Minn.; CDL:245250-C)
74608	Hewitt, J.T.; Peterson, D.M. (1981) Analysis of Soybeans Treated with a Single or Split Application of MBR 12325-9 (Potassium Salt of Mefluidide) 2S Herbicide: Report No. 756. (Unpublished study received May 22, 1981 under 7182-12; submitted by 3M Co., St. Paul, Minn.; CDL:245248-A)
74609	3M Company (1981) Toxicity Data Summary Table IC: Acute Toxicity Studies: Supplement V. Summary of studies 245249-B through 245249-E. (Unpublished study received May 22, 1981 under 7182- 12; CDL:245249-A)
74610	O'Malley, K.D.; Hart, G.E.; Ebbens, K.L.; et al. (1981) Acute Oral Toxicity Screen with MBR 12325-9 2S in Albino Rats: Experiment No. 0980AR0687; Report No. 775. (Unpublished study received May 22, 1981 under 7182-12; prepared by Riker Laboratories, Inc., submitted by 3M Co., St. Paul, Minn.; CDL:245249-B)
74611	Markoe, D.M., Jr.; O'Malley, K.D.; Ebbens, K.L.; et al. (1981) Acute Dermal Toxicity Study with MBR 12325-9 2S in Albino Rabbits: Experiment No. 0880AB0686; Report No. 776. (Unpublished study received May 22, 1981 under 7182-12; prepared by Riker Laboratories, Inc., submitted by 3M Co., St. Paul, Minn.; CDL: 245249-C)
74612	Markoe, D.M., Jr.; O'Malley, K.D.; Ebbens, K.L.; et al. (1981) Primary Skin Irritation Test with MBR 12325-9 2S in Albino Rabbits: Experiment No. 0880EB0684; Report No. 777. (Unpublished study received May 22, 1981 under 7182-12; prepared by Riker Laboratories, Inc., submitted by 3M Co., St. Paul, Minn.; CDL: 245249-D)
74613	Markoe, D.M., Jr.; O'Malley, K.D.; Ebbens, K.L.; et al. (1981) Acute Ocular Irritation Test with MBR 12325-9 2S in Albino Rabbits: Experiment No. 0880EB0685; Report No. 778. (Unpublished study received May 22, 1981 under 7182-12; prepared by Riker Laboratories, Inc., submitted by 3M Co., St. Paul, Minn.; CDL: 245249-E)
41893800	PBI/Gordon Corp. (1991) Submission of Data to Support the Reregist- ration of Potassium Salt of Mefluidide: Toxicology Data. Trans- mittal of 3 Studies.
41893801	Murphy, D.; Peters, G. (1991) Mefluidide: A 96-Hour Flow-Through Acute Toxicity Test with the Bluegill (<i>Lepomis macrochirus</i>): Lab Project Number: 281A-112. Unpublished study prepared by Wildlife International Ltd. 56 p.

- 41893802 Murphy, D.; Peters, G. (1991) Mefluidide: A 96-Hour Flow-Through Acute Toxicity Test with the Rainbow Trout (*Oncorhynchus mykiss*) Final Report: Lab Project Number: 281A-111. Unpublished study prepared by WildLife International Ltd. 56 p.
- 41893803 Holmes, C.; Peters, G. (1991) Mefluidide: A 48-Hour Flow-Through Acute Toxicity Test with the Cladoceran (*Daphnia magna*): Final Report: Lab Project Number: 281A-110. Unpublished study prepared by WildLife International Ltd. 55 p.
- 41920200 PBI/Gordon Corporation (1991) Submission of product identity and ingredient data on potassium salt of mefluidide in compliance with a phase IV data call in response. Transmittal of 2 studies.
- 41920201 Cahoy, R. (1991) Product Identity and Composition of Potassium Salt of Mefluidide. Unpublished study prepared by PBI/Gordon Corp. 31 p.
- 41920202 Armbruster, J. (1991) Analysis and Certification of Product Ingredients for Potassium Salt of Mefluidide. Unpublished study prepared by PBI/Gordon Corporation. 36 p.
- 42029600 PBI Gordon Corp. (1991) Submission of toxicity data to support the reregistration of Mefluidide (Potassium Salts). Transmittal of 1 study.
- 42029601 Siglin, J. (1991) 21-Day Dermal Toxicity Study in Rabbits with Mefluidide Technical: Final Report: Lab Project Number: 3229.9. Unpublished study prepared by Springborn Labs, Inc. 259 p.
- 42251400 PBI Gordon Corp. (1992) Submission of product chemistry data to support the reregistration of Mefluidide, Potassium Salts. Transmittal of 5 studies.
- 42251401 Sweetapple, G. (1991) Potassium Salt of Mefluidide--Determination of Melting Point: Lab Project Number: 4102-91-0203-AS-001. Unpublished study prepared by Ricerca, Inc. 21 p.
- 42251402 Sweetapple, G. (1991) Potassium Salt of Mefluidide--Determination of Bulk Density: Lab Project Number: 4102-91-0204-AS-001. Unpublished study prepared by Ricerca, Inc. 20 p.
- 42251403 Thomas, E. (1991) Potassium Salt of Mefluidide--Determination of pH: Lab Project Number: 4102-91-0205-AS-001. Unpublished study prepared by Ricerca, Inc. 24 p.
- 42251404 Sanders, J. (1992) Potassium Salt of Mefluidide--Determination of Stability: Lab Project Number: 4102-91-0260-AS-001. Unpublished study prepared by Ricerca, Inc. 43 p.
- 42251405 Hambrick, A. (1991) Potassium Salt of Mefluidide--Analytical Characterization: Lab Project Number: 4102-91-0128-AS-001. Unpublished study prepared by Ricerca, Inc. 58 p.
- 42282000 PBI/Gordon Corp. (1992) Submission of product chemistry data in support of reregistration of the Potassium Salt of Mefluidide. Transmittal of 2 studies.
- 42282001 Gallacher, A. (1992) Dissociation of Mefluidide Acid and Potassium Salt of Mefluidide Acid in Water: Lab Project Number: 4102-91-0334-AS. Unpublished study prepared by Ricerca, Inc. 69 p.
- 42282002 Gallacher, A. (1992) Potassium Salt of Mefluidide: Analytical Consideration: Lab Project Number: 4102-91-0256-AS. Unpublished study prepared by Ricerca, Inc. 67 p.
- 42302300 PBI/Gordon Corp. (1992) Submission of Data To Support Reregistration of Potassium Salt of Mefluidide: Solubility Study. Transmittal of 1 study.
- 42302301 Douglass, M. (1992) Potassium Salt of Mefluidide--Determination of Solubility: Lab Project Number: 4102-91-0211-AS-001. Unpublished study prepared by Ricerca, Inc. 85 p.

- 42323500 PBI Gordon Corp. (1992) Submission of product chemistry data to support the reregistration of Mefluidide, Potassium salts. Transmittal of 1 study.
- 42323501 Douglass, M. (1992) Potassium Salt of Mefluidide--Determination of Vapor Pressure: Lab Project Number: 4102-91-0212-AS. Unpublished study prepared by Ricerca, Inc. 61 p.
- 42371400 PBI Gordon Corp. (1992) Submission of product chemistry data to support the reregistration of the chemical Potassium Salt of Mefluidide. Transmittal of 1 study.
- 42371401 Douglass, M. (1992) Potassium Salt of Mefluidide--Determination of Octanol/Water Partition Coefficient: Lab Project Number: 4102-91-0213-AS. Unpublished study prepared by Ricerca, Inc. 47 p.
- 42562400 PBI/Gordon Corp. (1992) Submission of toxicity data in support of the reregistration of Technical Mefluidide. Transmittal of 4 studies.
- 42562401 Graves, W.; Swigert, J. (1992) Technical Mefluidide: A 96-hour Shell Deposition Test with the Eastern Oyster (*Crassostrea virginica*): Final Report: Lab Project Number: 281A-121. Unpublished study prepared by Wildlife International, Ltd. 46 p.
- 42562402 Graves, W.; Swigert, J. (1992) Technical Mefluidide: A 96-hour Flow-through Acute Toxicity Test with the Saltwater Mysid (*Mysidopsis bahia*): Final Report: Lab Project Number: 281A-122A. Unpublished study prepared by Wildlife International, Ltd. 44 p.
- 42562403 Graves, W.; Swigert, J. (1992) Technical Mefluidide: A 96-hour Flow-through Acute Toxicity Test with the Sheepshead Minnow (*Cyprinodon variegatus*): Final Report: Lab Project Number: 281A-123. Unpublished study prepared by Wildlife International, Ltd. 47 p.
- 42562404 Murli, H. (1992) Technical Mefluidide: Measuring Chromosomal Aberrations in Chinese Hamster Ovary (CHO) Cells: Final Report: Lab Project Number: 15167-0-437. Unpublished study prepared by Hazleton Washington, Inc. 49 p.
- 42562800 PBI/GORDO Corp. (1992) Submission of toxicity data to support reregistration of Diethanol Amine and Potassium Salts of Mefluidide. Transmittal of 2 studies.
- 42562801 Hoxter, K.; Bernard, W.; Smith, G. (1992) An Acute Contact Toxicity Study with the Honey Bee: Diethanolamine Salt of Mefluidide: Final Report: Lab Project Number: 281-111A. Unpublished study prepared by Wildlife Int'l Ltd. 16 p.
- 42562802 Hoxter, K.; Bernard, W.; Smith, G. (1992) An Acute Contact Toxicity Study with the Honey Bee: Potassium Salt of Mefluidide: Final Report: Lab Project Number: 281-112A. Unpublished study prepared by Wildlife Int'l Ltd. 16 p.
- 43020800 PBI/Gordon Corp. (1993) Submission of Environmental Fate Data in Support of Reregistration of DEA and Potassium Salts of Mefluidide. Transmittal of 1 Study.
- 43020801 Obrist, J. (1993) Leaching Characteristics of Aged (carbon 14)-Mefluidide Residues in a Sandy Loam Soil: Final Report: Lab Project Number: HWI 6384-108. Unpublished study prepared by Hazleton Wisconsin, Inc. 76 p.
- 43120000 PBI/Gordon Corp. (1994) Submittal of Environmental Fate Data in Support of Reregistration of DEA and Potassium Salts of Mefluidide. Transmittal of 1 study.
- 43120001 Bashir, M. (1994) Anaerobic Aquatic Metabolism of (carbon 14)-Mefluidide in a Representative Lake Water/Sediment: Final Report: Lab Project Number: HWI 6384-106. Unpublished study prepared by Hazleton Wisconsin, Inc. 69 p.
- 43162200 PBI/Gordon Corp. (1994) Submittal of Aerobic Soil Metabolism Data in Support of

- Reregistration of Mefluidide. Transmittal of 1 study.
- 43162201 Bashir, M. (1994) Aerobic Soil Metabolism of (carbon 14)-Mefluidide: Final Report: Lab Project Number: HWI 6384-104. Unpublished study prepared by Hazleton Wisconsin, Inc. 84 p.
- 43184700 PBI/GORDON Corp. (1994) Submittal of Product Chemistry Data in Support of Reregistration of DEA Mefluidide. Transmittal of 8 studies.
- 43184708 Armbruster, J. (1994) Preparation Procedure for the TGAI of Potassium Salt of Mefluidide: Supplemental. Unpublished study prepared by PBI/GORDON Corp. 10 p.
- 92090000 PBI/Gordon Corporation (1990) Reregistration Phase 3 Response: CAS Reg. No. 83601-83-6.
- 92090001 Armbruster, J. (1990) PBI/Gordon Corporation Phase 3 Summary of MRID 00074605 and Related MRIDs 00125260, 40618601. Formulated MBR 12325-K 2S Herbicide/Plant Growth Regulator; Formulators Manual; Mefluidide -- Octanol/Water Partition Coefficient. Prepared by 3M CO. 8 p.
- 92090003 Wilson, R. (1990) PBI/Gordon Corporation Phase 3 Summary of MRID 00047118. Acute Oral Toxicity Study in Rats with Technical MBR 12325 (Lot No. 6): Test No. AT 3-65. Prepared by RIKER LABORATORIES, INC. 6 p.
- 92090004 Wilson, R. (1990) PBI/Gordon Corporation Phase 3 Summary of MRID 00074610. Acute Toxicity Screen with MBR 12325-9 2S in Albino Rats: Experiment No. 0980AR0687. Prepared by RIKER LABORATORIES, INC. 6 p.
- 92090005 Wilson, R. (1990) PBI/Gordon Corporation Phase 3 Summary of MRID 00074611. Acute Toxicity with MBR 12325-9 2S in Albino Rabbits: Experiment No. 0880AB0686. Prepared by RIKER LABORATORIES, INC. 6 p.
- 92090006 Wilson, R. (1990) PBI/Gordon Corporation Phase 3 Summary of MRID 00074613. Acute Ocular Irritation Test with MBR 12325-9 2S in Albino Rabbits: Experiment No. 0880EB0685. Prepared by RIKER LABORATORIES, INC. 6 p.
- 92090007 Wilson, R. (1990) PBI/Gordon Corporation Phase 3 Summary of MRID 00074612. Primary Skin Irritation Test with MBR 12325-9 2S in Albino Rabbits: Experiment No. 0880EB0684. Prepared by RIKER LABORATORIES, INC. 6 p.
- 92090008 Wilson, R. (1990) PBI/Gordon Corporation Phase 3 Summary of MRID 00047136. A 90-Day Feeding Study in Rats with Technical MBR12325 (Lot No. 9): Study I; IRDC 102-025. Prepared by INTERNATIONAL RESEARCH & DEVL. CORP. 8 p.
- 92090009 Wilson, R. (1990) PBI/Gordon Corporation Phase 3 Summary of MRID 00047140. A 90-Day Feeding Study in Rats with Technical MBR 12325 (Lot No. 9) Study II: IRDC 102-024. Prepared by INTERNATIONAL RESEARCH & DEVL. CORP. 8 p.
- 92090010 Wilson, R. (1990) PBI/Gordon Corporation Phase 3 Summary of MRID 00082737 and Related MRIDs 00061930. Chronic Feeding/Oncogenicity in the Rat: MBR 12325 Technical: Project No. IRDC 102/028. Prepared by INTERNATIONAL RESEARCH & DEVL. CORP. 9 p.
- 92090011 Wilson, R. (1990) PBI/Gordon Corporation Phase 3 Summary of MRID 00132995. Twelve Month Diet Feeding Study of MBR 12325 in Dogs: Project No. 0280CD0021. Prepared by RIKER LABORATORIES, INC. 10 p.
- 92090012 Wilson, R. (1990) PBI/Gordon Corporation Phase 3 Summary of MRID 00082747 and Related MRIDs 00067572, 00132994. Lifetime Carcinogenicity Study in Mice: MBR 12325 Technical: IRDC 102-026. Prepared by INTERNATIONAL RESEARCH & DEVL. CORP. 13 p.

- 92090013 Wilson, R. (1990) PBI/Gordon Corporation Phase 3 Summary of MRID 00132996. Genetic Toxicology Studies with EL-565 (Compound 151065): Study 821115GPA1969. Prepared by LILLY RESEARCH LABORATORIES. 8 p.
- 92090014 Wilson, R. (1990) PBI/Gordon Corporation Phase 3 Summary of MRID 00132996. Genetic Toxicology Studies with EL-565 (Compound 151065): Study 820908MLA1969. Prepared by LILLY RESEARCH LABORATORIES. 8 p.
- 92090015 Wilson, R. (1990) PBI/Gordon Corporation Phase 3 Summary of MRID 00132996. Genetic Toxicology Studies with EL-565 (Compound 151065): Studies 820803UDS1969 and 820824UDS1969. Prepared by LILLY RESEARCH LABORATORIES. 7 p.
- 92090017 Goldenthal, E.; Jessup, D.; Geil, R. (1990) PBI/Gordon Corporation Phase 3 Reformat of MRID 00082737 and Related MRIDs 00061930. Chronic Feeding/Oncogenicity in Rats: MBR 12325 Technical: IRDC 102-028. Prepared by INTERNATIONAL RESEARCH & DEVL. CORP. 529 p.
- 92090018 Goldenthal, E.; Jessup, D.; Geil, R. (1990) PBI/Gordon Corporation Phase 3 Reformat of MRID 00082747 and Related MRIDs 00067572, 00132994. Lifetime Carcinogenicity Study in Mice: MBR 12325 Technical: IRDC 102-026. Prepared by INTERNATIONAL RESEARCH & DEVL. CORP. 511 p.
- 92090999 PBI/Gordon Corporation (1990) Reregistration Phase 3 Response: CAS Reg. No. 83601-83-6. Correspondence and Supporting Material.

Appendix E. Generic Data Call-In (GDCI)

Note that a complete generic DCI, with all pertinent instructions, will be sent to registrants under separate cover.

Appendix F. Product-Specific Data Call-In (PDCI)

Note that a complete product-specific DCI, with all pertinent instructions, will be sent to registrants under separate cover.

Appendix G. EPA'S Batching of Mefluidide Products for Meeting Acute Toxicity Data Requirements for Reregistration



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

October 22, 2007

MEMORANDUM

SUBJECT: MEFLUIDIDE [PC Codes 114001, 114002, 114003], Acute Mammalian Toxicity Batching Appendix for MEFLUIDIDE RED Document.

FROM: Marianne Lewis, Biologist [sign. M.Lewis 10/22/07]
Product Reregistration Branch
Special Review and Reregistration Division (7508P)

TO: Wilhelmena Livingston, CRM
Special Review Branch
Special Review and Reregistration Division (7508P)

Attached is the batching appendix for Mefluidide. Please let me know if you have any questions regarding this document.

EPA'S BATCHING OF MEFLUIDIDE 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 MEFLUIDIDE as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

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

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

Twelve products were found which contain Mefluidide as the active ingredient. These products have been placed into 3 sections: **Mefluidide** (PC Code 114001 – contains one product placed in a No Batch group); **Mefluidide diethanolamine salt** (PC Code 114002 – contains nine products placed in 2 batches and a No Batch group); **Mefluidide potassium salt** (PC Code 114003 – contains two products placed in a batch). All were placed in these batches in accordance with the active and inert ingredients and type of formulation.

Batching Instructions:

Mefluidide diethanolamine salt - PC Code 114002:

Batch 2: EPA Reg. No. 2217-768 may not cite data conducted on any other products in this batch.

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.

Mefluidide (PC Code 114001)

No Batch	EPA Reg. No.	Percent Active Ingredient
	538-200	Mefluidide: 0.02 Paclbutrazol: 0.20

Mefluidide diethanolamine salt (PC Code 114002)

Batch 1	EPA Reg. No.	Percent Active Ingredient
	2217-759	28.0
	2217-767	28.0

Batch 2	EPA Reg. No.	Percent Active Ingredient
	2217-768	3.200
	2217-787	0.009
	2217-788	0.115
	2217-809	0.059

No Batch	EPA Reg. No.	Percent Active Ingredient
	538-181	0.49
	2217-763	15.0
	2217-802	Mefluidide: 21.45 Imazethapyr: 4.09 Imazapyr: 0.15

Mefluidide potassium salt (PC Code 114003)

No Batch	EPA Reg. No.	Percent Active Ingredient
	2217-765	12.0
	2217-766	24.0

Appendix H. List of Registrants to be Sent this Data Call-in

- 1) PBI/Gordon Corporation

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 following address for the Document Processing Desk.:

Document Processing Desk (distribution code)*
Office of Pesticide Programs (7504P)
Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington, DC 20460-0001

* Distribution Codes are as follows:
(APPL) Application for product registration
(AMEND) Amendment to existing registration
(CAN) Voluntary Cancellation
(EUP) Experimental Use Permit
(DIST) Supplemental Distributor Registration
(SLN) Special Local Need
(NEWCO) Request for new company number
(NOTIF) Notification
(PETN) Petition for Tolerance
(XFER) Product Transfer

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. If you want these forms mailed or faxed to you, please contact Lois White, white.lois@epa.gov or Floyd Gayles, gayles.floyd@epa.gov.

If you have any questions concerning how to complete these forms, please contact OPP’s ombudsperson for conventional pesticide products: Linda Arrington, (703) 305-5446

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 <http://www.epa.gov/pesticides/registrationkit/>

Dear Registrant:

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

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.
2. Pesticide Registration (PR) Notices
 - a. 83-3 Label Improvement Program-Storage and Disposal Statements
 - b. 84-1 Clarification of Label Improvement Program
 - c. 86-5 Standard Format for Data Submitted under FIFRA
 - d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
 - e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
 - f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
 - g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
 - h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

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

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader.)
 - a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
 - b. EPA Form No. 8570-4, Confidential Statement of Formula
 - c. EPA Form No. 8570-27, Formulator's Exemption Statement
 - d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
 - e. EPA Form No. 8570-35, Data Matrix
4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader.)
 - a. Registration Division Personnel Contact List
 - 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 website.
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 website: <http://npic.orst.edu>

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.

Appendix J: Mefluidide Human Health Risk Assessment



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

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

May 30, 2007

SUBJECT: Mefluidide, Diethanolamine Mefluidide, and Potassium Mefluidide-Phase 2 (30- Day Error only Correction), HED Chapter of the Reregistration Eligibility Decision Document (RED). PC Code: 114001, 114002, 114003. Reregistration Case No. 2370. DP Barcode D334500.

FROM: Yan Donovan, Chemist and Risk Assessor
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And

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THROUGH: Susan Hummel
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TO: Wilhemena Livingston, Chemical Review Manager
Reregistration Branch I
Special Review & Reregistration Division (7508W)

Attached is Health Effect Division's phase II risk assessment for mefluidide RED. This is a revised risk assessment (from phase I) incorporating registrant's error only comments dated May 22, 2007. The team reviewers who contributed to the disciplinary chapters and the risk assessment are listed below:

Hazard Identification Assessment; Abdallah Khasawinah, D322246, 1/31/07.

Occupational and Residential Exposure Assessment; Yan Donovan, D324823, 2/28/07.
Incident Report; M. Hawkins, D324824, 07/25/06.
Drinking Water Assessment; James Hetrick from EFED, D334508, 03/08/07.

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1.0 EXECUTIVE SUMMARY

A risk assessment is being conducted for mefluidide, mefluidide diethanolamine salt, and mefluidide potassium salt to support the mefluidide RED. For the purposes of this assessment, all of the three active ingredients are collectively referred to as mefluidide.

Mefluidide is a member of the class of anilide. Mefluidide is a plant growth regulator that is applied postemergence when needed. It is used to control ornamental and non-ornamental woody plants, ground cover, hedges trees, turf grasses, grass and broadleaf weeds by inhibiting plant cell division, stem elongation and seed head development. It is also registered for growth control of low maintenance turf on rights-of-ways, airports, public and industrial sites. Mefluidide products can also be used on residential lawns. There are multiple active ingredient products that contain an additional plant growth regulator and herbicides such as paclobutrazol, imazapyr, and imazethapyr. These ingredients are not assessed in this document. Current formulations include granular, liquid ready- to- use, and soluble concentrate/liquid. Mefluidide can be applied as a band treatment, broadcast, spot treatment, and spray. The equipment used to apply mefluidide includes backpack sprayer, groundboom, hand held pump sprayer, handgun sprayer, hose-end sprayer, power sprayer, high pressure handwand, and spreader (push-type and belly grinder).

Based on the structural similarities of mefluidide and its diethanolamine (DEA) and potassium salts, where they all share the same anion- anilide, and the physical and chemical properties of the DEA and potassium salts, where they dissociate 100% back to free mefluidide in aqueous environments, the risk assessment team concluded that mefluidide DEA and potassium salts are biologically equivalent to mefluidide and thus they share the same toxicity as the free mefluidide. Therefore, it is reasonable to bridge mefluidide toxicity data to mefluidide salts and vice versa.

The toxicology data base of mefluidide and its salts is considered adequate for the purposes of hazard and dose response assessment. Mefluidide has low acute toxicity by the oral, dermal and inhalation routes (toxicity category III and IV). It is a weak eye or dermal irritant (toxicity category III and IV). Mefluidide did not cause dermal sensitization in the guinea pig. In rats and rabbits, critical effects of acute toxicity were tremors, hunched posture, salivation, reduced body weight and body weight gain.

Subchronic and chronic toxicity of mefluidide is manifested by decreased body weight and body weight gain in several species tested (rats, rabbits and dogs). Dogs appeared to be most sensitive species with the critical toxicological effects of cortical nephrosis and body weight loss. In rats and rabbits, critical effects observed were tremors, hunched posture, salivation, reduced body weight and body weight gain. Based on lack of evidence of carcinogenicity in both rats and mice, mefluidide was considered as not likely to be carcinogenic to humans. Mefluidide exhibited a negative response in various genotoxicity screening assays.

Developmental effects of mefluidide in rats included increased number of early resorptions and mean postimplantation loss. These effects were observed at the same dose that caused maternal toxicity indicating there was no increased susceptibility to fetuses (LOAEL = 115 mg/kg/day, NOAEL = 58 mg/kg/day). The maternal toxicity included tremors, decreased body weight, weight gain and mortality. In rabbit, the LOAEL/NOAEL for developmental toxicity were above the highest dose tested (60 mg/kg/day). Although this study is not acceptable alone, taking into the consideration of the results from the 14-day rabbit oral study where mortality was seen at 100 mg/kg/day, and tremors and 100% mortality were noted at 200 mg/kg/day, the NOAEL from the rabbit developmental study is acceptable. In the 3-generation rat reproduction toxicity study, the offspring toxicity was characterized by decreased body weights in both sexes and both litters in all generations. The reproductive LOAEL was not observed (NOAEL = 346/604 mg/kg bw/day in males and females).

Endpoints and dose responses have been selected for all exposure routes and durations, except for dermal exposure, where it was determined that no quantitative dermal risk assessment is needed.

There are no agricultural or any food related pesticide uses of mefluidide. Therefore, no dietary exposure from food is expected. However, there is potential for drinking water exposure due to the outdoor uses of mefluidide. A drinking water assessment was conducted by the Environmental Fate and Effects Division (EFED) using Tier II (PRZM-EXAMS) for surface water modeling and Tier I (SCI-GROW) for groundwater modeling. The mefluidide acid concentrations in surface water are not expected to exceed 32 µg/L (= 32 ppb) for the 1 in 10 year daily peak concentration, 10 µg/L (= 10 ppb) for the 1 in 10 year annual concentration, and 5 µg/L for the 30 year annual average concentration. Mefluidide acid concentrations in ground water are not expected to exceed 1.0 µg/L.

Dietary (Water only) Exposure and Risk Estimates

Acute and chronic dietary (water only) risk assessments were conducted using the Dietary Exposure Evaluation Model (DEEM). The dietary exposure assessments were performed using exposures from surface water only, as there are no food uses for this chemical. The estimated surface drinking water concentration (32 ppb) was used in acute dietary while the 10 ppb was used for chronic. The analysis results indicated that the dietary risks are below the Agency's level of concern. At the 95th percentile, the acute dietary exposure to U.S. population was 0.0017 mg/kg/day, which utilized < **1%** of the acute reference dose (aRfD). The exposure for all infants, which was the most highly exposed population subgroup, was 0.006 mg/kg/day, which utilized **1% of the aRfD**. For chronic dietary exposure, the exposure for U.S. population was 0.0002 mg/kg/day, which utilized **1%** of the chronic reference dose (cRfD). The exposure for all infants, which was the most highly exposed population subgroup, was 0.0007mg/kg/day, which utilized **5% of the cRfD**.

Residential Exposure and Risk Estimates

None of the labels prohibit use by homeowners. The residential handler risks were assessed using standard assumptions, maximum label rates, Outdoor Residential Exposure Task Force (ORETF) studies and Pesticide Handlers Exposure Database (PHED) unit exposure data. The MOEs are all >100, which means the risks are not of concern.

Residential Post Application Exposure and Risk Estimates

Since no dermal endpoints were selected, the residential post- application assessments were only conducted for Children (through incidental oral). Incidental oral exposures include exposures from hand- to- mouth, object- to- mouth and soil ingestion of treated turf (all considered short-term). Calculations used the Residential SOPs and maximum label rates. The combined MOE is >100 which means that the risk is below EPA's level of concern. The residential post- application exposures to toddlers from ingesting granules that have been applied to residential turf were also assessed using a standard method as outlined in the Residential SOPs. The MOE was then calculated using the acute dietary NOAEL of 58 mg/kg/day and it is > 100. This means that the risks for toddler exposures from granular ingestion are not of concern.

Aggregate Risk Assessment (food + water + residential exposure)

Although an aggregate risk assessment is not required under current Agency policies for non-food use chemicals, to ensure that the public health is adequately protected, a screening level aggregate risk assessment was conducted for mefluidide. For acute and chronic aggregate risks, the only exposure is from drinking water. As stated above, the dietary exposures (drinking water only) do not exceed 1% of the aRfD/cRfD for adult and 5% of the aRfD/cRfD for children. For short- term, no aggregate is needed for adults since there are no residential post- application exposures to adults. When considering the dietary exposure (drinking water only) as a background exposure to Children for short-term risk, the level of dietary exposure (0.0007 mg/kg/day from chronic food) is negligible when compared to the combined incidental oral exposure (0.019 mg/kg/day) or the granule ingesting dose (0.098 mg/kg/day). No intermediate-term residential risk was identified. Therefore, short- and intermediate- term aggregate is not of concern.

Occupational Exposure and Risk Estimates

The MOEs for occupational handler exposures were calculated for short/intermediate term inhalation exposures using standard assumptions and unit exposure data. The unit exposure data were taken from the PHED and the ORETF studies for professional lawn care operators. All of the MOEs are > 100 with baseline personal protective equipment (PPE) which means that the risks are not of concern and respiratory protection is not needed.

Occupational post application dermal risks were not assessed because there is not likely to have occupational post-application scenario. In addition, no dermal endpoints were selected. Mefluidide is only applied outdoors and it is not a volatile compound, inhalation exposures are negligible.

Risk Characterization

All MOEs for occupational and residential handlers are greatly above 100. No refinement is needed. The risk assessments for post- application exposures for Children are conservative because they are based upon day 0 TTRs and soil residue values and did not account for dissipation.

Environmental Justice Considerations:

Potential areas of environmental justice concerns, to the extent possible, were considered in this human health risk assessment, in accordance with U.S. Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," <http://www.eh.doe.gov/oepa/guidance/justice/eo12898.pdf>).

As a part of every pesticide risk assessment, OPP considers a large variety of consumer subgroups according to well-established procedures. In line with OPP policy, HED estimates risks to population subgroups from pesticide exposures that are based on patterns of that subgroup's food and water consumption, and activities in and around the home that involve pesticide use in a residential setting. Extensive data on food consumption patterns are compiled by the USDA under the Continuing Survey of Food Intake by Individuals (CSFII) and are used in pesticide risk assessments for all registered food uses of a pesticide. These data are analyzed and categorized by subgroups based on age, season of the year, ethnic group, and region of the country. Additionally, OPP is able to assess dietary exposure to smaller, specialized subgroups and exposure assessments are performed when conditions or circumstances warrant. Whenever appropriate, non-dietary exposures based on home use of pesticide products and associated risks for adult applicators and for toddlers, youths, and adults entering or playing on treated areas postapplication are evaluated. Further considerations are currently in development as OPP has committed resources and expertise to the development of specialized software and models that consider exposure to bystanders and farm workers as well as lifestyle and traditional dietary patterns among specific subgroups.

Review of Human Research:

This risk assessment relies in part on data from studies in which adult human subjects were intentionally exposed to a pesticide or other chemical. These studies (listed in Appendix B) have been determined to require a review of their ethical conduct, and have received that review.

2.0 INGREDIENT PROFILE

Mefluidide is a plant growth regulator that is applied postemergence when needed. It is used to control the growth of ornamental and non-ornamental woody plants, ground cover, hedges, trees, turf grasses, grass and broadleaf weeds by inhibiting plant cell division, stem elongation and seed head development. It is registered for uses on low maintenance turf on rights-of-ways, airports, and industrial sites. It can also be used on ornamental and or shade trees, ornamental ground cover, ornamental herbaceous plants, golf course, hospitals/medical institutions premises ornamental lawns and turf, and residential lawns. There are multiple active ingredient products that contain an additional plant growth regulator and herbicides such as paclobutrazol, imazapyr and imazethapyr. Current formulations include granular, liquid ready- to- use, and soluble concentrate/liquid. Mefluidide can be applied as a band treatment, broadcast, spot treatment, and spray. The equipment used to apply mefluidide includes backpack sprayer, groundboom, hand held pump sprayer, handgun sprayer, hose-end sprayer, power sprayer, high pressure handwand, and spreader (push-type and belly grinder). The two registrants for mefluidide, PBI/Gordon (technical and end-use registrant) and The Scotts Company (end-use registrant) are supporting all of the existing uses for reregistration on their respective labels.

2.1. Summary of Registered/Proposed Uses

Based on the information provided by the registrant at the 11-08-06 SMART meeting, all existing mefluidide label uses (total 11 product labels) are supported by the registrant. The registrant also indicated that among all labels, only three have active sales: Embark 2S (EPA Reg # 2217-759), Embark T&O (EPA Reg#2217-768), and Stronghold (EPA Reg#2217-802).

HED has analyzed all existing mefluidide product labels. The label suggested use patterns, formulations, application methods and maximum application rates are summarized in Table 2.1 below.

Table 2.1 – Summary of Use Patterns, Formulations, and Application Rates for Mefluidide.					
Product Type	Product Label/names	Application Equipment	Use Sites	Maximum application rates	Maximum Spray dilution
Liquid	2217-759 (EMBARK 2-S)	High pressure handwand	Ornamental trees,	1.0 lbs ai/A	0.01 lbs ai/gallon
		Groundboom, Turfgun	Turfgrass, golf course, rights-of-ways		0.067 lbs ai/gallon
Liquid	2217-763 (EMBARK 1-S)	Groundboom, Backpack sprayer	Turf, commercial-industrial, public area	1.0 lbs ai/A	0.067 lbs ai/gallon
Liquid	2217-765 (EMBARK	Groundboom, Backpack sprayer	Turf, commercial-industrial, public	1.0 lbs ai/A	0.067 lbs ai/gallon

	1-L)		area		
Liquid	2217-766 (EMBARK 2-L)	Groundboom, Backpack sprayer	Turf, commercial- industrial, public area	1.0 lbs ai/A	0.067lbs ai/gallon
Liquid	2217-768 (EMBARK E-Z-TU- USE)	Hand pump (pressure spray), Hose end sprayers	Turf grass	1.0 lbs ai/A	0.008 lbs ai/gallon
			Ornamentals	0.43 lbs ai/A	0.01 lbs ai/gallon
Liquid	2217-802 (EH1135 PGR)	Conventional power spray	Turf, commercial- industrial	0.43 lbs ai/A	0.029 lbs ai/gallon
Granules	538-181 (St. Aug. GR w/Fertilizer)	Spreader	Lawn	0.50 lbs ai/A	N/A
Granules	538-200 (Scotts Turf Manager)	Spreader	Lawn	0.04 lbs ai/A	N/A
RTU	2217-787 (EMBARK R-T-U Northern)	Sprinkler can	Residential areas	0.11 lbs ai/A	N/A
RTU	2217-788 (EMBARK R-T-U Southern)	Sprinkler can	Residential areas	1.23 lbs ai/A	N/A
RTU	2217-809 (ER 721)	Sprinkler can	Residential areas	1.0 lbs ai/A	N/A

RTU = Ready- to- Use

2.2 Structure and Nomenclature

TABLE 2.2a. Test Compound Nomenclature (Mefluidide)	
Chemical Structure	
Empirical Formula	C ₁₁ H ₁₃ F ₃ N ₂ O ₃ S
Common name	Mefluidide
Company experimental name	MBR 12325
IUPAC name	5'-(1,1,1-trifluoromethanesulfonylamino)acet-2',4'-xylidide
CAS name	<i>N</i> -[2,4-dimethyl-5-[(trifluoromethyl)sulfonyl]amino]phenyl]acetamide
CAS Registry Number	53780-34-0
End-use product/EP	St. Aug.GR w/Fertilizer (Reg. #538-181), Scotts Turf Manager (Reg.#538-200)
Chemical Class	Plant growth regulators
Known Impurities of Concern	None

TABLE 2.2b. Test Compound Nomenclature (Diethanolamine Mefluidide)	
Chemical Structure	
Empirical Formula	C ₁₅ H ₂₄ F ₃ N ₃ O ₅ S
Common name	Diethanolamine Mefluidide
Company experimental name	MBR 12325
IUPAC name	5'-(1,1,1-trifluoromethanesulfonylamino)acet-2',4'-xylylide - 2,2'-iminodiethanol (1:1)
CAS name	<i>N</i> -[2,4-dimethyl-5-[[trifluoromethyl]sulfonyl]amino]phenyl]acetamide compound with 2,2'-iminobis[ethanol] (1:1)
CAS Registry Number	53780-36-2 (This substance is a derivative of mefluidide [53780-34-0]).
End-use product/EP	EMBARK 2-S (Reg.# 2217-759), EMBARK 1-S (Reg.# 2217-763), EMBARK E-Z-TU-USE (Reg.# 2217-768), EH1135 PGR (Reg.# 2217-802), EMBARK R-T-U Northern (Reg.# 2217-787), EMBARK R-T-U Southern (Reg.# 2217-788), ER 721 (Reg.# 2217-809)
Chemical Class	Plant growth regulators
Known Impurities of Concern	None

TABLE 2.2c. Test Compound Nomenclature (Potassium Mefluidide)	
Chemical Structure	
Empirical Formula	C ₁₁ H ₁₂ F ₃ KN ₂ O ₃ S
Common name	Mefluidide
Company experimental name	MBR 12325
IUPAC name	potassium (<i>EZ</i>)- <i>N</i> -[5-(1,1,1-trifluoromethanesulfonamido)-2,4-xylyl]acetamide
CAS name	<i>N</i> -[2,4-dimethyl-5-[[trifluoromethyl)sulfonyl]amino]phenyl]acetamide monopotassium salt
CAS Registry Number	83601-83-6
End-use product/EP	EMBARK 1-L (Reg.# 2217-765), EMBARK 2-L (Reg.# 2217-766)
Chemical Class	Plant growth regulators
Known Impurities of Concern	None

2.3 Physical and Chemical Properties

TABLE 2.3.a Physicochemical Properties (Mefluidide)		
Parameter	Value	Reference
Molecular Weight	310.3	HED memo of 3/13/89, A. Smith. Accession No. 259274. RCB No. 126
Melting point/range	183-185 °C	
pH	4.6 @ 25°C (1% aqueous dispersion)	
Density	Not available	
Water solubility (25 °C)	0.18g/L at 25°C	
Solvent solubility (temperature not specified)	N-Octanol. = 17 g/L	
Vapor pressure (25°C)	<1.0E-4 mmHg @ 25°C	
Dissociation constant, pKa	pKa = 4.6	
Octanol/water partition coefficient, Log(K _{ow}) (25 °C)	Remain outstanding	
UV/visible absorption spectrum	Max at 287 nm	

TABLE 2.3b. Physicochemical Properties (Diethanolamine Mefluidide)		
Parameter	Value	Reference
Molecular Weight	413.3	HED memo of 3/2/93, C. Olinger, D166847 and D179233. MRIDs 41913301 and 02, 422513 01 through 04, 42309901, 42283301 through 03, 42331401 and 02.
Melting point/range	106-108 °C	
pH	6.98 @ 25°C (1% aqueous dispersion)	
Density	0.69 g/cm ³ typical @ 25°C	
Water solubility (20 °C)	566 mg/g at 25°C	
Solvent solubility (temperature not specified)	N-Octanol. = 22 mg/g	
Vapor pressure (25°C)	<1.0 E ⁻⁷ mmHg @ 25°C	HED memo of W. Smith, 2/16/93, D183266. MRID Nos: 42355501.
Dissociation constant, pKa	100% dissociates in aqueous solution. Mefluidide pKa = 4.6	HED memo of 3/2/93, C. Olinger, D166847 and D179233. MRIDs 41913301 and 02, 422513 01 through 04, 42309901, 42283301 through 03, 42331401 and 02.
Octanol/water partition coefficient, Log(K _{ow}) (25 °C)	3.2 x 10 ⁻²	
UV/visible absorption spectrum	Max at 254 nm	

TABLE 2.3c. Physicochemical Properties (Potassium Mefluidide)		
Parameter	Value	Reference
Molecular Weight	348.4	HED memo of 11/24/92, F. Toghrol, D179244. MRIDs: 42251401 through 05, 42282001, 42282002, 42302301, and 42323501.
Melting point/range	118- 120 °C	
pH	8.6 @ 25°C (1% aqueous dispersion)	
Density	0.85 g/cm ³ typical @ 25°C	
Water solubility (25 °C)	510 mg/g	
Solvent solubility (temperature not specified)	N-Octanol. = 57 mg/g	
Vapor pressure (25°C)	< 1.0 E ⁻⁷ mmHg @ 25°C	
Dissociation constant, pKa	100% dissociates in aqueous solution. Mefluidide pKa = 4.6	
Octanol/water partition coefficient, Log(K _{ow}) (25 °C)	Not available	
UV/visible absorption spectrum	Not available	

Based on the structural activities of mefluidide and its DEA and potassium salts, where they all have similar structures (identical benzene ring and functional groups, i.e., share the same anion- anilide), and the above physical and chemical properties of the salts where they dissociate 100% back to free mefluidide in aqueous environment, the risk assessment team determined that mefluidide DEA and potassium salts are biologically equivalent to mefluidide and thus they share the same toxicity as the free mefluidide. Therefore, it is reasonable to bridge mefluidide toxicity data to mefluidide salts and vice versa.

3.0 METABOLISM ASSESSMENT

3.1 Rat Metabolic Profile

Mefluidide was almost completely absorbed following oral ingestion (approximately 96%) and rapidly eliminated within 24 hours. A majority of dose was eliminated in urine (86-89 %) and remainder in feces after a single oral dose in 24 hours. Residue consisted of mefluidide (97%) and 2 unidentified metabolites (1.2% and 0.5%) and unidentified polar material (0.7%). Excretion of the radioactivity in expired air was not detected. The chemical is unlikely to accumulate in body since it was excreted almost completely within 24 hrs and steadily declined thereafter.

3.2 Nature of the Residue in Foods

Not applicable. There are no food uses.

3.3 Environmental Degradation

The only identified degradation product was 5-amino-2, 4-dimethyltrifluoromethanesulfonilide. It was found at a maximum daily concentration of 2.8% of applied dose (MRID 43162201, aerobic soil). The risk assessment team concluded that this degradate is not of concern based on its structure (structurally similar to the parent, there fore it is not likely to be significantly more toxic than the parent), and the fact that it is a minor degradate (<10% of the applied dose). The residue of concern for drinking water assessment is parent only.

4.0 HAZARD CHARACTERIZATION/ASSESSMENT

4.1 Hazard characterization

Mefluidide has shown low acute toxicity by the oral, dermal and inhalation routes (Toxicity Category III and IV). It is a weak eye or dermal irritant (Toxicity Category III and IV). However, the precursor of mefluidide (S-15733: manufacturing starting material) caused eye irritation (Toxicity Category II). Mefluidide did not cause dermal sensitization in the guinea pig. In rats and rabbits, critical effects of acute oral toxicity (occurring at doses of 100 mg/kg/day and above) were tremors, hunched posture, salivation, reduced body weight and body weight gain.

Mefluidide and its diethanolamine salt subchronic and chronic toxicity are manifested by decreased body weight and body weight gain in several species tested (rats, rabbits and dogs). Dogs are most sensitive to these effects, which occur at doses as low as 15 mg/kg/day in diets fed for one year. In addition, dogs fed with mefluidide for one year exhibited chronic cortical nephrosis at doses of 150 mg/kg/day. Increased incidence of liver hyperplastic nodules in both sexes was observed in mice fed with mefluidide at doses of 270 mg/kg/day and higher, but there was no oncogenic response in mice at doses as high as 900 mg/kg/day. Rats fed with mefluidide at doses up to 300 mg/kg/day did not exhibit any carcinogenic response either. Based on lack of carcinogenic response in both rats and mice, mefluidide is considered as not likely to be carcinogenic to humans.

Mefluidide exhibited a negative response in various genotoxicity screening assays (bacterial reverse mutation, *in vitro* mouse lymphoma gene mutation, *in vitro* mammalian chromosome aberration, *in vivo* sister chromatid exchange, unscheduled DNA synthesis).

Mefluidide and its DEA salt were not dermally toxic when tested in rabbits at limit doses of 1000 mg/kg/day for 21 days. Effects were limited to slight erythema at the application site at the 1000 mg/kg/day dose.

Mefluidide or its DEA salt has not been tested for subacute or subchronic inhalation toxicity. However, both of them are in category IV for acute inhalation toxicity.

Developmental effects of Mefluidide in rats included increased number of early resorptions and mean postimplantation loss. These effects were observed at the same dose that caused maternal toxicity indicating there was no increased susceptibility to fetuses. The maternal toxicity included tremors, decreased body weight, weight gain and mortality. In rabbit, the LOAEL/NOAEL for developmental toxicity were above the highest dose tested (60 mg/kg/day). In the 3-generation reproduction toxicity study in rats, the offspring toxicity was characterized by decreased body weights in both sexes and both litters in all generations. The reproductive LOAEL was not observed (NOAEL = 346/604 mg/kg bw/day). The offspring toxicity was observed at the highest dose tested (346 mg/kg/day) that also produced maternal toxicity indicating there was no increased post-natal susceptibility for the mefluidide.

There is no evidence of increased pre- or post-natal susceptibility in the developmental study or in the multi-generation reproduction study in rat. Although the LOAEL/NOAEL for developmental toxicity in the rabbits were not established, the concern is low for the increased susceptibility to the rabbit fetuses since the developmental effects were not seen at the highest dose tested (60 mg/kg/day) which is above the developmental NOAEL in rat (58 mg/kg/day) and well above (40X) the dose that is used to establish chronic RfD (1.5 mg/kg/day). Therefore, there is no residual uncertainty for pre- and/or post natal susceptibility.

The toxicology profile of mefluidide does not indicate a potential concern for estrogens, androgen and/or thyroid mediated toxicity.

The toxicology profile of mefluidide and its DEA salt is adequate for the purposes of hazard and dose response assessment.

Table 4.1a. Acute Toxicity of Mefluidide and its salts (114001, 114002, 114003)				
Guideline No.	Study Type	MRID	Results (LD ₅₀ /LC ₅₀)	Toxicity Category
870.1100 (81-1)	Acute Oral (female rat) Mefluidide tech		>4000 mg/kg MRID 00047118	III
870.1100 (81-1)	Acute Oral (mouse) Mefluidide tech		1920.2 mg/kg MRID 00047117	III
870.1100 (81-1)	Acute Oral (mouse) Mefluidide tech		829.8 mg/kg MRID 00047116	III
870.1100 (81-1)	Acute Oral (dog) Mefluidide tech	MRID 00049627;	Not established emesis precluded evaluation at 100, 500, 2000 mg/kg doses	III
870.1200 (81-2)	Acute Dermal (female rabbit) Mefluidide tech		>4000 mg/kg MRID 00047122 & 00049628 & 00083817	IV
870.1300 (81-3)	Acute inhalation – rat DEA salt of Mefluidide		>5.2 mg/L MRID 41888801	IV

870.1300 (81-3)	Acute inhalation – rat Mefluidide tech.	>5.4 mg/L MRID 41964601	IV
870.2400 (81-4)	Primary Eye Irritation (rabbit) Mefluidide tech	minimal irritation MRID 00047126, 00049630	III
870.2400 (81-4)	Primary Eye Irritation (rabbit) DEA Mefluidide	minimal irritation MRID43481203	III
870.2500 (81-5)	Primary Skin Irritation (rabbit), Mefluidide tech	Not a dermal irritant MRID 00047124, 00049629, 00083819	IV
87.2600 (81-6)	Dermal Sensitization (guinea pig), Mefluidide	Not a dermal sensitizer MRID 41887701	N/A
87.2600 (81-6)	Dermal Sensitization (guinea pig), Mefluidide	Not a dermal sensitizer MRID 00082076	N/A

Table 4.1b Toxicity Profile of Mefluidide and its salts (114001, 114002, 114003)

Guideline No./ Study type	MRID No.(year)/Doses/ classification	Results
Non-guideline 21-day Oral - dog	00047137, (1975) 0, 1000, 3000, 10000 ppm Vistar tech, 93% a.i./d (0, 25, 75, 250 mg/kg/d) One dog/sex/dose range finding Acceptable/non-guideline	LOAEL = not established. NOAEL > 250 mg/kg/d,
Non-guideline 5-week - mouse	00082072, (1976) 0, 1800, 6000 ppm Vistar tech, 93% a.i./d (0, 270, 900 mg/kg/d) (Dietary 5/sex/dose) range finding Acceptable/non-guideline	LOAEL = not established NOAEL = 900 mg/kg/d,
None-guideline 28-Day oral dietary [rat]	00047135, (1973), 0, 1000, 3000 or 10000 ppm Vistar tech, 93% a.i. (0, 100, 300, 1000 mg/kg/d) (Dietary 5 rats/sex/dose) range finding Acceptable/non-guideline	LOAEL = not established. NOAEL > 1000 mg/kg/d,
870.3100 (82-1a) 90-Day oral dietary [rat]	00047136, (1975), 0, 300, 1000 or 6000 ppm Vistar tech, 93% a.i. (0, 15, 50, 300 mg/kg/d) (10 rats/sex/dose) 00047140 (1975) 0, 300, 1000, 3000 ppm (0, 15, 50, 150 mg/kg/day). (10 females/dose) Acceptable/Guideline	LOAEL = 300 mg/kg/d, based on decreased body weight, body weight gain and food consumption in the females. NOAEL = 150 mg/kg/d (in conjunction with MRID # 00047140),
870.3150 82-1(b) 90-Day oral dietary [dog]	00047141, (IBT Study , 1977), 0, 300, 1000 or 6000 ppm Vistar tech, 93% a.i. (0, 7.5, 25, 150 mg/kg/d) (4/sex/dose) Unacceptable/guideline (LOAEL was not observed)	LOAEL = not established. NOAEL = 150 mg/kg/d.
870.3200 82-2 21-Day Dermal toxicity - rabbit	00082073, (1977) 0, 1, 3, 10 ml of 2S formulation/kg/day (Formulation containing 24% a.i., equivalent to 0, 240, 720, or 2400 mg mefluidide/kg/day) (4 rabbits/sex/dose) Acceptable/Non-guideline (NOAEL was not observed)	Dermal LOAEL = 240 mg/kg/day, based on irritation, inflammation and necrosis at test sites. Systemic LOAEL = 240 mg/kg/day, based on clinical chemistry (increased alkaline phosphatase and alanine aminotransferase) and organ weights (decreased spleen weight in females and increased liver weights in males). Edema and swelling with myelin loss in sciatic nerve was seen in 720 and 2400 mg/kg/day dose group. Dehydration observed

Table 4.1b Toxicity Profile of Mefluidide and its salts (114001, 114002, 114003)

Guideline No./ Study type	MRID No.(year)/Doses/ classification	Results
	Note: This study assessed the dermal toxicity of 24 % formulation mefluidide	at 2400 mg/kg/day dose. Dermal and systemic NOAELs were not established.
870.3200 82-2 21-Day Dermal toxicity - rabbit	42029601 (1991) 0, 100, 500 or 1000 mg a.i./kg/d Mefluidide 58.2% a.i. (5/rabbits/sex/dose) Acceptable/guideline	Dermal toxicity LOAEL = 1000 mg/kg/day based on erythema at the test site. Dermal toxicity NOAEL = 500 mg/kg/day Systemic toxicity LOAEL was not established. Minor hematological and clinical chemistry findings at 1000 mg/kg/day dose reported, that were within normal biological variation and did not correlate to histopathological findings. Systemic toxicity NOAEL = 1000 mg/kg/day
870.3200 82-2 21-Day Dermal toxicity - rabbit	41972901 (1991) 0, 100, 500 or 1000 mg a.i./kg/d Mefluidide DEA salt 28.78% a.i. (5/rabbits/sex/dose) Acceptable/ guideline	Dermal and systemic toxicity LOAEL was not established. Minor incidences of erythema at 500 mg and 1000 mg/kg/day dose. Increased liver weight (absolute and relative) noted at 1000 mg/kg dose but no correlating histopathological findings. Minor statistical increases in liver enzymes AST and ALT. Dermal and systemic NOAEL = 1000 mg/kg/day
Non-guideline 1-year feeding (Rat)	00132993, (1981) 0, 60, 200, 600 ppm Vistar tech, 93% a.i. (0, 3, 10, 30 mg/kg/d) (20 rats/sex/dose) Addendum to 2-year feeding study. Acceptable/non-guideline	LOAEL = not established NOAEL = 30 mg/kg/d,
870.4100b 83-1b Chronic Oral Feeding [dog]	00132995, (1982) 0, 60, 600, 6000 ppm Vistar tech, 93% a.i. (0, 1.5, 15, 150 mg/kg/d) (6 dogs/sex/dose) Acceptable/guideline	LOAEL = 15 mg/kg/d, based on decreased body weight (15%) and body weight gain (50%) in the males. Chronic cortical nephrosis was observed at 150 mg/kg/day dose. NOAEL = 1.5 mg/kg/d,
870.4100b 83-2b Carcinogenicity Dietary [mouse]	00082747, (1979) 0, 600, 1800, 6000 ppm Vistar tech, 93% a.i. (0, 90, 270, 900 mg/kg/d) (60 mice/sex/dose) Acceptable/guideline	LOAEL = 270 mg/kg/day, based on increased incidence of liver hyperplastic nodules in both sexes. NOAEL = 90 mg/kg/day. No oncogenicity up to and including the highest dose tested.
870.4300 83-5 2-year feeding/carcinogenicity [rat]	00061930, 00082737 (1979) 0, 600, 1800, 6000 ppm Vistar tech, 93% a.i. (0, 30, 90, 300 mg/kg/d) (50 rats/sex/dose) Acceptable/guideline	LOAEL = 30 mg/kg/d, based on body weight loss. NOAEL < 30 mg/kg/d, No oncogenicity up to and including the highest dose tested.
870.3700a 83-3(a) Developmental	00132992, (1981) 0, 15, 30, 60 mg/kg/d Unacceptable/guideline	Maternal LOAEL = not established. Maternal NOAEL > 60 mg/kg/day, Developmental NOAEL > 60 mg/kg/day,

Table 4.1b Toxicity Profile of Mefluidide and its salts (114001, 114002, 114003)

Guideline No./ Study type	MRID No.(year)/Doses/ classification	Results
Toxicity, gavage [rat]	(LOAEL was not observed)	Developmental LOAEL = not established.
870.3700a 83-3(a) Developmental Toxicity Gavage [rat]	42097201 (range finding) 42097701 (teratology), 1991 Range finding: 0, 100, 200, 400, 600 or 800 mg a.i./kg/d Teratology study: 0, 50, 200 or 400 mg a.i./kg/d Mefluidide technical 58.2% a.i. Acceptable/Guideline	Maternal LOAEL = 400 mg/kg/d based on reduced gain and food consumption. Higher dose in the range finding study of 600 mg/kg/day produced excessive mortality. Maternal NOAEL = 200 mg/kg/d Developmental LOAEL = 400 mg/kg/d based on slight fetal toxicity as indicated by a slight nonstatistical increase in 14 th rib. Developmental NOAEL = 200 mg/kg/d
Non-guideline Range Finding Developmental Toxicity, gavage[rat]	42026101, (1991) 0, 100, 200, 400, 600or 800 mg diethanolamine salt of mefluidide (28.78%)/kg/d (6 female rats/dose) Range finding Acceptable/non-guideline	Maternal LOAEL: 115 mg a.i./kg/day based on clinical signs (tremors, hunched posture, and salivation), maternal body weight gain and food consumption. Maternal NOAEL: 58 mg a.i./kg/day; Developmental LOAEL: 230 mg a.i. /kg/day based on significantly decreased fetal body weight. Developmental NOAEL: 173 mg a.i. /kg/day, The dosage levels of 0, 50, 200 and 400 mg of the 28.78% formulation/kg/day were selected for the definitive developmental study.
870.3700a 83-3(a) Developmental Toxicity, gavage [rat]	42026102, (1991) 0, 50, 200 400 mg diethanolamine salt of mefluidide (28.78%)/kg/d (25 females/dose) Doses adjusted for 100 % purity were 0, 14, 58, or 115 mg/kg/day. Acceptable/guideline	Maternal LOAEL = 115 mg a.i./kg/day based on mortality, clinical signs (tremors, stained nose, urine and vaginal discharge), decreased body weight and weight gain. Maternal NOAEL = 58 mg a.i./kg/day), Developmental LOAEL = 115 mg a.i./kg/day based on increased number of early resorptions and mean post-implantation loss. Developmental NOAEL: 58mg a.i./kg/day
Non-guideline 14-Day Oral gavage [rabbit]	00047138, (1975) 0, 100, 200, 400, 800 mg/kg/d Vistar tech, 93% a.i. 4 females/dose range finding Acceptable/non-guideline	LOAEL = < 100 mg/kg/day (females), based on mortality (1/3 deaths) at 100 mg/kg/d. Tremors and 100% mortality were noted at the levels of 200 mg/kg/d and above. Histopathology not reported. NOAEL: not established,
870.3700b 83-3(b) Developmental Toxicity, gavage [rabbit]	00047139, (1975) 0, 15, 30, 60 mg technical MBR 12325/kg/d (purity not reported). Unacceptable by itself, however, if combined with the 14-day oral study (00047138), it is acceptable.	Maternal LOAEL = not established. Maternal NOAEL = 60 mg/kg/day, Developmental LOAEL = not established. Developmental NOAEL = 60 mg/kg/day,
870.3800 (83-4)	00082748, (1979)	The parental systemic LOAEL = 346/604 mg/kg bw/day (M/F), based on decreased body weights.

Table 4.1b Toxicity Profile of Mefluidide and its salts (114001, 114002, 114003)

Guideline No./ Study type	MRID No.(year)/Doses/ classification	Results
3-generation reproduction [rat]	0, 600, 1800, 6000 ppm, 93% a.i. (M/F: 0/0, 34/60, 102/183, 346/604 mg/kg/d) Acceptable/guideline	The parental systemic NOAEL = 102/183 mg/kg bw/day in males/females. The offspring LOAEL = 346/604 mg/kg bw/day in males/females, based on decreased body weights in both sexes and both litters in all generations. The offspring NOAEL = 102/183 mg/kg bw/day in males/females. The reproductive LOAEL was not observed. The reproductive NOAEL = 346/604 mg/kg bw/day in males/females.
870.5100 84-2 Bacterial reverse mutation	00132996, (1983) EL-565 (Lily compound 151065: mefluidide technical) tested at 0.1 – 1000 µg/ml Acceptable/Guideline	No reverse mutations were noted in any of 8 tester strains of <i>Salmonella typhimurium</i> and two tryptophan autotrophs of <i>E. coli with or without metabolic activation</i>
870.5100 84-2 Bacterial reverse mutation	41888804, (1991) 0, 100, 333, 667, 1000, 3330, or 5000 µg/plate diethanolamine salt of mefluidide (28.78%)/ Acceptable/guideline	DEA mefluidide did not increase the number of histidine revertants per plate in any of the tester strains with or without metabolic activation.
870.5300 84-2 <i>In-vitro</i> Mouse lymphoma - gene mutation	00132996, (1983) EL-565 (Lily compound 151065: mefluidide technical)0, 1, 25, 50, 100, 250, 500, 750 or 1000 µg/ml Acceptable/guideline	There was no evidence of mutation in the presence or absence of metabolic activation.
870.5375 84-2 <i>In-vitro</i> mammalian chromosome aberration test	41888803, (1991) Diethanolamine salt of mefluidide (28.8%) 500,- 5010 µg a.i. /ml (without S9 mix) or 500, - 5000 (with S9 mix) Acceptable/guideline	No significant increase in structural chromosomal aberration with or without metabolic activation was seen, however, the results were considered equivocal.
' 84-2 <i>In-vitro</i> mammalian chromosome aberration test	(1992) concentrations of 1250 to 5000 Φg/ml (w S9 mix) or 200-1600 (wt S9 mix)	Not mutagenic in Chinese Hamster Ovary cells
870.5550 84-2 Unscheduled DNA Synthesis	41888802, (1991) Diethanolamine salt of mefluidide (28.8%) Concentrations of 100, 250, 500, 1000, 2000, 3000 µg/ml in trial 1; 1000, 1500, 2000, 3000, 3500 µg/ml in trial 2. Acceptable/guideline	No unscheduled DNA synthesis response in the absence of moderate to severe cytotoxicity.
870.5550 84-2	00132996, (1983) EL-565 (Lily compound 151065:	No indication of DNA repair synthesis was observed in cultured rat hepatocytes treated with

Table 4.1b Toxicity Profile of Mefluidide and its salts (114001, 114002, 114003)

Guideline No./ Study type	MRID No.(year)/Doses/ classification	Results
Unscheduled DNA Synthesis	mefluidide technical) Tested at 0.5 to 1000 nmoles/mL	the test material (EL-565 (Lily compound 151065: mefluidide technical))
870.5915 84-2 <i>In-vivo</i> Sister Chromatid Exchange	00132996, (1983) EL-565 (Lily compound 151065: mefluidide technical) (0, 12.5, 25, 50, or 100 mg/kg. Acceptable/Guideline	Negative in sister chromatid exchange in <i>in-vivo</i> bone marrow of Chinese hamster assay.
870.5915 85-1 Metabolism- male rat	MRID is not known: Steifer, LJ (1978). 3M Company Report Number 852 (1-26-78) Dose: 1 or 10 mg/kg of C-14, labeled mefluidide Acceptable/None-Guideline	By 24 hrs of post-treatment, 86-89% of the dose was found in urine with the remainder in the feces. Residue consisted of mefluidide (97%) and 2 unidentified metabolites (1.2% and 0.5%) and unidentified polar material (0.7%).
870.6200 81-8 Demyelination study - Chicken	0097684 (1977) 1000, 3000, 5000, 10,000 and 20,000 mg/kg/day. Non-Acceptable/Non-Guideline	NOAEL < 1000 mg/kg/day; LOAEL: 1000 mg/kg/day based on clinical signs (hypoactivity, ataxia, tremors, lethargy and dyspnea) that were subsided by 48 hrs following dosing. The test material did not induce delayed neurotoxicity in hens at the LD 50 dosage of 8500 mg/kg. (Limit dose - 1 g/kg).

M = Males; F = Females

4.2 Hazard considerations For Women and Children

4.2.1. Adequacy of the Toxicity Database

The toxicology database for mefluidide is considered adequate. The following acceptable studies are available:

- Developmental toxicity studies in rats
- Developmental toxicity studies in rabbits
- Two-generation reproduction study in rats

4.2. 2. Evidence of Neurotoxicity

Acute and subchronic neurotoxicity studies were not performed. Clinical signs of neurotoxicity (such as tremors, ataxia, atonia, decreased limb tone, salivation) were seen in several studies (14-day oral in rabbit at or above 200 mg/kg/day, demyelination study in chickens at 1000 mg/kg/day and two developmental toxicity studies in rats at 115 mg/kg/day. Edema and swelling with myelin loss in sciatic nerve was observed in a dermal toxicity study in rabbits at doses of 720 mg/kg and above. However, these effects were not seen in an additional dermal test of similar duration using a 58.2% mefluidide formulation or diethanolamine salt of mefluidide 28.8%.

4.2.3. Developmental Toxicity Study Conclusions

Developmental Toxicity Study - Rabbits:

In a developmental toxicity study (MRIDs 00047139 and 00047138), technical MBR 12325 (Lot #9) in 4% gum acacia was administered to 16-20 New Zealand White rabbits/dose group via gavage at dose levels of 0, 15, 30, or 60 mg/kg bw/day from gestation days (GD) 6-18.

There were no treatment-related effects on survival, clinical signs, body weight, food consumption, or cesarean parameters.

The maternal LOAEL was not observed. The maternal NOAEL is 60 mg/kg bw/day (the highest dose tested).

There were no effects of treatment on the numbers of litters, live fetuses, dead fetuses, or resorptions, or on fetal body weights, sex ratio, or post-implantation loss. There were no treatment-related external, visceral, or skeletal variations or malformations.

The developmental LOAEL was not observed. The developmental NOAEL is 60 mg/kg bw/day (the highest dose tested).

This developmental toxicity study in rabbits has a number of deficiencies: a LOAEL was not observed; test material purity was not provided; no information on dose formulation preparation or storage was provided; and no analyses of homogeneity, stability, or concentration were reported. However, when combined with the 14-day oral gavage study in rabbits (MRID 00047138), where a LOAEL of <100 mg/kg bw/day based on mortality and tremor was established, this developmental toxicity study is considered acceptable and satisfies the guideline for a developmental toxicity study (OPPTS 870.3700b; OECD 414) in rabbits.

Developmental Toxicity Study - Rats:

In a developmental toxicity study (MRID 42026102), Diethanolamine salt of Mefluidide (28.78% a.i. Lot # JB0624) in distilled water was administered to pregnant Sprague Dawley Crl:CD BR VAF/Plus (25/dose) by gavage at dose levels of 0, 50, 200 or 400 mg/kg bw/day (adjusted doses for 100 % purity were 0, 14, 58, or 115 mg/kg/day, respectively) from days 6 through 15 of gestation.

Animals were checked daily for clinical signs, mortality. Body weights were measured on gestation day 0, 6, 9, 12, 16 and 20. Unscheduled deaths, scheduled sacrifice and c-sections were subjected to gross necropsy examination. Each fetus was examined for external/visceral/skeletal anomalies, sexed and then weighed.

Evidence of maternal toxicity included transient clinical signs (tremors, dark material around the nose, few feces, urine stain and reddish vaginal discharge), decreased body weight gain (11-61%), decreased food consumption and mortality (2/25 females found dead on GD 11 and 16) observed at the 400 mg/kg/day levels. At the 400 mg/kg dose, the clinical signs of toxicity appeared within 2 days after dosing in few animals, and after few days of dosing in some others and more than half of the animals at this dose were free from clinical signs of toxicity. No external malformations or developmental variations were observed associated with any fetus. Fetal toxicity was manifested by increase in the number of early resorptions which resulted in increase in mean postimplantation loss at 400 mg/kg/day dose.

After adjusting to the pure active ingredient, the maternal NOAEL is 58 mg/kg/day and the LOAEL is 115 mg/kg/day based on clinical signs (tremors, dark material around the nose, urine stain and reddish vaginal discharge), decreased body weight gain, decreased food consumption and mortality (2/25 females). The developmental toxicity NOAEL is also 58 mg/kg/day, the LOAEL is 115 mg/kg/day based on increase in the number of early resorptions and increase in mean postimplantation loss.

This developmental toxicity study is classified **acceptable/Guideline** and it does satisfy the guideline requirement for a developmental toxicity study (OPPTS 870.3700; OECD 414) in the rat.

4.2.4. Reproductive Toxicity Study

In a three-generation reproduction study (MRID 00082748), MBR 12325 (Mefluidide; 93% a.i., Lot #25) was administered in the diet to 20 male and 40 female Charles River CD® rats/dose group at dose levels of 0, 600, 1800, or 6000 ppm (equivalent to Males/Females - 0/0, 34/60, 102/183, and 346/604 mg/kg bw/day). When approximately 100 days old, the P generation animals were mated (1 male: 2 females) for up to 15 days to produce the F1a litter. Following weaning of the F1a litters, 50 F1a offspring/sex/dose were selected for a 2-year chronic feeding study, and the remaining F1a offspring were discarded. The P generation was reduced to 10 males/20 females per dose group. After a 10-day post-weaning rest period, these P animals were mated again to produce the F1b litter. Upon weaning, 10 male and 20 female F1b offspring/dose group were selected to be parents of the F2 generation. This study design was continued for three generations with 2 litters per generation.

There were no effects on food consumption, organ weights, gross pathology, or histopathology.

Numerous absolute and relative (to bw) organ weights in the 6000 ppm parents were significantly ($p < 0.05$) different from the controls, however, none of these differences were corroborated by any macroscopic or microscopic findings indicating these decreases were most likely not related to treatment. Thus, it is likely that they were attributable to decreased body weights at this dose.

The only deaths included one 6000 ppm F1 female, one 6000 ppm F2 male, and one 1800 ppm F2 female. It was stated that macroscopic and microscopic findings in these animals were unremarkable. Therefore, these deaths were considered incidental and were not treatment related.

At 6000 ppm, body weights were decreased by 1-8% in males and 1-12% in females throughout the study in the P generation, attaining significance ($p < 0.05$) at Week 18 in the males and Weeks 8, 18, 19, and 27 in the females. In the F1 generation at this dose, body weights were decreased throughout the study in the males (decr. 13-21%) and females (decr. 10-21%), attaining significance ($p < 0.01$) at Weeks 27, 37, and 56 in both sexes. Similarly in the F2 generation, body weights were decreased throughout the study in the 6000 ppm males (decr. 14-21%) and females (decr. 11-23%), attaining significance ($p < 0.01$) at Weeks 57, 66, and 85 in both sexes.

At 1800 ppm, only minor and infrequent decreases in body weights were noted. There were no treatment-related findings at 600 ppm.

The parental systemic LOAEL is 6000 ppm (346/604 mg/kg bw/day in males/females), based on decreased body weights in both sexes in all generations. The parental systemic NOAEL is 1800 ppm (102/183 mg/kg bw/day in males/females).

There were no effects of treatment on post-natal survival (i.e., viability and lactation) indices in the pups at any dose. There were no treatment-related findings at 600 or 1800 ppm.

At 6000 ppm, body weights were decreased by up to 27% compared to controls throughout the post-natal period in both litters in each generation (i.e., F1a, F1b, F2a, F2b, F3a, and F3b litters). These decreases attained significance in both sexes at PND 21.

The offspring LOAEL is 6000 ppm (346/604 mg/kg bw/day in males/females), based on decreased body weights in both sexes and both litters in all generations. The offspring NOAEL is 1800 ppm (102/183 mg/kg bw/day in males/females).

There were no effects of treatment on male or female fertility indices or gestation survival index.

The reproductive LOAEL was not observed. The reproductive NOAEL is 6000 ppm (346/604 mg/kg bw/day in males/females).

This study is **acceptable/guideline** and satisfies the guideline requirement for a three-generation reproductive study (OPPTS 870.3800; OECD 416) in rats.

4.2.5. Additional Information from Literature sources

There was no published information on this subject.

4.3. Hazard Identification and Toxicity Endpoint Selection

4.3.1. Acute Reference Dose (aRfD)

Females age 13-49 : Acute dietary endpoint for child bearing females (females 13+ years old) was determined from the developmental toxicity study in rat (MRID 42026102). A NOAEL of 58 mg/kg/day was derived based on developmental toxicity (increased number of early resorptions and mean post-implantation loss) at a LOAEL of 115 mg/kg/day. An UF of 100X (10-fold for inter-species extrapolation, 10-fold for intra-species variability) was applied to the NOAEL of 58 mg/kg/day to derive the aRfD.

$\text{Acute RfD (Females 13-50 years old)} = \frac{58 \text{ mg/kg (NOAEL)}}{100 \text{ (UF)}} = 0.58 \text{ mg/kg}$

Acute Reference Dose (aRfD) - General Population

The acute RfD for the general population including infants and children was determined from the developmental toxicity study in rat (MRID 42026102). A NOAEL of 58 mg/kg/day was derived based on maternal toxicity (clinical signs: tremors) at a LOAEL of 115 mg/kg/day. An UF of 100X (10-fold for inter-species extrapolation, 10-fold for intra-species variability) was applied. The selected endpoint of toxicity is appropriate for this exposure since clinical signs of toxicity occurred within two days of dosing.

$$\text{Acute RfD (general population)} = \frac{58 \text{ mg/kg (NOAEL)}}{100 \text{ (UF)}} = 0.58 \text{ mg/kg}$$

4.3.2. Chronic Reference Dose (cRfD)

The cRfD of 0.015 mg/kg/day was determined on the basis of the Chronic Oral Feeding – dog (MRID 00132995); NOAEL of 1.5 mg/kg/day and LOAEL of 15.0 mg/kg/day based on decreased body weight (15%) and body weight gain (50%) in the males. This study provided the lowest NOAEL (1.5 mg/kg/d) in the database that provides the most protective limits for human effects. An UF of 100X (10-fold for interspecies extrapolation, 10-fold for intraspecies variability) was applied to the NOAEL of 1.5 mg/kg/day to derive the cRfD to give and RfD of 0.015 mg/kg/day.

4.3.3. Incidental Oral Exposure (Short-and Intermediate-term durations: 1 day – 6 months)

Points of departure for these scenarios were based on the rat developmental study (MRID 42026102). NOAEL = 58 mg/kg bw/day, LOAEL = 115 mg/kg bw/day based on mortality and clinical signs. These data were also supported by the rabbit developmental study (NOAEL = 60 mg/kg bw/day) and rabbit 14 day oral study (LOAEL = 100 mg/kg bw/day based on mortality). The level of concern for residential exposure is for MOEs = 100 and for occupational exposure is for MOEs = 100.

4.3.4. Dermal Absorption Factor

A dermal penetration study is not available. A dermal absorption factor is derived by extrapolation from the rabbit 21-day dermal (MRID 41972901) and rabbit 14 day oral (MRID 00082073) studies. The dermal systemic NOAEL in the 21-day study is 1000 mg/kg/day based on minor increases in liver enzymes. In the 14 day rabbit oral study (MRID 00047138), the LOAEL is less than 100 mg/kg/day based on mortality and clinical signs (tremors) and the NOAEL is <100 mg/kg/day, therefore, the calculated dermal absorption factor would at the most be (100/1000) x 100 = 10%.

4.3.5. Dermal Exposure (Short and Intermediate: (1-30 days and 30 d-180 days)

Three subacute (21-day) dermal toxicity studies were considered. The two more recent studies (MRID 42029601 and 41972901) showed no systemic effects at the limit dose. Only one study (MRID 00082073) with 24% active ingredient showed toxic effects (Edema and swelling with myelin loss in sciatic nerve at 720 and 2400 mg/kg/day). These effects were not seen in the more recent GLP dermal studies using a 58.2% mefluidide formulation (MRID

42029601) or diethanolamine salt of mefluidide 28.8% (MRID 41972901). The risk assessment team determined that no quantitative dermal assessment is needed due to the following:

- 1) Two 21-day dermal toxicity studies with rabbits indicated no dermal systemic toxicity at 1000 mg/kg/day (the highest dose tested). The one study that showed toxicity indicated that effects only occurred at high doses.
- 2) The rat developmental study indicated no developmental concern (developmental NOAEL equals to maternal NOAEL),
- 3) The acute dermal toxicity of mefluidide, where the acute dermal LD50 is >4000 mg/kg, it is not a skin irritant and is not a dermal sensitizer.

4.3.6. Inhalation (Short- and Intermediate-Term)

Endpoint for this scenario was determined from the rat developmental study. NOAEL = 58 mg/kg bw/day, LOAEL = 115 mg/kg bw/day based on mortality and clinical sings. These data were also supported by the rabbit developmental study (NOAEL = 60 mg/kg bw/day) and rabbit 14 day oral study (LOAEL = 100 mg/kg bw/day based on mortality). Since oral study was selected for inhalation exposure assessment an inhalation-absorption factor of 100% oral equivalent should be used.

4.3.7. Margins of Exposure

These are summarized in the following table:

Route Duration	Short-Term (1-30 Days)	Intermediate-Term (1 - 6 Months)
Occupational (Worker) Exposure		
Dermal	NA	NA
Inhalation	100	100
Residential (Non-Dietary) Exposure		
Oral	100	100
Dermal	NA	NA
Inhalation	100	100

4.3.8. Classification of Carcinogenic Potential

Mefluidide was negative for carcinogenicity in mouse (MRID 00082747) and rat (MRID 00061930 7 00082737) bioassays. It was also evaluated for genotoxicity in several tests and found negative. It is unlikely that mefluidide will pose a cancer risk to humans.

Table 4.3. Summary of Toxicological Dose and Endpoints for Mefluidide and its salt (114001, 114002, 114003) Used in Human Risk Assessment

Exposure Scenario	Point of Departure	Uncertainty Factors	Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (general population)	NOAEL = 58 mg/kg/day	UF _A = 10X UF _H = 10X	Acute RfD = <u>Maternal NOAEL</u> Uncertainty Factor = 0.58 mg/kg /day	MRID 42026102 Developmental toxicity - rat; LOAEL= 115.0 mg/kg/day based on mortality(within 5 days of dosing) and clinical signs (within 2 days of dosing), and the NOAEL of 58 mg/kg/day.
Acute Dietary (Females 13+)	NOAEL = 58 mg/kg/day	UF _A = 10X UF _H = 10X	Acute RfD = <u>Develop. NOAEL</u> Uncertainty Factor = 0.58 mg/kg	MRID 42026102 Developmental toxicity - rat; LOAEL= 115.0 mg/kg/day based on increased number of early resorptions and mean postimplantation loss. NOAEL = 58 mg/kg/day
Chronic Dietary (All populations)	NOAEL = 1.5 mg/kg/day	UF _A = 10X UF _H = 10X	Chronic RfD = <u>NOAEL</u> Uncertainty Factor = 0.015 mg/kg/day	MRID 00132995 Chronic Oral Feeding - dog; LOAEL= 15.0 mg/kg/day based on decreased body weight (15%) and body weight gain (50%) in the males at 15 mg/kg/day.
Short-Term Incidental Oral (1-30 days)	NOAEL = 58 mg/kg/day	UF _A = 10X UF _H = 10X	Residential LOC for MOE = 100	MRID 42026102 Developmental toxicity - rat; NOAEL = 58 mg/kg bw/day, LOAEL = 115 mg/kg bw/day based on mortality and clinical sings. These data were also supported by the rabbit developmental study (MRID 00047139) (NOAEL = 60 mg/kg bw/day) and rabbit 14 day oral study (LOAEL = 100 mg/kg bw/day based on mortality).
Intermediate-Term Incidental Oral (1-6 months)				
Short-Term Dermal (1 to 30 days)	Dermal NOAEL = 1000 mg/kg/day	UF _A = 10X UF _H = 10X	No quantitative dermal assessment is needed.	Three subacute (21-day) dermal toxicity studies were considered. The risk assessment team determined that no quantitative dermal assessment is needed due to the following: 1) Two 21-day dermal toxicity studies with rabbits indicated no
Intermediate-Term Dermal (1 to 6 months)				

Table 4.3. Summary of Toxicological Dose and Endpoints for Mefluidide and its salt (114001, 114002, 114003) Used in Human Risk Assessment

Exposure Scenario	Point of Departure	Uncertainty Factors	Level of Concern for Risk Assessment	Study and Toxicological Effects
				dermal systemic toxicity at 1000 mg/kg/day (the highest dose tested). The one study that showed toxicity indicated that effects only occurred at high doses. 2) the rat developmental study indicated no developmental concern (developmental NOAEL = maternal NOAEL), 3) Acute toxicity of mefluidide, where acute dermal LD50 is >4000 mg/kg, not a skin irritant and is not a dermal sensitizer.
Short-Term Inhalation (1 to 30 days)	Oral NOAEL = 58 mg/kg/day	$UF_A = 10X$ $UF_H = 10X$	Residential LOC for MOE = 100;	MRID 42026102 Developmental toxicity - rat; NOAEL = 58 mg/kg bw/day, LOAEL = 115 mg/kg bw/day based on mortality and clinical sings. These data were also supported by the rabbit developmental study (NOAEL = 60 mg/kg bw/day) and rabbit 14 day oral study (LOAEL = 100 mg/kg bw/day based on mortality).
Intermediate-Term Inhalation (1 to 6 months)	(inhalation-absorption rate = 100% oral equivalent)		Occupational LOC for MOE = 100	
Cancer	Mefluidide was negative for carcinogenicity in mouse (MRID 00061930 7 00082737) bioassays. It was also evaluated for genotoxicity in several tests and found negative.			

Point of Departure (POD) = a data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. UF = uncertainty factor, UF_A = extrapolation from animal to human (intraspecies), UF_H = potential variation in sensitivity among members of the human population (interspecies), NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, RfD = reference dose (a = acute, c = chronic), MOE = margin of exposure, LOC = level of concern, NA = Not Applicable. Safety Factor = UF = 100.

5.0 Public Health Data

5.1 Incident Reports

(HED memo of 07/25/06, M. Hawkins, D324824)

The following data bases have been consulted for the poisoning incident data on the active ingredient Mefluidide and salts:

- 1) OPP Incident Data System (IDS) - No reports for mefluidide or its salts in the Incident Data System.
- 2) Poison Control Centers - No reports located in the Poison Control Center records from 1993 through 2003 involving mefluidide.
- 3) California Department of Pesticide Regulation - Detailed description of 1 case submitted to the California Pesticide Illness Surveillance Program (1982-2003) was reviewed. In the case, a worker reported a rash on the side of their face after several workers passed a vehicle that sprayed the product.
- 4) National Pesticide Information Center (NPIC) - From 1984-1991 inclusively, mefluidide was not reported to be involved in human incidents.
- 5) National Institute of Occupational Safety and Health's Sentinel Event Notification System for Occupational Risks (NIOSH SENSOR) - Of 5,899 reported cases from 1998-2003, none involved mefluidide.

In conclusion, there was only one report of an ill effect from exposure to mefluidide in the available data bases.

6.0 EXPOSURE CHARACTERIZATION/ASSESSMENT

6.1 Dietary Exposure/Risk Pathway

6.1.1 Food Exposure/Risk Pathway

None. No food uses.

6.1.2 Water Exposure/Risk Pathway

Drinking water Assessment; James Hetrick (D334508, 03/08/07)

Possible routes of dissipation for mefluidide are photodegradation on soil surfaces and microbial-mediated degradation. Mefluidide is not prone to abiotic hydrolysis or photolysis in sterile buffer solutions within the environmentally relevant pH range of 4 to 9. There are data showing mefluidide undergoes rapid photodegradation ($t_{1/2} = 2$ to 3 days) in natural well water. On soil surfaces, mefluidide photodegraded with a half-life of 116.4 hours. Mefluidide in aerobic soils degraded with a half-life of 12 days. The only degradation product was 5-amino-2,4-dimethyltrifluoromethanesulfonilide. It was found at a maximum daily concentration of 2.8% of applied dose (MRID 43162201, aerobic soil). Mefluidide dissipated with a half-life of 2.0 to 3.3 days in warm-season turf soil in Georgia and 1.2 to 1.4 days in cool-season grass soil in Missouri. Mefluidide dissipated from grass foliage at half-lives of 1.7 to 6.91 days (upper 90th percentile of mean half-life= 4.0414 day, $k = 0.1715 \text{ days}^{-1}$).

No surface or ground water monitoring data were found for mefluidide. Drinking water assessment was conducted using Tier II (PRZM-EXAMS) for surface water modeling and Tier I (SCI-GROW) for groundwater modeling. Because mefluidide use is associated with

turf, the aquatic exposure assessment was conducted using the PA and FL turf scenarios. These use scenarios were selected to represent of rights-of-way, residential turf, industrial areas with turf (i.e., airports, etc.), and golf courses. The turf scenarios are expected to be conservative estimate of mefluidide runoff potential because they assume 100% of the watershed is treated with mefluidide as well as the runoff scenarios are located in areas with high runoff potential. The mefluidide acid concentrations in surface water are not expected to exceed 32 µg/L for the 1 in 10 year daily peak concentration, 10 µg/L for the 1 in 10 year annual concentration, and 5 µg/L for the 30 year annual average concentration. Mefluidide acid concentrations in ground water are not expected to exceed 1.0 µg/L. These concentrations have not been adjusted for any crop area factor (CAF) because the crop area factors do not account for non-agricultural uses such as turf, ornamentals, etc. Uncertainty in the assessment is the persistence of mefluidide acid in aerobic aquatic environments. This assessment was conducted using an estimated aerobic aquatic half-life of 72 days (Guidance for Chemistry and Management Practice Input Parameters for Use in Modeling the Environmental Fate and Transport of Pesticides, Version 2, 11/7/2000). Because this estimated half-life was designed to approximate upper 90th percentile of the mean half-life, it is anticipated to be a conservative estimate of mefluidide acid persistence in aquatic environments.

6.2 Dietary Exposure Estimates

Acute and chronic dietary risk assessments were conducted using the Dietary Exposure Evaluation Model (DEEM-FCID™, Version 2.03) which uses food consumption data from the U.S. Department of Agriculture's Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994-1996 and 1998.

Acute Dietary Exposure from Drinking Water

An acute dietary exposure assessment was performed for mefluidide considering exposures from surface water only, as there are no food uses for this chemical. An estimated drinking water concentration (EDWC) for surface water (32 ppb) provided by the Environmental Fate and Effects Division (EFED) was used in this assessment. Ground water sources were not included, as the EDWCs for this water source are minimal in comparison to surface water. The drinking water exposure analysis result in dietary risk estimates for surface water only are below the Agency's level of concern for acute exposure. At the 95th percentile, the exposure to U.S. population was 0.0017 mg/kg/day, which utilized <1% of the acute reference dose (aRfD). The exposure for all infants, which was the most highly exposed population subgroup, was 0.006 mg/kg/day, which utilized **1% of the aRfD**. Conservative screening-level drinking water estimates were used in this assessment (i.e., the highest peak surface water level for a one in ten year concentration), therefore the dietary risk estimates were reported at the 95th percentile of exposure.

Chronic Dietary Exposure from Drinking Water

A chronic dietary exposure from drinking water only was also performed using surface water EDWC value (10 ppb). For the U.S. population the exposure was 0.0002 mg/kg/day, which

utilized **1%** of the chronic reference dose (cRfD). The exposure for all infants, which was the most highly exposed population subgroup, was 0.0007mg/kg/day, which utilized **5% of the cRfD**.

Table 6.2. Summary of Drinking Water Exposure and Risk for Mefluidide						
Population Subgroup	Acute Dietary 95 th Percentile			Chronic Dietary		
	aRfD (mg/kg/day)	Dietary Exposure (mg/kg/day)	% aRfD	cRfD (mg/kg/day)	Dietary Exposure (mg/kg/day)	% cRfD
General U.S. Population	0.58	0.001672	<1	0.015	0.000211	1
All Infants (< 1 year old)		0.006303	1		0.000691	5
Children 1-2 years old		0.002623	<1		0.000313	2
Children 3-5 years old		0.002396	<1		0.000293	2
Children 6-12 years old		0.001668	<1		0.000202	1
Youth 13-19 years old		0.001356	<1		0.000152	1
Adults 20-49 years old		0.001549	<1		0.000197	1
Adults 50+ years old		0.001399	<1		0.000207	1
Females 13-49 years old		0.001558	<1		0.000196	1

For detailed DEEM input and result files, please see Attachment I.

6.3 Residential (Non-Occupational) Exposure/Risk Pathway

Occupational and Residential Exposure Assessment; Yan Donovan, D324823, 2/28/07.

Mefluidide is intended for both occupational and residential uses. None of the labels prohibit use by homeowners. The residential products are typically formulated as granules, or as liquid concentrates, or ready- to- use sprinkler can sprays. Spot and broadcast treatments are both included on the labels. Exposures are expected to be short term in duration.

6.3.1. Residential Handler Exposure and Risks

Residential Handler Scenarios, Data Sources and Assumptions

Scenarios

Based on the product labels, the following scenarios were assessed.

1. Load/Apply Granules with Belly Grinder

2. Load/Apply Granules with a Broadcast Spreader
3. Mix/Load/Apply with a Hose-end Sprayer (Mix your own)
4. Mix/Load/Apply with Hand Held Pump Sprayer.

Data Sources

Exposure data for scenario #1 was taken from PHED because no unit exposure data is available from ORETF for this specific scenario. Exposure data for scenarios #2 and #3 were taken from the residential portion of the ORETF Handler Study. Exposure data for scenario #4 was taken from MRID 44459801, a study involved low pressure handwand and RTU trigger sprayer application of carbaryl to home vegetable plants. This study was reviewed by Jeff Dawson in document D287251, has since been purchased by ORETF.

Assumptions Regarding Residential Applicators

- Broadcast spreaders and hose end sprayers would be used for broadcast treatments and the other application methods would be used for spot treatments only.
- The application rate of 1.0 lb ai/acre is from mefluidide labels.
- An area of 0.023 acre (1000 square feet) would be treated per application during spot treatments and an area of 0.5 acre would be treated during broadcast applications.

Residential Handler Exposure and Risk Estimates

A summary is included in Table 6.3.1. The MOEs are > 100 and the risks are below EPA's level of concern.

Table 6.3.1- Mefluidide Short Term MOEs for Homeowner Applications to Lawns

Scenario	Application Rate	Area Treated or Amount Applied	Inhalation Unit Exposure (per lbs ai handled)	Inhalation Dose (mg/kg/day)	Inhalation MOE
Load/Apply granules with Belly Grinder (spot treatment)	0.5 lb ai/acre	0.023 acre/day	62 µg (PHED)	1.0E-05	6,000,000
Load/Apply Granules with a Broadcast Spreader	0.5 lb ai/acre	0.5 acre/day	0.91 µg (ORETF)	3.3E-06	18,000,000
Mix/Load/Apply with a Hose-end Sprayer (Mix your own)	1.0 ai/acre	0.5 acre/day	16 µg (ORETF)	1.1E-04	500,000
Mix/Load/Apply with Hand Held Pump Sprayer (use on turf)	1.0 lb ai/acre	0.023 acre/day	9 µg (MRID44459801)	3.0E-06	20,000,000
Mix/Load/Apply with Hand Held Pump Sprayer (use on ornamentals)	0.01 lbs ai /gallon	5 gallons	9 µg (MRID44459801)	6.0E-06	9,000,000

6.3.2. Residential Post Application Exposure and Risks

Residential Post Application Exposure Scenarios, Data Sources and Assumptions

Scenarios

The following exposure scenario was assessed for residential turf post application risks:

Short Term Incidental Oral Exposures of Toddlers Playing on Treated Turf

General Assumptions

The following general assumptions are taken from the Standard Operating Procedure (SOPs) of December 18, 1997 and ExpoSAC Policy #12 “Recommended Revisions to the Standard Operating Procedures for Residential Exposure Assessments of February 22, 2001.

- An assumed initial TTR value of 5% of the application rate is used for assessing hand to mouth exposures.
- An assumed initial TTR value of 20% of the application rate is used for assessing object to mouth exposures.
- Soil residues are contained in the top centimeter and soil density is 0.67 mL/gram.
- Three year old toddlers are expected to weigh 15 kg.
- Hand-to-mouth exposures are based on a frequency of 20 events/hour and a surface area per event of 20 cm² representing the palmar surfaces of three fingers.
- Saliva extraction efficiency is 50 percent meaning that every time the hand goes in the mouth approximately ½ of the residues on the hand are removed.
- An exposure duration of 2 hours per day is assumed for toddlers playing on turf.

Assumptions Specific to Mefluidide

The following assumptions that are specific to mefluidide are used for assessing residential post application exposures.

- The application rate of 1.0 lbs ai/acre as stated in the label was used. Although RTU product (EPA Reg # 2217-788) has the highest application rate of 1.23 lbs ai/acre, this product is considered to be used as spot treatment. As a result, the 1.23 lbs ai/acre is not considered a representative rate for turf use.

Calculation Methods

The above factors were used in the standard residential SOP formulas to calculate the incidental oral exposures from hand- to- mouth, object- to- mouth and soil ingestion on treated turf. These formulas are described in the cited ORE memo. The MOEs were calculated using the short/intermediate term incidental oral endpoint which has a NOAEL of 58 mg/kg/day.

The MOEs are summarized in Table 6.3.2A. All of the MOEs exceeded 100. This means that the risks are below EPA’s level of concern.

Table 6.3.2A - Mefluidide MOEs for Residential Post Application Turf Exposures (Application Rate = 1.0 lb ai/acre)			
Toddler Exposure Scenario	TTR and soil Residue Levels	Dose (mg/kg/day)	MOE
Hand to Mouth Ingestion	0.56 ug/cm ²	0.0150	4,000
Object to Mouth Ingestion	2.2 ug/cm ²	0.0037	16,000
Soil Ingestion	7.5 ppm	5.0E-05	1,000,000
Total of Above		0.019	3,000

The risk assessment for toddler turf exposures are conservative because it is based on day zero TTRs and soil residues and does not account for dissipation. The combined MOE is considered highly conservative since each of the single scenarios (hand-to-mouth, object-to-mouth, or soil ingestion) is assessed based on conservative assumptions, and that the likelihood of all three scenarios occur at the same time is very rare.

Residential Turf Granule Ingestion Exposure and Risks

Scenarios

The following exposure scenario was assessed

Acute Exposures of Toddlers from Incidental Oral Ingestion of Granules

Assumptions

The following assumptions were used to assess the risk of incidental oral ingestion of granules:

- The assumed ingestion rate is 0.3 gram/day based on the Residential SOP 2.3.1. This is based on the assumption that if 150 lbs of product were applied to a ½ acre lawn, the amount of product per square foot would be 3 g/ft² and a child would consume one-tenth of the product available in a square foot.
- Three year old toddlers are expected to weigh 15 kg.
- The granules contain a maximum of 0.49 percent mefluidide ai based upon product #538-181.

Calculation Methods and Risks

The above factors were used to calculate the potential dose rate and the absorbed dose using the Residential SOP 2.3.1 formulas as shown in Table 6.3.2B. MOEs were then calculated using the acute dietary NOAEL of 58 mg/kg/day and they exceed 100. This means that the risks for toddler exposures from granular ingestion are below EPA’s level of concern.

Table 6.3.2B - Granule Ingestion Risks for Mefluidide			
Percent ai	Potential Dose Rate¹ (mg/day)	Absorbed Dose² (mg/kg/day)	Acute MOE³
0.49	1.47	0.098	590
1. Potential Dose Rate (PDR) = 0.3 gram/day * (Percent ai/100)* 1000 mg/gram 2. Absorbed Dose = PDR/BW 3. MOE = NOAEL/Dose where the NOAEL = 58 mg/kg/day			

7.0 AGGREGATE RISK ASSESSMENTS AND RISK CHARACTERIZATION

7.1 Aggregate Risk

Aggregate Risk Assessment (food + water + residential exposure)

Although an aggregate risk assessment is not required under current Agency policies for non-food use chemicals, to ensure that the public health is adequately protected, a screening level aggregate risk assessment was conducted for mefluidide. For acute and chronic aggregate risks, the only exposure is from drinking water. As stated above, the dietary exposures (drinking water only) do not exceed 1% of the aRfD/cRfD for adult and 5% of the aRfD/cRfD for children. For short-term, no aggregate is needed for adults since there are no residential post-application exposures to adults. When considering the dietary exposure (drinking water only) as a background exposure to Children for short-term risk, the level of dietary exposure (0.0007 mg/kg/day) is negligible when compared to the combined incidental oral exposure

(0.019 mg/kg/day, Table 6.3.2A above) or the granule ingesting dose (0.098 mg/kg/day, Table 6.3.2B above). No intermediate-term residential post application exposure was identified. Therefore, short- and intermediate- term aggregate is not of concern.

7.2 Cancer Risk

Based on lack of evidence of carcinogenicity in both rats and mice, mefluidide was considered as not likely to be carcinogenic to humans. No cancer assessment is needed.

8.0 CUMULATIVE RISK CHARACTERIZATION/ASSESSMENT

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 as to mefluidide and any other substances and mefluidide does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that mefluidide has a common mechanism of toxicity with other substances. 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/>.

9.0 OCCUPATIONAL EXPOSURE/RISK PATHWAY

(Occupational and Residential Exposure Assessment; Yan Donovan, D324823, 2/28/07).

Mefluidide products are intended for both occupational and residential uses.

9.1 Short/Intermediate-Term Handler Risk

Based upon the application methods listed in Table , the following exposure scenarios were identified and assessed.

- Mix/Load Liquid Formulations
- Groundboom Application
- Turfgun Application
- Right of Way Application
- Mix/Load/Apply Liquids with a Backpack Sprayer
- Mix/Load/Apply Liquids with a Turfgun
- Load/Apply Granules with a Push Cyclone

Occupational Handler Exposure Assumptions and Data Sources

Exposure Assumptions

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

- The daily acreages treated were taken from EPA Science Advisory Council for Exposure Standard Operating Procedure #9 “Standard Values for Daily Acres Treated in Agriculture,” Revised July 5, 2000.
- The maximum application rate for turf areas is 1.0 lbs ai per acre as listed in the Mefluidide labels.
- The maximum application rate for ornamental trees is 0.01 lbs ai per gallon based upon the Label #2217-759.
- A body weight of 70 kg was assumed because the endpoint is not gender specific.
- The inhalation absorption rate is 100%.
- Baseline indicates that no respirator is worn.

Handler Exposure Data Sources

The handler exposure data were taken from the Pesticide Handler Exposure Database (PHED) and the Outdoor Residential Exposure Task Force (ORETF). The PHED data were used primarily for the golf course, ornamental trees, and rights- of - ways (ROW) scenarios and the ORETF data were used for lawn care scenarios. The detailed values specific to each exposure scenario can be found in the above cited ORE memo.

Occupational Handler Exposure and Risk Estimates

Daily inhalation doses and Margins of Exposure (MOEs) were calculated using standard HED methodology. The MOEs for occupational handlers are summarized in Table 9.1. All of the MOEs are > 100 with baseline PPE which means that the risks are not of concern and respiratory protection is not needed.

Table 9.1 – Mefluidide Inhalation MOEs for Occupational Handlers

Exposure Scenario	Use Site	Application Rate	Daily Amount Treated or Applied	Inhalation Unit Exposure at Baseline (µg/lb ai handled)	MOE at Baseline Level¹
Mixer/Loader (M/L)					
M/L Liquids for Turfgun (20 PCOs)	PCO ² Turf	1.0 lb ai/acre	100 acres	1.2	34,000
M/L Liquids for High pressure Handwand	Ornamental trees	0.01lb ai/gallon	1000 gallons	1.2	340,000
M/L Liquids for Groundboom	Golf Courses	1.0 lb ai/acre	40 acres	1.2	85,000
M/L Liquids for ROW Sprayer	Right of Way	0.067 lb ai/gallon	1000 gallons	1.2	50,000
Applicator					
Groundboom Application	Golf Courses	1.0 lb ai/acre	40 acres	0.74	140,000
ROW Sprayer Application	Non Turf Areas ³	0.067 lb ai/gallon	1000 gallons	3.9	16,000
Turfgun Application	PCO Turf	1.0 lb ai/acre	5 acres	1.0	812,000
Mixer/Loader/Applicator (M/L/A)					
M/L/A Liquid Flowables with Turfgun	PCO Turf	1.0 lb ai/acre	5 acres	1.9	427,000
M/L/A Liquids with Backpack Sprayer	Non Turf Areas	0.067 lb ai/gallon	40 gallons	30	50,000
M/L/A Granules with Push Cyclone	PCO Turf	0.5 lb ai/acre	5 acres	7.5	217,000
1. Baseline PPE indicates no respirator. 2. PCO Turf includes residential lawns, commercial lawns and other lawn areas treated by a Pest Control Operator (PCO). 3. Non Turf Areas include roadsides, Rights of Way (ROW) and other similar non-crop areas.					

Occupational Handler Risk Characterization

All the MOEs for occupational handlers are greatly above HED’s level of concern (100), no refinement is needed. However, HED recommends the level of PPE required on the current labels are not to be changed as a result of this assessment.

9.2 Post-application Exposure and Risk

Occupational post application dermal risks were not assessed because there is not likely to have occupational post-application scenario. In addition, no dermal endpoints were selected. Mefluidide is only applied outdoors and it is not a volatile compound, inhalation exposures are negligible (Vapor pressures are < 1.0E-4 torr at 25° C for mefluidide, < 1.0E-7 torr at 25° C for mefluidide DEA salt and potassium salt).

10.0 DATA NEEDS AND LABEL REQUIREMENTS

None.

Attachment I

Filename: C:\Documents and Settings\ydonovan\DEEM
Files\Mefluidide\Mefluidide.R98
Chemical: Mefluidide and Salts
RfD(Chronic): .015 mg/kg bw/day NOEL(Chronic): 1.5 mg/kg bw/day
RfD(Acute): .58 mg/kg bw/day NOEL(Acute): 58 mg/kg bw/day
Date created/last modified: 03-22-2007/09:27:32/8 Program ver.
2.03
Comment: Acute Exposure from drinking water only

EPA		Crop	Def Res	Adj.Factors	
Code	Grp	Commodity Name	(ppm)	#1	#2
86010000	O	Water, direct, all sources	0.032000	1.000	1.000
86020000	O	Water, indirect, all sources	0.032000	1.000	1.000

U.S. Environmental Protection Agency Ver. 2.02
 DEEM-FCID ACUTE Analysis for MEFLUIDIDE AND SALTS (1994-98 data)
 Residue file: Mefluidide.R98 Adjustment factor #2 NOT used.
 Analysis Date: 03-22-2007/09:46:53 Residue file dated: 03-22-2007/09:44:59/8
 NOEL (Acute) = 58.000000 mg/kg body-wt/day
 Daily totals for food and foodform consumption used.
 Run Comment: "Exposure from drinking water only"

=====
 Summary calculations (per capita):

	95th Percentile			99th Percentile			99.9th Percentile		
	Exposure	% aRfD	MOE	Exposure	% aRfD	MOE	Exposure	% aRfD	MOE
U.S. Population:	0.001672	0.29	34696	0.003140	0.54	18472	0.006282	1.08	9232
All infants:	0.006303	1.09	9202	0.009035	1.56	6419	0.016185	2.79	3583
Children 1-2 yrs:	0.002623	0.45	22112	0.004380	0.76	13240	0.006371	1.10	9104
Children 3-5 yrs:	0.002396	0.41	24206	0.003756	0.65	15443	0.006130	1.06	9462
Children 6-12 yrs:	0.001668	0.29	34771	0.002774	0.48	20912	0.003788	0.65	15312
Youth 13-19 yrs:	0.001356	0.23	42768	0.002282	0.39	25420	0.004104	0.71	14133
Adults 20-49 yrs:	0.001549	0.27	37449	0.002594	0.45	22362	0.004692	0.81	12362
Adults 50+ yrs:	0.001399	0.24	41469	0.002000	0.34	28997	0.003244	0.56	17881
Females 13-49 yrs:	0.001558	0.27	37238	0.002507	0.43	23137	0.004446	0.77	13046

Filename: C:\Documents and Settings\ydonovan\DEEM
 Files\Mefluidide\Mefluidide-Chronic.R98
 Chemical: Mefluidide and Salts
 RfD(Chronic): .015 mg/kg bw/day NOEL(Chronic): 1.5 mg/kg bw/day
 RfD(Acute): .58 mg/kg bw/day NOEL(Acute): 58 mg/kg bw/day
 Date created/last modified: 03-22-2007/09:44:59/8 Program ver.
 2.03
 Comment: Chronic Exposure from drinking water only

EPA		Crop	Def Res	Adj.Factors	
Code	Grp	Commodity Name	(ppm)	#1	#2
86010000	0	Water, direct, all sources	0.010000	1.000	1.000
86020000	0	Water, indirect, all sources	0.010000	1.000	1.000

U.S. Environmental Protection Agency
 DEEM-FCID Chronic analysis for MEFLUIDIDE AND SALTS
 Residue file name: C:\Documents and Settings\ydonovan\DEEM
 Files\Mefluidide\Mefluidide-Chronic.R98

Ver. 2.00
 (1994-98 data)

Adjustment factor #2 NOT used.
 Analysis Date 03-22-2007/10:15:37 Residue file dated: 03-22-2007/10:14:22/8
 Reference dose (RfD, Chronic) = .015 mg/kg bw/day
 COMMENT 1: Chronic Exposure from drinking water only

=====
 Total exposure by population subgroup
 =====

Population Subgroup	Total Exposure	
	mg/kg body wt/day	Percent of Rfd
U.S. Population (total)	0.000211	1.4%
U.S. Population (spring season)	0.000209	1.4%
U.S. Population (summer season)	0.000226	1.5%
U.S. Population (autumn season)	0.000204	1.4%
U.S. Population (winter season)	0.000204	1.4%
Northeast region	0.000192	1.3%
Midwest region	0.000213	1.4%
Southern region	0.000200	1.3%
Western region	0.000241	1.6%
Hispanics	0.000239	1.6%
Non-hispanic whites	0.000206	1.4%
Non-hispanic blacks	0.000200	1.3%
Non-hisp/non-white/non-black	0.000258	1.7%
All infants (< 1 year)	0.000691	4.6%
Nursing infants	0.000256	1.7%
Non-nursing infants	0.000856	5.7%
Children 1-6 yrs	0.000294	2.0%
Children 7-12 yrs	0.000191	1.3%
Females 13-19 (not preg or nursing)	0.000148	1.0%
Females 20+ (not preg or nursing)	0.000210	1.4%
Females 13-50 yrs	0.000204	1.4%
Females 13+ (preg/not nursing)	0.000205	1.4%
Females 13+ (nursing)	0.000292	1.9%
Males 13-19 yrs	0.000155	1.0%
Males 20+ yrs	0.000189	1.3%
Seniors 55+	0.000207	1.4%
Children 1-2 yrs	0.000313	2.1%
Children 3-5 yrs	0.000293	2.0%
Children 6-12 yrs	0.000202	1.3%
Youth 13-19 yrs	0.000152	1.0%
Adults 20-49 yrs	0.000197	1.3%
Adults 50+ yrs	0.000207	1.4%
Females 13-49 yrs	0.000196	1.3%

Appendix B: Review of Human Research

Studies reviewed for ethical conduct:

No MRID - PHED Surrogate Exposure Guide

00031050 Feldman, R.J., Maibach, H.I. (1974) Percutaneous penetration of some pesticides and herbicides in man. *Toxicology and Applied Pharmacology* 28(?):126-132. (Also In unpublished submission received Apr 23, 1980 under 10279-7; submitted by Purdue Frederick Co., Norwalk, Conn.; CLD:242321-R)

Studies reviewed by the Human Studies Review Board:

44416201 Gledhill, A. (1997) Dichlorvos: A Study to Investigate Erythrocyte Cholinesterase Inhibition Following Oral Administration to Healthy Male Volunteers: Lab Project Number: XH5170: Y09341: C05743. Unpublished study prepared by Zeneca Central Toxicology Lab. 104 p.

Appendix K: Mefluidide Ecological and Fate and Effects Assessment

**U. S. ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460**



OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Date: September 13, 2007

Chemical: Mefluidide, Mefluidide -DEA and Mefluidide-K

PC Code: 114001,114002, 114003

DP Barcode: D334512

MEMORANDUM

SUBJECT: Response to comments Phase III for Reregistration of
Mefluidide acid, Mefluidide -DEA and Mefluidide-K

Mefluidide acid (CAS Reg. No.53780-34-0)
Mefluidide-DEA (CAS Reg. No.53780-36-2)
Mefluidide-K (CAS Reg. No. 83601-83-6)

TO: Wilhelmena Livingston
Special Review and Re-Registration Division (7508P)

FROM: Marie Janson, Environmental Scientist
James Hetrick, Ph.D., Senior Scientist Advisor
Tom Bailey, Ph.D., Branch Chief
Environmental Risk Branch I
Environmental Fate and Effects Division (7507P)

Attached please find the Environmental Fate and Effects Division's (EFED) revised environmental risk assessment, which is for response to comments Phase III.

Public comment: Drinking Water Risk Assessment Comments

Please remove mention of annual sales volume information from page 2 of the document.

EFED response:

EFED removed mention of annual sales volume information from page 2 of the drinking water risk assessment.

Environmental Fate and Effects Chapter Comments

Public comment:**Page 44, Terrestrial Plant**

PBI-Gordon has submitted a new Seed Germination/Seedling Emergence Study (MRID 47190701), which should help to refine the risk assessment to non target terrestrial species.

EFED response:

EFED incorporated results of a the preliminary review of the seedling emergence study MRID 47190701 in the revised risk assessment

Public comment:**Section 3.3.1.2 Terrestrial Animals****Avian -**

'The LC50 of 3750 mg ae/Kg diet was selected for evaluating birds on a sub acute dietary basis exposed to Mefluidide-K , Mefluidide-DEA, and Mefluidide for the terrestrial risk assessment'

PBI-Gordon Response –

The mefluidide-DEA and mefluidide-K forms dissociate in the spray tank within minutes as supported by MRID 42283301 and 42282001, respectively. Therefore the compound of concern for both animals and birds should be mefluidide acid. Instead of using an LC50 value of 3750 mg ae/Kg based on mefluidide-DEA dietary study, the LC50 of > 5000 mg ae/kg (ppm) from the mefluidide acid dietary studies, MRID 41602102 (Bobwhite Quail) and MRID 41602103 (Mallard Duck), should have been used for the risk assessment on birds. Both of these studies were listed as supplemental due to lack of classification of the test material. The test material used in both studies was Lot 1094 of technical mefluidide acid as characterized in MRID 41601601.

On page 63, the Agency stated *"The LD50 value of 5000 mg ae/bw if applied to the above modeled scenario would result in no acute LOC exceedances for birds. Based on the mean Kanaga assessment, no acute LOC exceedances occurred for birds (1.0 lb ae/A at 3 spray applications)"*

EFED response:

The risk assessment strategy is designed to bridge the environmental fate and effects data for the mefluidide-K and mefluidide-DEA, mefluidide to mefluidide acid. Therefore, the most sensitive endpoint for the three mefluidide compounds (mefluidide, mefluidide-K, mefluidide-DEA) was selected to represent all mefluidide compounds for aquatic and terrestrial organisms in each category.

EFED stated the following for mammals in the risk assessment: For mammal toxicity assessments, data evaluating Mefluidide-K, Mefluidide-DEA and Mefluidide toxicity have been bridged because toxicity is expected to come from the benzene ring of mefluidide. Therefore, the most sensitive Mefluidide endpoint was selected to represent mammals for all application scenarios.

In addition, EFED concurs with the following statement from the HED risk assessment: "Based on the structural similarities of mefluidide and its diethanolamine (DEA) and potassium salts, where they all share the same anion- anilide, and the physical and chemical

properties of the DEA and potassium salts, where they dissociate 100% back to free mefluidide in aqueous environments, the risk assessment team concluded that mefluidide DEA and potassium salts are biologically equivalent to mefluidide and thus they share the same toxicity as the free mefluidide. Therefore, it is reasonable to bridge mefluidide toxicity data to mefluidide salts and vice versa."

Public comment:

Mammals –

'The LD50 of 829.8 mg ae/kg bw was selected for evaluating mammals on a acute dietary basis exposed to mefluidide-K, mefluidide-DEA, and mefluidide for the terrestrial risk assessment.'

PBI-Gordon Response –

The acute oral study in mice, MRID 00047116, selected for the terrestrial risk assessment on mammals was a preliminary study and never intended to be a definitive study. This study was conducted with 5 animals/dose whereas the definitive mouse study, MRID 00047117, was conducted with 10 animals/dose and at higher dose levels. This latter definitive study generated an LD50 of 1920.2 mg ae/kg bw. Both studies were conducted with the same strain of mice, but with different test materials. The test material for the preliminary study was prepared in the lab and was yellow colored while the test material for the definitive study was prepared in a pilot plant and was a white color and would be more representative of production material. In the definitive study there were no effects at the low dose, 830 mg ae/kg bw and only 1 death out of 10 animals at 1260 mg ae/kg. Further evidence showing that the mouse LD50 should be 1920.2 mg ae/kg comes from the mouse carcinogenicity dietary study, MRID 00082747, where levels of 0, 600, 1800, and 6000 ppm (0, 90, 270, and 900 mg/kg/day) were fed for 78 weeks and resulted in a NOAEL of 90 mg/kg/day with survival rates.

After feeding mice at 270 mg/kg/day for 3 days they would have been exposed to nearly the LD50 level reported in MRID 00047116 above and yet there was still 70% + combined species survival at the end of 78 weeks.

Based on the weight of evidence the mouse LD50 of 1920.2 mg ae/kg should be used in the mammalian risk assessment instead of 829.8 mg ae/kg. By using the revised LD50 values of >2000 mg ae/kg-bw for birds and 1920.2 mg ae/kg-bw for mammals, the NOAEC for birds would be revised to >51 mg ae/kg and the NOAEC for mammals would be revised to >49 mg ae/kg. Additionally if one uses the LD50 of >4315 mg ae/kg from acute avian oral study MRID 00073632, even greater safety could be demonstrated for mefluidide acid.

EFED response:

EFED will use the most conservative endpoint. The color of the test material does not matter, as long as it is the correct ingredient, especially when both studies were conducted in the same way (with the same strain of mice). Even if one study was conducted a bit differently than the other, to ensure that terrestrial organisms are adequately protected it is EFED's policy to base the risk assessment on the most sensitive endpoint.

Public comment: PBI/Gordon - Proposed Label language for products containing Mefluidide

After discussions with EPA SRRD personnel, to minimize off target movement of applied product, the following label language is proposed for all products containing mefluidide.

Droplet Size

To minimize off-target movement of this product, please apply product using spray equipment which produces a medium to coarse droplet spectrum.

EFED response:

Agdrift was recalculated for medium to course droplet size and incorporated into the risk assesment with buffers and LOC exceedences.

Public comment:

We recieved a comment from region 9 commenting about the selection of propanil toxicity data as a substitute for missing mefluidide data. Both herbicides are anilides, but their structures are very different. Of more concern is that propanil is a photosynthesis inhibitor while mefluidide is a growth regulator. The different structures and the different modes of action suggest that propanil effects will not be good predictors of mefluidide effects.

EFED response:

Although propanil and mefluidide have similar chemical structures, they have different mode of action for plants. Propanil is a photosynthesis inhibitor in contrast to mefluidide which inhibits plant cell division, stem elongation and seed head development. Also, propanil has reported sublethal effects in fish and aquatic invertebrates where mefluidide does not at similar or lower concentrations such as; surfacing (fish and invertebrates), erratic movement (invertebrates), loss of equilibrium (fish), quiescent (fish), labored respiration (fish), lying on side (fish), hypersensitivity to disturbances (fish) and lying on the bottom of test vessel (fish and invertebrates). Even though propanil effects may not be good predictors of mefluidide effects, in the absence of mefluidide data, EFED believes propanil data could be used to estimate the acute to chronic ratio for mefluidide. Note that uncertainties exist with these extrapolated endpoints and propanil data are not considered complete substitutes for missing effects data for mefluidide. Other anilide herbicides such as Chloranocryl, Monalide and Pentanochlor were also considered, however no information was available for these chemicals.

RE-REGISTRATION ELIGIBILITY DOCUMENT
ENVIRONMENTAL FATE AND EFFECTS SCIENCE CHAPTER

Environmental Fate and Ecological Risk Assessment

for

Mefluidide (PC Code 114001)
CAS # 53780-34-0

AND

Mefluidide-DEA (PC Code 114002)
CAS # 53780-36-2

AND

Mefluidide-K (PC Code 114003)
CAS #83601-83-6

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Branch Chief Approval

Tom Bailey, Ph.D., Branch Chief

Date of Approval: 9/13/07

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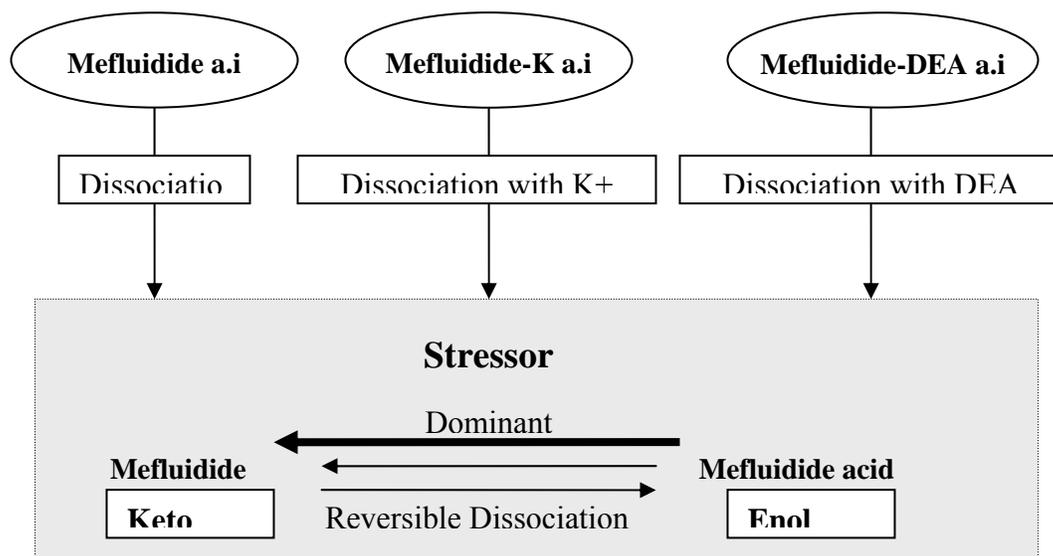
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1. Executive Summary

1.1 Nature of Stressor

Mefluidide is a post-emergent, anilide growth regulator used to control ornamental and non-ornamental woody plants, ground cover, hedges trees, turf grasses, grass and broadleaf weeds. It is also registered for growth control of low maintenance turf on rights-of-ways, airports, and industrial sites. It is formulated as the mefluidide, diethanolamine salt of mefluidide (mefluidide-DEA), and potassium salt of mefluidide (mefluidide-K). Based on the ionic nature of mefluidide-K and mefluidide-DEA and two unreviewed dissociation studies, mefluidide-K and mefluidide-DEA will dissociate rapidly and completely to form mefluidide acid. The two unreviewed dissociation studies (MRIDs 422833-01 and 42282001) indicated mefluidide-K completely dissociated in 7 minutes and mefluidide-DEA completely dissociated in 3 minutes. Mefluidide acid is in equilibrium¹ with mefluidide (Figure 1). In order to assess the environmental fate and effects of mefluidide-K, mefluidide-DEA, mefluidide, the risk assessment strategy was to bridge the environmental fate and ecological toxicity data for the mefluidide, mefluidide-K, and mefluidide-DEA to the formation of mefluidide acid. For purposes of this assessment, mefluidide acid will be used as an analog for mefluidide, mefluidide-DEA and mefluidide-K.

Figure 1. Enol-Keto Equilibrium of Mefluidide-K and Mefluidide



1 The acetamide functional group in mefluidide exhibits in a enol-keto equilibrium with mefluidide acid . This equilibrium is expected to favor the formation of the keto form (mefluidide) over the enol form (mefluidide acid) (Morrison and Boyd, 1976).

1.2 Potential Risk to Non Target Organisms

This screening-level (Level I) risk assessment focused on the use of mefluidide-K, mefluidide-DEA, and mefluidide on ornamental and turf areas. Results suggest that levels of mefluidide in the environment, when compared with measured toxicity for the most sensitive organisms of selected taxa, are likely to result in direct risks to listed and non-listed species from several different taxa. Indirect risks are also identified for listed and non-listed non-target organisms.

For the aquatic assessment, estimated environmental concentrations (EECs) in surface water were calculated for mefluidide acid using the Tier II PRZM/EXAMS models and employing maximum label application rates for mefluidide, mefluidide-K, mefluidide-DEA. Turf application scenarios in Florida and Pennsylvania were modeled for the exposure assessment.

This screening level risk assessment shows that use of **mefluidide is below the Agency's level of concern for direct acute (listed and non-listed) and chronic toxic exposure to aquatic freshwater and estuarine marine organisms and acute aquatic plants**. In contrast, the use of **mefluidide is above the Agency's level of concern for direct acute (listed and nonlisted) and chronic toxic exposure to mammals, birds and acute (listed and nonlisted) exposure to terrestrial and semi aquatic plants**.

The following toxicity data was not available for Agency review³:

- Chronic freshwater fish (72-5)
- Chronic freshwater invertebrates (72-4 b)
- Chronic estuarine marine fish (72-4 a)
- Chronic estuarine marine invertebrates (72-4 b)
- Seedling emergence (123-1 a) A preliminary assesement was completed from a recently submitted seedling emergence study (MRID47190701) however, these results are uncertain until a full review of the study is performed.
- Chronic bird (74-1)
- (EC₀₅ or NOAEC) was not provided for vascular and nonvascular plants (123-2)
- In the absence of data, EFED:
 - Used available toxicity data of propanil² a structurally similar anilide herbicide

² Other anilide herbicides considered were chloranocryl, monalide and pentanochlor, however no ecotoxicity data were-available for these chemicals. The chemical structures of mefluidide

- Assumed that EC₂₅ toxicity values for terrestrial plants (vegetative vigor) are equivalent to (seedling emergence) measurement endpoints
- Used available data from mefluidide mammal toxicity data to evaluate chronic toxicity to birds.

The Tier I terrestrial plant model, TERRPLANT, was used to assess risks to terrestrial and semi-aquatic plants. LOCs were exceeded for both terrestrial and semi-aquatic plants (monocots and dicots) for both spray and granular applications. All the above modeled scenarios with T-REX and TERRPLANT are summarized in APPENDIX D. Specific direct risks of concern to non-target terrestrial organisms are summarized as follows:

- **Mammalian Acute Listed** LOCs were exceeded for 15 g and 35 g mammals exposed to application rates for mefluidide-DEA and mefluidide-K (1.0 lb ae/A at 3 applications) consuming short grass, broadleaf plants, or small insects and 1000 g mammals that consume short grass.
- **Mammalian Acute Listed** LOCs were exceeded for the LD₅₀s/sq-ft for 15g and 35 g mammals based on one granular application of mefluidide at 0.5 lbs ae/acre.
- **Mammalian Acute Restricted Use** LOCs were exceeded for 15 g and 35 g mammals that consume short grass exposed to application rates for mefluidide-DEA and mefluidide-K (1.0 lb ae/A at 3 applications).
- **Mammalian Acute Restricted Use** LOCs were exceeded for the LD₅₀s/sq-ft for small and medium-sized mammals based on one granular application of mefluidide at 0.5lbs ae/acre.
- **Mammalian Chronic** LOCs (dose-based) were exceeded for 15 g mammals that consume short grass exposed to application rates for mefluidide-DEA and mefluidide-K (1.0 lb ae/A at 3 applications)
- **Avian Acute Listed** LOCs were exceeded for 20 g birds that consume short grass, tall grass and broadleaf plants and small insects and 100 g birds that consume short grass for the 1.0 lb ae/A modeled scenario. Non-definitive toxicity endpoints do not allow for calculations of definitive RQs, however the ratio of non- definitive endpoints (EECs) in this case results in acute RQs ranging from <0.0 to <0.25.
- **Avian Acute Listed** LOCs were exceeded for the LD₅₀s/sq-ft for 20 g birds based on one granular application of mefluidide at 0.5 lbs ae/acre.

and propanil are provided in Appendix B. ³ Submitted ecotoxicity data are summarized in Appendix A.

- **Avian Acute Restricted Use** LOCs were exceeded for 20 g birds that consume short grass for the 1.0 lba ae/A application rate modeled scenario. Non-definitive toxicity endpoints do not allow for calculations of definitive RQs, however the ratio of non-definitive endpoints (EECs) in this case results in acute RQs of < 0.25.
- **Avian Acute Restricted Use** LOCs were exceeded for the LD₅₀s/sq-ft for 20 g birds based on one granular application of mefluidide at 0.5 lbs ae/acre.
- **Avian Chronic** LOCs (dietary-based) exceedances occurred for birds for the 1.0 lb ae/A modeled scenario. Non-definitive toxicity endpoints do not allow for calculations of definitive RQs, however the ratio of non-definitive endpoints (EECs) in this case results in acute RQs ranging from 2.9 to 6.32.
- **Terrestrial and Semi-aquatic Plants (Listed Species and Non-Listed Species)** LOCs were exceeded for monocots and dicots with the 1.0 lb ae/A spray applications of mefluidide-K and mefluidide-DEA. LOCs were exceeded for dicots and monocots (granular applications) with 0.5 lb ae/acre of mefluidide. Dicots demonstrated more sensitivity than monocots in all application scenarios.

A summary of the potential for direct and indirect effects to listed species, summarized by taxonomic group, is provided in **Table 1.1**.

The results of this risk assessment suggest that the patterns of mefluidide use are such that they coincide in time and space to areas frequented by avian and mammalian wildlife. These areas have been demonstrated as use by wildlife as sources of food and cover. The potentially problematic wildlife food items suggested by this risk assessment are likely to be present in and around the treated areas. In addition, there is potential for indirect effects to all taxonomic groups due to changes in habitat caused by vegetation changes. Some uses of mefluidide may not pose a threat for avian and mammalian wildlife, such as industrial sites that are not frequented by wildlife

Table 1. 1 Listed Species Risks Associated With Direct or Indirect Effects Due to Applications of Mefluidide		
Listed Taxonomy	Direct Effects	Indirect Effects
Terrestrial and semi-aquatic plants – monocots		Yes^c
	Yes	
Terrestrial and semi-aquatic plants – dicots		Yes^c
	Yes	
Terrestrial invertebrates	None	Yes^c
Birds	Yes (acute estimated values),	Yes^{c,d,e}
	Yes(chronic estimated values),	

Table 1. 1 Listed Species Risks Associated With Direct or Indirect Effects Due to Applications of Mefluidide		
Listed Taxonomy	Direct Effects	Indirect Effects
Terrestrial phase amphibians	Yes (acute estimated values), Yes(chronic estimated values),	Yes ^{c, e}
Reptiles	Yes (acute estimated values), Yes(chronic estimated values),	Yes ^{c,d, e}
Mammals	Yes (acute and chronic)	Yes ^{c, d, e}
Aquatic vascular plants	None Acute and None (EC₀₅ estimated values)	Yes ^c
Aquatic non-vascular plants ^a	None Acute and None (EC₀₅ estimated values)	Yes ^c
Freshwater fish	None(acute), None(chronic estimated values)	Yes ^c
Aquatic phase amphibians	None(acute), Unknown(chronic) ^b	Yes ^c
Freshwater crustaceans	None (acute), None (chronic estimated values)	Yes ^c
Mollusks	None (acute), None chronic estimated values	Yes ^c
Marine/estuarine fish	None (acute), None (chronic estimated values)	Yes ^c
^a At the present time no aquatic non-vascular plants are included in Federal listings of threatened and listed species. The taxonomic group is included here for the purposes of evaluating potential contributions to indirect effects to other taxonomy and as a record of exceedances should future listings of non-vascular aquatic plants warrant additional evaluation of Federal actions.		
^b Terrestrial phase amphibians and reptiles estimated using birds as surrogates. Aquatic amphibians estimated using freshwater fish as surrogates.		
^c Listed and Non-listed LOC exceeded for terrestrial and semi-aquatic plants.		
^d Listed, Restricted Use, and Acute LOC exceeded for some feeding guilds and size classes of birds.		
^e Listed, Restricted Use, and Chronic LOC exceeded for some feeding guilds and size classes of mammals.		

1.3 Conclusions Exposure Characterization

The risk assessment strategy is designed to bridge the environmental fate and effects data for the mefluidide-K and mefluidide-DEA, mefluidide to mefluidide acid. Based on the ionic nature of mefluidide-K and mefluidide-DEA and two unreviewed dissociation studies, mefluidide-K and mefluidide-DEA will dissociate rapidly and completely to form mefluidide acid. The two unreviewed dissociation studies (MRIDs 422833-01 and 42282001) indicated mefluidide-K completely dissociated in 7 minutes and mefluidide-DEA completely dissociated in 3 minutes. The reported pKa for mefluidide acid (4.6) occurs at pH~7, with

50% or greater dissociation at pHs \leq 4.6. Mefluidide acid is in equilibrium³ with mefluidide (Figure 1). The only degradation product identified for mefluidide was 5-amino-2,4-dimethyltrifluoromethanesulfonilide. Mefluidide is moderately persistent and mobile in soil. Estimated environmental concentrations (EECs) in surface water were calculated for mefluidide acid using the Tier II PRZM/EXAMS models with the maximum proposed application rates for mefluidide, mefluidide-K, and mefluidide-DEA on turf. Estimated concentrations are expressed in acid equivalence because mefluidide acid is a common intermediate compound among mefluidide, mefluidide-K, and mefluidide-DEA. Peak (1-in-10 year) surface water EECs were approximately 7.054 $\mu\text{g ae/L}$ and 10.573 $\mu\text{g ae/L}$ for the Pennsylvania Turf and Florida turf scenarios, respectively.

Routes of exposure evaluated in this risk assessment focused on runoff and spray drift from ground spray with mefluidide applied at application rates of mefluidide-K and mefluidide-DEA and runoff from granular applications with mefluidide.

For the terrestrial assessment, EECs for mefluidide were calculated using the terrestrial Tier I model T-REX using the maximum application rate for mefluidide, mefluidide-K, and mefluidide-DEA. Modeling was based on a foliar half-life of 4 days, 3 applications per season and 42 day interval. Upper bound dietary EECs for mefluidide-DEA and mefluidide-K application rate of 1.0 lb ae/A (spray application) were 240.17 mg ae /kg on short grass, 110.08 mg ae /kg on tall grass, 135.09 mg ae /kg on broadleaf plants, or small insects and 15.01 mg ae /kg for fruits, pods, seeds, and large insects.

For a single granular application of mefluidide at the maximum application rate, 0.5 lbs ae/acre, the EEC was calculated as 5.21 mg ae/sq ft. This LD₅₀/ sq ft approach can only be applied for single applications. Since the chemical is not incorporated into the soil immediately after application, it is assumed that 100% of the material is available to birds and mammals (USEPA 1992).

1.4 Conclusions Effects Characterization

The risk assessment strategy is designed to bridge the environmental fate and effects data for the mefluidide-K and mefluidide-DEA, mefluidide to mefluidide acid. Therefore, the most sensitive endpoint for the three mefluidide compounds (mefluidide, mefluidide-K, mefluidide-DEA) was selected to represent all mefluidide compounds for aquatic and terrestrial organisms in each category. Most of the toxicity endpoints are within one order of magnitude when comparing the mefluidide and mefluidide-DEA. There was an incomplete toxicity database on mefluidide-K to allow for comparisons of toxicity.

Table 1.2, 1.3 and 1.4 provides a summary of acute and chronic toxicity data used for risk quotient calculation for mefluidide-K, mefluidide-DEA and mefluidide application.

Table 1.2: Summary of endpoints (LC₅₀ or EC₅₀, mg ae/L) for Aquatic Toxicity used in RQ calculations for Mefluidide¹			
TAXONOMIC GROUP	Acute endpoint	Chronic endpoint	MRID/ Estimated value
Acute freshwater fish	>68.47* Rainbow Trout		MRID 418937-02
Chronic freshwater fish		>0.267 ²	Estimated value acute to chronic ratio
Acute freshwater inverts	>77.25* Daphnid		MRID 418937-03
Chronic freshwater inverts		>5.54 ²	Estimated value acute to chronic ratio
Acute estuarine/marine fish	>84.75* Sheepshead minnow		MRID 425623-03
Chronic estuarine/marine fish		>0.267 ²	Estimated value acute to chronic ratio
Acute estuarine/marine inverts	67* Eastern oyster		MRID 425624-01
Chronic estuarine/marine inverts		>5.54 ²	Estimated value acute to chronic ratio

¹For terrestrial plants data evaluating mefluidide-K, mefluidide-DEA and mefluidide have been bridged for the terrestrial risk assessment. *most sensitive species tested

² acute to chronic ratio from propanil extrapolation

Table 1.3: Summary of endpoints (LC₅₀ or EC₅₀, mg ae/L aquatic organisms) for Plant Toxicity used in RQ calculations for Mefluidide¹			
TAXONOMIC GROUP	Acute endpoint	NOAEC or EC₀₅	
Acute vascular plant	0.515* Lemna		MRID 435266-01 Tier I (8% growth stimulation) Used this value as EC ₅₀
Vascular plant(EC ₀₅)		>0.29 ²	Estimated value acute to

			chronic ratio
Acute non-vascular plant	0.629* Navicula		MRID 435266-05 Tier I (11.5% growth reduction) Used this value as EC ₅₀
Non-vascular plant(EC ₀₅)		>0.786 ²	Estimated value acute to chronic ratio
Terrestrial Plant: Vegetative Vigor	Monocot:* Sorghum EC ₂₅ 0.105 lb ae/A Dicot:* Mustard EC ₂₅ 0.0054 lb ae/A	Monocot: * Sorghum NOAEC 0.045 lb ae/A Dicot:* Mustard NOAEC 0.0029 lb ae/A	MRID 435496-01
Terrestrial Plant: Seedling Emergence	Monocot: Sorghum EC ₂₅ 0.105 lb ae/A Dicot:* Mustard EC ₂₅ 0.0054 lb ae/A	Monocot: Sorghum NOAEC 0.045 lb ae/A Dicot:* Mustard NOAEC 0.0029 lb ae/A	Estimated value from vegetative vigor study MRID 435496-01

¹For terrestrial plants data evaluating mefluidide-K, mefluidide-DEA and mefluidide have been bridged for the terrestrial risk assessment.

² acute to chronic ratio from propanil extrapolation

*most sensitive species tested

Table 1.4: Summary of endpoints (LD₅₀ or LC₅₀ mg ae/kg) for Terrestrial Toxicity data used in RQ calculations for Mefluidide¹			
TAXONOMIC GROUP	Acute endpoint	Chronic endpoint	
Acute Avian	>1500* Bobwhite		MRID 416019-01 Used this non-definitive

	quail		endpoint as LD50
Chronic Avian		38	Estimated value acute to chronic ratio based on mefluidide mammal data
Acute Dietary Avian	>3750*		
Acute mammal	829.8* mouse		MRID 00047116
Chronic mammal		102* rat	MRID 00082748

¹For terrestrial plants data evaluating mefluidide-K, mefluidide-DEA and mefluidide have been bridged for the terrestrial risk assessment.

² acute to chronic ratio from propanil extrapolation

*most sensitive species tested

1.5. Uncertainties, Assumptions, Limitations, and Data Gaps

- Ecotoxicity data for chronic risks to birds exposed to mefluidide were not available. Therefore, EFED calculated estimates for measurement endpoints for chronic toxicity to birds by evaluating the available data from mammal toxicity data (acute and chronic) and extrapolating the findings to available data for mefluidide, mefluidide-DEA and mefluidide-K to estimate possible effects measurement endpoints. These extrapolated endpoints are uncertain and are not considered complete substitutes for missing effects data. Additional information on these estimated values are provided in Appendix E. Submission of a chronic bird study would quantify risks associated with exposure of mefluidide to birds.
- The magnitude of toxicity to terrestrial plants is uncertain because only one terrestrial vegetative vigor plant study was available for full review and conducted on fresh weight and not dry weight as required by EPA guidelines. . A preliminary review on a recently submitted seedling emergence study (MRID 471907-01) was conducted. These results are uncertain until a full review of the study is performed. The results of the preliminary review are summarized in Appendix E. Therefore, to estimate possible effects measurement endpoints for seedling emergence, EFED assumed that EC₂₅ toxicity values for terrestrial plants (vegetative vigor) are equivalent to (seedling emergence) measurement endpoints for mefluidide, mefluidide-DEA and mefluidide-K. These estimated endpoints are uncertain and are not considered complete substitutes for missing effects data. Additional information on these estimated values are provided in Appendix E.
- The available dietary toxicity studies on avian species failed to established definitive acute LD₅₀ values (i.e., the lethality values exceed the highest dose tested). Therefore, use of this value adds uncertainty and may overestimate risk to avian species. Submission of an acute bird study with definitive LD₅₀ values would quantify risks associated with exposure of mefluidide to birds.

- Exposure estimates for this screening level risk assessment focused on the mefluidide, mefluidide-K and mefluidide-DEA. Information or data is not available to evaluate degradates as a potentially significant contributor to aquatic risk and which may affect the outcome of risk conclusions are not considered in this risk characterization. Therefore, this assessment may require further analysis to evaluate degradates as a potential contributor to aquatic risk.
- In all cases, EFED concluded that resulting estimated risk quotients, had they been based on definitive effects measurement endpoints, would not trigger concerns for acute or chronic risks to freshwater fish, chronic estuarine marine fish, chronic estuarine marine invertebrates, chronic freshwater invertebrates, vascular plants (EC_{05} or NOAEC) and non-vascular plants (EC_{05} or NOAEC). In contrast, EFED concluded that resulting estimated risk quotients for terrestrial organisms would trigger concerns for chronic risks to birds and (listed and nonlisted) terrestrial and semi aquatic plants.

2. Problem Formulation

Problem formulation is used to establish the direction and scope of an ecological risk assessment. According to the Guidelines for Ecological Risk Assessment (USEPA, 1998), problem formulation consists of defining the problem and purpose for the assessment, and developing a plan for analyzing and characterizing risk. The critical components of the problem formulation are selection of the assessment endpoints, formulation of risk hypotheses and the conceptual model, and development of an analysis plan. The analysis plan and supporting rationale are aimed at determining whether the uses of mefluidide as a growth regulator to control ornamental and non-ornamental woody plants, ground cover, hedges trees, turf grasses, grass and broadleaf weeds, turf on rights-of-ways, airports, and industrial sites could result in exposures that cause unreasonable adverse effects (risk) to non-target organisms including those federally listed as threatened or endangered (hereafter referred to as “listed”). The maximum application rate for mefluidide applied as ground spray is 1.0 lb ae/A for mefluidide-K and mefluidide-DEA. The maximum application rate for mefluidide, as a granular formulation, is 0.5 lb ae/A. Mefluidide, mefluidide-K, mefluidide-DEA can be applied 3 times per season.

2.1 Stressor Source and Distribution

2.1.1 Environmental Fate Summary

Based on the review of the environmental fate data, mefluidide is moderately persistent and mobile in terrestrial environments. Possible routes of dissipation for mefluidide are photodegradation on soil surfaces, microbial mediated degradation, leaching, and runoff.

There are no aerobic aquatic metabolism data to assess the environmental fate of mefluidide in aquatic environments.

Because a bridging strategy was employed to link mefluidide-K, mefluidide-DEA, mefluidide to mefluidide acid, exposure estimates for this screening level risk assessment focused on mefluidide acid. Environmental fate data were not available to evaluate exposure for mefluidide degradation products.

2.1.2 Pesticide Type, Class and Mode of Action

Mefluidide is an herbicide in the anilide chemical class. The mode of action is through inhibiting plant cell division, stem elongation and seed head development.

2.1.3 Use Characterization

Mefluidide is used to control ornamental and non-ornamental woody plants, ground cover, hedges trees, turf grasses, grass and broadleaf weeds. It is also registered for growth control of low maintenance turf on rights-of-ways, airports, and industrial sites. There are multiple active ingredient products that contain an additional plant growth regulator and herbicides such as, paclobutrazol, imazapyr, and imazethapyr. Current formulations include; granular, liquid-ready to use, and soluble concentrate/liquid. Mefluidide can be applied as a band treatment, broadcast, spot treatment, and spray. The equipment used to apply mefluidide includes; backpack sprayer, boom sprayer, ground equipment, hand held sprayer, handgun, hose-end sprayer, power sprayer, pressure sprayer, and spreader.

The highest use areas for mefluidide include South Carolina, North Carolina, Virginia, West Virginia, California, Nevada, Arizona, and New Mexico. The maximum application rate for mefluidide applied as ground sprays is 1.0 lb ae/A for mefluidide-K and mefluidide-DEA. The maximum application rate for mefluidide, as a granular formulation, is 0.5 lb ae/A. Mefluidide, mefluidide-K, mefluidide-DEA can be applied 3 times per season.

The uses that will be included in the re-registration assessment are; agricultural/farm structures/buildings and equipment, agricultural/nonagricultural uncultivated areas/soils, airports/landing fields, commercial industrial lawns, commercial institutional/industrial premises/equipment (indoor/outdoor), golf course turf, hospitals/medical institutions premises (human veterinary), household domestic dwellings outdoor premises, industrial areas (outdoor), nonagricultural outdoor buildings/structures, nonagricultural rights-of-way/fencerows/hedgerows, ornamental and or shade trees, ornamental ground cover, ornamental herbaceous plants, ornamental lawns and turf, ornamental non-flowering plants, ornamental woody shrubs and vines, paths/patios, paved area (private roads/sidewalks), recreational areas, and residential lawns.

2.2 Assessment Endpoints

2.2.1 Ecosystems Potentially at Risk

Ecosystems potentially at risk are expressed in terms of the selected assessment endpoints. The typical assessment endpoints for screening-level pesticide ecological risks are reduced survival and reproductive and growth impairment for both aquatic and terrestrial animal species. Aquatic animal species of potential concern include freshwater fish and invertebrates, estuarine/marine fish and invertebrates, and amphibians. Terrestrial animal species of potential concern include birds, mammals, and beneficial insects. For both aquatic and terrestrial animal species, direct acute and direct chronic exposures are considered. In order to protect threatened and listed species, all assessment endpoints are measured at the individual level. Although endpoints are measured at the individual level, they provide insight about risks at higher levels of biological organization (e.g. populations and communities). For example, pesticide effects on individual survivorship have important implications for both population rates of increase and habitat carrying capacity.

For terrestrial and semi-aquatic plants, the screening assessment endpoint is the perpetuation of populations of non-target species (crops and non-crop plant species). Existing testing requirements have the capacity to evaluate emergence of seedlings and vegetative vigor. The endpoints of seedling emergence (estimated endpoint) and vegetative vigor may not address all terrestrial and semi-aquatic plant life cycle components, it is assumed that impacts at emergence and in active growth have the potential to impact individual ability to compete and reproductive success.

For aquatic plants, the assessment endpoint is the maintenance and growth of standing crop or biomass. Measurement endpoints for this assessment endpoint focus on vascular plants (*Lemna gibba*) and non-vascular plants (i.e., green algae) growth rates and biomass measurements.

The ecological relevance of selecting the above-mentioned assessment endpoints is as follows: (1) complete exposure pathways exist for these receptors; (2) the receptors may be potentially sensitive to pesticides in affected media and in residues on plants, seeds, and insects; and (3) the receptors could potentially inhabit areas where pesticides are applied, or areas where runoff and/or spray drift may impact the sites because suitable habitat is available.

2.2.2 Ecological Effects

Each assessment endpoint requires one or more “measures of ecological effect,” which are defined as changes in the attributes of an assessment endpoint itself or changes in a surrogate entity or attribute in response to exposure to a pesticide. Ecological measurement endpoints for the screening level risk assessment are based on a suite of registrant-submitted toxicity studies performed on a limited number of organisms in the following broad groupings:

- Birds (mallard duck and bobwhite quail), also used as a surrogate for terrestrial phase amphibians and reptiles (no chronic data submitted on birds),
- Mammals (chronic data on laboratory rat, acute data on laboratory mouse),
- Freshwater Fish (bluegill sunfish and rainbow trout), also used as a surrogate for aquatic phase amphibians. (no chronic data submitted on freshwater fish)
- Freshwater invertebrates (waterflea) (no chronic data submitted on freshwater invertebrates),
- Estuarine/marine fish (no chronic data on estuarine/marine fish submitted),
- Estuarine/marine invertebrates (no chronic data on estuarine/marine invertebrates submitted),
- Aquatic plants (freshwater and estuarine/marine).
- Terrestrial Plants (vegetative vigor, preliminary review seedling emergence study)

Within each of these very broad taxonomic groups, an acute and chronic endpoint is selected from the available test data, as the data sets allow. Additional ecological effects data were available for other taxa and have been incorporated into the risk characterization as other lines of evidence, including acute contact and oral toxicity on honeybees and acute risk to earthworm.

A complete discussion of all toxicity data available for this risk assessment and the resulting measurement endpoints selected for each taxonomic group are included in Section 3 of this document. A summary of the assessment and measurement endpoints selected to characterize potential ecological risks associated with exposure to mefluidide is provided in Table 2.2.

Table 2.2 Summary of Assessment Endpoints and Measures of Effect for Mefluidide, Mefluidide-DEA¹ and Mefluidide-K¹	
Assessment Endpoint	Measures of Effect
1. Abundance (i.e., survival, reproduction, and growth) of individuals and populations of birds	1a. Bobwhite quail acute oral LD ₅₀ 1b. Bobwhite quail and mallard duck subacute dietary LC ₅₀ 1c. NOAEC estimated value

2. Abundance (i.e., survival, reproduction, and growth) of individuals and populations of mammals	2a. Laboratory mouse acute oral LD ₅₀ 2b. Laboratory rat LD ₅₀ 2c. Laboratory rat chronic NOAEC
3. Survival of individuals and communities of freshwater fish and invertebrates	3a. Rainbow trout and bluegill sunfish acute LC ₅₀ 3b. Water flea acute EC ₅₀ 3. NOAEC estimated values
4. Survival of individuals and communities of estuarine/marine fish and invertebrates	4 a. Sheepshead minnow LC ₅₀ 4 b. Eastern oyster EC ₅₀ 4 d. NOAEC estimated values
5. Survival of beneficial insect populations	5a. Honeybee acute contact LD ₅₀
6. Maintenance and growth of individuals and populations of aquatic plants from standing crop or biomass	6a. Vascular plant (i.e., <i>Lemna</i>) EC ₅₀ values for growth rate and biomass measurements 6b. Non-vascular plant (i.e., <i>Navicula</i>) EC ₅₀ values for growth rate and biomass measurements 6c. EC05s estimated values for vascular and non-vascular plants
7. Maintenance and growth of individuals and populations of terrestrial plants from standing crop or biomass	7a. Vegetative Vigor EC ₂₅ values for growth rate and biomass measurements 7. Seedling Emergence EC ₂₅ estimated values for growth rate and biomass measurements

LD₅₀ = Lethal dose to 50% of the test population.

LC₅₀ = Lethal concentration to 50% of the test population.

EC₅₀/EC₂₅ = Effect concentration to 50%/25% of the test population.

NOAEC = No observed adverse effect level.

LOAEC = Lowest observed adverse effect level.

¹ The risk assessment strategy is designed to bridge the environmental fate and effects data for the mefluidide-K and mefluidide-DEA to mefluidide. Therefore, the most sensitive endpoint for the three mefluidide compounds (mefluidide, mefluidide-K, mefluidide-DEA) was selected to represent all mefluidide compounds for aquatic and terrestrial organisms in each category.

2.3

Conceptual Model

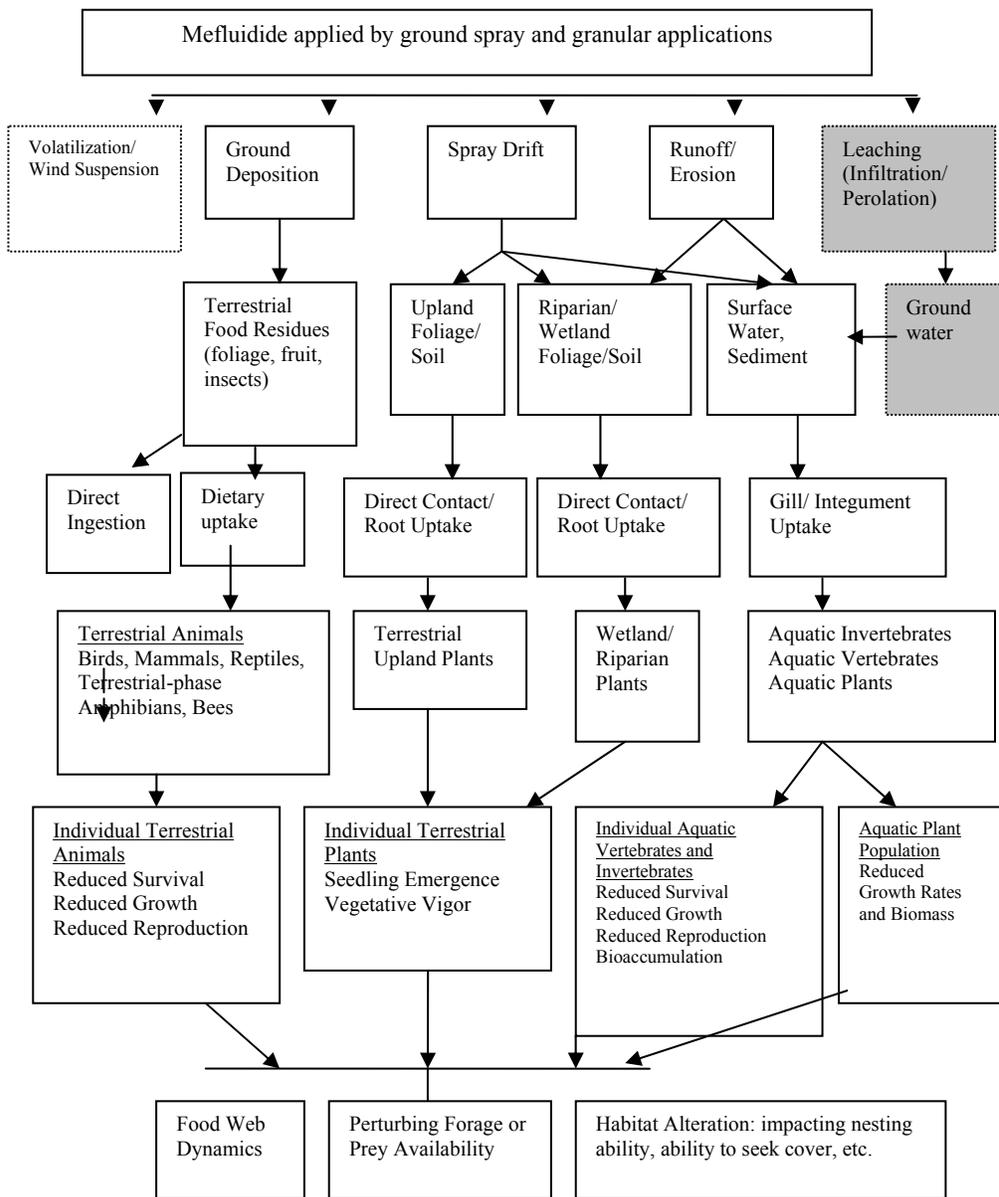
In order for a chemical to pose an ecological risk, it must reach ecological receptors in biologically significant concentrations. An exposure pathway is the means by which a contaminant moves in the environment from a source to an ecological receptor. For an ecological exposure pathway to be complete, it must have a source, a release mechanism, an environmental transport medium, a point of exposure for ecological receptors, and a feasible route of exposure. In addition, the potential mechanisms of transformation (i.e., which degradates may form in the environment, in which media, and how much) must be known, especially for a chemical whose metabolites/degradates are of greater toxicological concern. In this assessment, mefluidide is only assessed. The assessment of ecological exposure pathways, therefore, includes an examination of the source and potential migration pathways for constituents, and the determination of potential exposure routes (e.g., ingestion, inhalation, and dermal absorption).

The source and mechanism of release of mefluidide and its salts is ground application (spray and granular) and is an herbicide growth regulator used to control ornamental and non-ornamental woody plants, ground cover, hedges trees, turf grasses, grass and broadleaf weeds. It is also registered for growth control of low maintenance turf on rights-of-ways, airports, and industrial sites. The conceptual model and subsequent analysis of exposure and effects are all based on mefluidide. Surface water runoff from the areas of application is assumed to follow topography. Additional release mechanisms include spray drift, and wind erosion, which may potentially transport site-related contaminants to the surrounding air. Potential emission of volatile compounds is not considered as a viable release mechanism for mefluidide because of a low Henry's Constant ($2.27E^{-7}$ atm m³/mol). The conceptual model shown in **Figure 2.1** generically depicts the potential source of mefluidide, release mechanisms, abiotic receiving media, and biological receptor types.

2.3.1 Conceptual Model Diagram

The conceptual model employs a bridging strategy to account for the dissociation of mefluidide-K and mefluidide-DEA with the formation of form mefluidide acid. Additionally, mefluidide is in a keto-enol equilibrium with mefluidide acid. Therefore, the conceptual model is focused on the fate and disposition of mefluidide acid in the environment, and mode of application (e.g., ground spray and granular application). A conceptual model (**Figure 2.1**) was developed that represents the possible relationships between the stressor, ecological endpoints, and the measurement endpoints. Risk to non-target animals is also possible from dermal contact or inhalation, but because these are not considered in the risk assessment, they are not shown in the diagram below.

Figure 2.1) Conceptual Model¹



¹ Shaded areas in the conceptual model are not assessed in the risk assessment.

2.3.2 Terrestrial Environment

The highest mefluidide residue levels are expected to be located on the surface soil and on foliage (e.g., short and tall grasses, broadleaf weeds), seeds, and insects on the treated agriculture field immediately following ground spraying.

While spray drift may result in transport of mefluidide to off-target field surface soil, foliage, and insects, the highest concentrations for these media are still expected to be those in the treated field. Birds, mammals, reptiles, and amphibians that ingest foliage, insects and/or soil invertebrates from either the treated area or from spray drift impacted areas are potentially exposed to mefluidide residues in their diet. Endpoints were included that represented reduced survival, growth, and reproduction in these taxonomic groups from dietary exposure. Because toxicity data for reptiles and terrestrial-phase amphibians are rarely available, risk assessment results for birds were used as surrogates to assess risks to reptiles and terrestrial-phase amphibians (USEPA 2004).

These animals may also be exposed to mefluidide by other exposure routes not accounted for in this risk assessment, such as incidental ingestion of the soil; dermal contact with the surface of the foliage or soil, direct impingement of sprayed material on the body at time of application, residues on dust particulates; and/or ingestion of residues in drinking water sources such as dew that form on plants and soil, puddles on the field or in spray drift impacted areas at the time of application or which form after a rain event, and/or surface water in spray drift and runoff impacted areas. Because of the low octanol/water partitioning coefficient ($\log K_{ow}=1.97$; $K_{ow}=94.5$) and a low Henry's Constant of ($2.27E^{-7}$ atm m³/mol) concerns for dermal and inhalation exposure would be minimal. Additional exposure pathways and routes following application includes uptake of mefluidide by plants from soil which can then be ingested by wildlife and which can then be ingested by other wildlife (i.e., food chain transfer).

Mefluidide may reach off-field terrestrial or riparian/wetland vegetation environments in spray drift at the time of application. Following a rain event mefluidide, may also reach off-field terrestrial or riparian/wetland vegetation environments in sheet and channel flow runoff.

2.3.3 Aquatic Environment

Direct application of mefluidide to streams, lakes, and ponds is forbidden by the product label. The highest mefluidide residue levels are expected to be located in surface waters adjacent to treated agricultural fields at the time of application due to spray drift and/or from runoff after a rain event.

Because mefluidide is moderately persistent in soils and has a low soil: water partition coefficient, there is high likelihood of transport by runoff. Exposure estimates for this screening level risk assessment focused on mefluidide. Information or data was not available to evaluate degradates as a potentially significant contributor to aquatic risk and is not

considered in this risk characterization. Fish, amphibians, and aquatic invertebrates that live in aquatic environments are potentially exposed to mefluidide residues in surface water by direct contact of their integument (covering of the body or a part such skin, gill membranes, cuticle, etc.) and via uptake through their gills or integument. Assessment endpoints were selected to assess reduced survival, growth, and reproduction in these taxonomic groups from combined direct contact with integument and uptake across the gill or integument. Because toxicity data for amphibians are rarely available, addressing risks for fish were used as a surrogate to assess risks to amphibians (USEPA 2004). Aquatic plants may be potentially exposed by contact with mefluidide residues in surface water or through sorption and uptake through roots from water compartments or across cell walls.

Leaching (infiltration/percolation) may result in transport of mefluidide through the soil column into groundwater which may, in some circumstances, flow into a surface water body. However, groundwater and surface water interactions are not in the exposure estimates for evaluating ecological risks.

Bioaccumulation of mefluidide in fish tissue is not expected due to a low octanol water partitioning coefficient ($\log K_{ow}=1.97$; $K_{ow}=94.5$). Mefluidide was not found to substantially accumulate ($BCF = 0$ to 1.11) in catfish tissues during bioconcentration studies (Accession Number 226851).

2.4 Risk Hypothesis

- Terrestrial vertebrates (birds, mammals, reptiles, terrestrial-phase amphibians) are subject to adverse direct effects such as reduced survival, growth, and reproduction when exposed to mefluidide residues as a result of labeled use of the pesticide.
- Non-target terrestrial plants are subject to adverse effects such as reductions in vegetative vigor and seedling emergence when exposed to mefluidide residues as a result of labeled use of the pesticide.
- Aquatic invertebrates, fish, and amphibians in surface waters (freshwater or saltwater) receiving spray drift or runoff from treated fields following mefluidide application are subject to adverse effects such as reduced reproduction, growth, and survival when exposed to mefluidide residues as a result of labeled use of the pesticide. Aquatic plants may be potentially exposed by contact with mefluidide residues in surface water or through sorption and uptake through roots from water compartments or across cell walls.

3 ANALYSIS

3.1 Use Characterization

Mefluidide is used to control ornamental and non-ornamental woody plants, ground cover, hedges trees, turf grasses, grass and broadleaf weeds. It is also registered for growth

control of low maintenance turf on rights-of-ways, airports, and industrial sites. There are multiple active ingredient products that contain an additional plant growth regulator and herbicides such as, paclobutrazol, imazapyr, and imazethapyr. Current formulations include; granular, liquid-ready to use, and soluble concentrate/liquid. Mefluidide can be applied as a band treatment, broadcast, spot treatment, and spray. The equipment used to apply mefluidide includes; backpack sprayer, boom sprayer, ground equipment, hand held sprayer, hose-end sprayer, power sprayer, pressure sprayer, and spreader.

The highest use areas for mefluidide include South Carolina, North Carolina, Virginia, West Virginia, California, Nevada, Arizona, and New Mexico. The maximum application rate for mefluidide applied as ground spray is 1.0 lb ae/A for mefluidide-K and mefluidide-DEA. The maximum application rates for mefluidide, as a granular formulation, is 0.5 lb ae/A. Mefluidide, mefluidide-K and mefluidide-DEA can be applied 3 times per season.

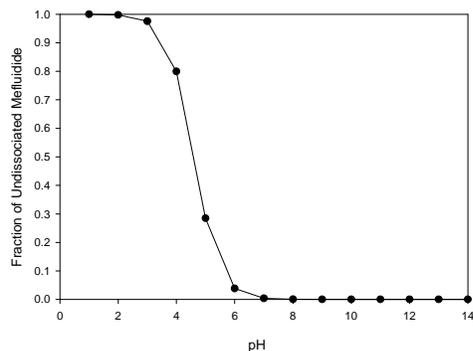
The uses that will be included in the reregistration assessment are: agricultural/farm structures/buildings and equipment, agricultural/nonagricultural uncultivated areas/soils, airports/landing fields, commercial industrial lawns, commercial institutional/industrial premises/equipment (indoor/outdoor), golf course turf, hospitals/medical institutions premises (human veterinary), household domestic dwellings outdoor premises, industrial areas (outdoor), nonagricultural outdoor buildings/structures, nonagricultural rights-of-way/fencerows/hedgerows, ornamental and or shade trees, ornamental ground cover, ornamental herbaceous plants, ornamental lawns and turf, ornamental non-flowering plants, ornamental woody shrubs and vines, paths/patios, paved area (private roads/sidewalks), recreational areas, and residential lawns.

3.2 Exposure Characterization

3.2.1 Environmental Fate and Transport Characterization

The risk assessment strategy is designed to bridge the environmental fate data for the mefluidide-K, mefluidide-DEA, mefluidide to mefluidide acid. Based on the ionic nature of mefluidide-K and mefluidide-DEA and two unreviewed dissociation studies, mefluidide-K and mefluidide-DEA will dissociate rapidly and completely to form mefluidide acid. The two unreviewed dissociation studies (MRIDs 422833-01 and 42282001) indicated mefluidide-K completely dissociated in 7 minutes and mefluidide-DEA completely dissociated in 3 minutes. The reported pKa for mefluidide acid is 4.6. These data suggest complete dissociation of mefluidide acid is expected to occur at pH~7 (Figure 2), with 50% or greater dissociation at pHs \leq 4.6. Mefluidide exhibits an enol-keto equilibrium with mefluidide acid (Figure 1).

Figure 2: Fraction of Undissociated Mefluidide as a Function of pH



Possible routes of dissipation for mefluidide are photodegradation on soil surfaces, microbial mediated degradation, leaching, and runoff. Mefluidide is not prone to abiotic hydrolysis or photolysis in sterile buffer solutions within the environmentally relevant pH range of 4 to 9 (Accession No. 226846, MRID 42935401). There are data showing mefluidide undergoes rapid photodegradation ($t_{1/2} = 2$ to 3 days) in natural well water (Accession No. 226851). On soil surfaces, mefluidide photodegraded with a half-life of 4.85 days. Nine unidentified photodegradation products were detected in the soil (MRID 43040801).

Mefluidide in aerobic soils degraded with a half-life of 12 days (MRID 43162201). The only degradation product was 5-amino-2,4-dimethyltrifluoromethanesulfonilide. It was found at a maximum daily concentration of 2.8% of applied mefluidide at 22 days post-treatment. Diethanolamine is a degradation product of mefluidide-DEA. Non-extractable radiolabeled mefluidide residues accounted for 32 to 37% at 366 days post-treatment. Evolved CO_2 accounted for 20.9% at 366 days post-treatment mefluidide was stable ($t_{1/2} > 1$ year) in anaerobic environments (MRID 43120001).

Mefluidide has Freundlich adsorption coefficients of 0.22 ($1/n=0.35$) in sand, 0.14 ($1/n=0.95$) in silt loam soil, 0.083 ($1/n=1.3$) in clay soil, and 0.11 ($1/n=1.0$) in sand sediment (MRID 42998201). There was no relationship of soil OC content and K_d . Aged residues of mefluidide were detected in the leachate of aged residue soil column leaching studies (MRID 43020801).

Mefluidide dissipated with a half-life of 2.0 to 3.3 days in warm-season turf soil in Georgia and 1.2 to 1.4 days in cool-season grass soil in Missouri (MRID 43276802 and 43276801). It was not detected in soil samples at depths greater than 6 inches. Degradation products were not evaluated in the field dissipation studies. Mefluidide dissipated from grass foliage at half-lives of 1.7 to 6.91 days (upper 90th percentile of mean half-life=4.0414 day, $k=0.1715 \text{ days}^{-1}$).

Bioaccumulation of mefluidide in fish tissue is not expected due to a low octanol water partitioning coefficient ($\log K_{ow}=1.97$; $K_{ow}=94.5$). It also was not found to substantially

accumulate (BCF = 0 to 1.11) in catfish tissues during bioaccumulation studies (Accession Number 226851).

There are no environmental fate data on 5-amino-2, 4-dimethyltrifluoro-methane-sulfonilide. Diethanolamine (DEA) degrades rapidly ($t_{1/2}$ = 1.7 to 5.8 days) in aerobic soil and water environments (MRID 43685901, 43685902, 44439401). In contrast, DEA is persistent ($t_{1/2}$ = 990 days) in anaerobic aquatic environments (MRID 43882901). Degradation products of diethanolamine are glycine, ethanolamine, and CO₂.

3.2.2 Measures of Aquatic Exposure

3.2.2.1 Aquatic Exposure Modeling

PRZM (3.12 beta) and EXAM (2.97.5) using PE4V01.pl (August 13, 2003) were used to estimate mefluidide residue concentrations in surface water. Because mefluidide use is associated with turf, the aquatic exposure assessment was conducted using the PA and FL turf scenarios. These use scenarios were selected to represent of rights-of-way, residential turf, industrial areas with turf (i.e., airports, etc.), and golf courses. It is important to note that all mefluidide uses (i.e., spot treatments, etc.) were expressed on a lbs ae/A basis. This approach is expected to be conservative because it assumes 100% of the watershed is treated with mefluidide. Application rates of mefluidide are expressed in acid equivalence to address the bridging of mefluidide-K, mefluidide-DEA, mefluidide to the assigned stressor (the two forms of mefluidide: enol/keto; same molecular weight). Table 3.4 contains a summary of the various labeled application rates which suggests that the maximum rate is that of mefluidide-DEA. Foliar dissipation half-lives for mefluidide were estimated from field dissipation studies for warm-season and cool season grasses (MRID 43276801 and MRID 43276802). PRZM /EXAMS input parameters for mefluidide are shown in **Table 3.1**. Estimated environmental concentrations are shown in **Table 3.2**.

Table 3.1. Input Parameters for Mefluidide Acid for PRZM/EXAMS Modeling for Aquatic Exposure Assessment

Variable Description	Input Value	Source of Info/Reference
Application date(s) (day/mo/yr)	15/05	Product label
Number of Applications	3	Label Recommendation
Application Interval (days)	42 days	Label Recommendation
Incorporation depth (cm)	Default=0	Product label

Application rate (kg a.e. ha ⁻¹)	Acid- 0.56 DEA salt- 1.12 K salt- 1.12	Bead Use Closure Memorandum
Application efficiency (fraction)	0.99	Spray Drift Task Force Data
Spray drift fraction: For aquatic ecological exposure assessment, use 0.05 for aerial spray; 0.01 for ground spray. For drinking water assessment, use 0.16 for aerial 0.064 for ground spray.	0.01	Spray Drift Task Force Data
Foliar extraction (frac./cm rain)	0.5 is the default unless field data is available	Default or field data
Decay rate on foliage (days-1)	T _{1/2} =4.0414 days Rate constant = 0.1715/day	Derived as 90 th percentile of the mean foliar dissipation half-life from field dissipation studies. This value also used for terrestrial modeling (MRID 43276801 MRID 43276802).
Volatilization rate from foliage (day-1)	0.0 is the default unless field data is available	Default or field data
Plant uptake factor (frac. of evap)	0.0	Default
Aerobic soil metabolism Half-life (days)	T _{1/2} =36 days Estimation = 3 X 12 days	MRID 43162201
Anaerobic Aquatic Metabolism Half-life (days)	Stable	MRID 43120001
Aerobic Aquatic Metabolism Half-life (days)	72 days Estimation= 2 X 36 days	No Data Available
Photodegradation in Water Half-life (days)	Stable	MRID 42935401
Adsorption Soil: Water Partitioning Coefficients	0.073 (lowest non-sand Kd)*	MRID 42998201
Molecular Weight (grams/mole)	310.6	Calculated for Mefluidide structure
Henry's Constant (atm m ³ /mol)	2.27E ⁻⁷	EFED One Liner
Vapor Pressure (torr)	1E-4	EFED One Liner
Solubility (mg/L)	180	EFED One Liner
Chemical Application Method	2	Foliar Application

1 Acid equivalence was calculated using the following equations:

$$\text{Mefluidide-DEA} = 310 \text{ g/mole (MW mefluidide)}/415.24 \text{ g/mole (MW mefluidide-DEA)} = 0.75 * \text{concentration of ai}$$

Mefluidide-K= 310 g/mole (MW mefluidide)/348.29 g/mole (MW mefluidide-K)=0.89*concentration of ai
 Mefluidide = 310 g/mole (MW mefluidide)/310 g/mole (MW mefluidide acid)= 1.0* concentration of ai

*there was no relationship of soil OC content. Therefore the lowest non-sand Kd was used.

The 1 in 10 year peak concentration for mefluidide is not expected to exceed 10.573 µg/L. The 1 in 10 year 21-day and 60-day average concentrations are not expected to exceed 9.623 µg/L and 8.448 µg/L, respectively. A major uncertainty in the assessment is the persistence of mefluidide acid in aerobic aquatic environments. This assessment was conducted using an estimated aerobic aquatic half-life of 72 days (Guidance for Chemistry and Management Practice Input Parameters for Use in Modeling the Environmental Fate and Transport of Pesticides, Version 2, 11/7/2000). Because this estimated half-life was designed to approximate upper 90th percentile of the mean half-life, it is anticipated to be a conservative estimate of mefluidide acid persistence in aquatic environments.

Table 3.2 Tier II Estimated Environmental Concentrations for Mefluidide Acid

Scenario	Chemical	1 in 10 year Concentration (ug ae/L)		
		Peak	21 day average	60 day average
FL Turf	Mefluidide	4.835	4.399	3.890
	Mefluidide-DEA	10.573	9.623	8.448
	Mefluidide-K	10.573	9.623	8.448
PA Turf	Mefluidide	3.031	2.900	2.638
	Mefluidide-DEA	7.054	6.738	6.265
	Mefluidide-K	7.054	6.738	6.265

3.2.2.1 Monitoring Data

NAWQA surface or ground water monitoring data were not found for mefluidide, mefluidide-K and mefluidide-DEA.

3.2.3 Measures of Terrestrial Exposure

The measures of exposure for terrestrial receptors in Agency ecological risk assessments can be obtained from monitoring data, field studies, GIS analysis, and exposure modeling. The TREX (v.1.3.1) model was used to generate measures of exposure for terrestrial organisms that may come in contact with areas where mefluidide may be used. This assessment focuses on all methods of exposure for terrestrial birds and mammals as a result of spray and granular applications of mefluidide. Other routes of exposure, primarily dermal, inhalation, and incidental soil ingestion were not evaluated in this assessment. The degree to which these routes of exposure may be important compared to exposure from dietary ingestion is an uncertainty. Even though these routes of exposure may be important to the

overall risk assessment, they require more analyses and data than those available for a screening-level assessment. However, inhalation is not likely to be an important exposure pathway because of the low Henry's Constant of mefluidide ($2.27E-7$ atm $m^3/mole$). Dermal exposure is not likely to be an important exposure pathway because of the low octanol/water partitioning coefficient ($\log K_{ow}=1.97$; $K_{ow}=94.5$). Mammalian toxicity studies for both inhalation and dermal exposure to mefluidide indicate low acute toxicity are summarized in Appendix E. Incidental soil ingestion is another possible route of exposure; available data suggests that up to 15% of the diet can consist of incidentally ingested soil depending on the species and feeding strategy (Beyer et al, 1994). Because mefluidide is moderately persistent in soils, incidental soil ingestion is a possible exposure pathway.

Exposure of free-ranging receptors is a function of the timing and extent of pesticide application with respect to the location and behavior of identified receptors. EFED's terrestrial exposure model generates exposure estimates assuming that the receptor is present on the use site at the time that pesticide levels are their highest.

The maximum pesticide residue concentration on food items is calculated from both initial applications and additional applications taking into account pesticide degradation between applications. In this assessment, three applications of mefluidide per season are applied as recommended by the label. Because mefluidide dissipates rapidly from turf foliage ($t_{1/2} = 4$ days) and the application intervals are long (42 days), the likelihood for carry-over of mefluidide residues between applications is low.

The current approach to screening-level terrestrial exposure estimation does not directly relate the timing of exposure to critical or sensitive population, community, or ecosystem processes. Therefore, it is difficult to address the temporal and spatial co-occurrence of mefluidide use based on application timing, application location and sensitive ecological processes. However, it is worth noting that pesticides are frequently used from spring through fall, which are times of active migrating, feeding, and reproduction for many wildlife species. The increased energy demands associated with these activities (as opposed to hibernation, for example) can increase the potential for exposure to pesticide contaminated food items since agricultural areas can represent a concentrated source of relatively easily obtained, high-energy food items. In this assessment, the spatial extent of exposure for terrestrial animal species is limited to the use area only.

It is assumed that given the typically lower metabolic demands of reptiles and amphibians compared to birds, exposure to birds would be greater due to higher relative food consumption. While this assumption is likely true, there are no supported relationships regarding the relative toxicity of a compound to birds and herpetofauna.

3.2.3.1 Terrestrial Exposure Modeling

Birds and Mammals

Estimated exposure concentrations for terrestrial receptors were determined using

the standard screening-level exposure model, TREX (v.1.3.1) (US EPA,2006). Maximum exposure levels were calculated for spray applications of mefluidide using maximum proposed application rates, maximum number of applications, and minimum application intervals for all proposed uses (**Table 3.3**). These exposure estimates are based on a database of pesticide residues on wildlife food sources associated with a specified application rate. Essentially, for a single application, there is a linear relationship between the amount of pesticide applied and the amount of pesticide residue present on a given food item. These relationships for the various food items are determined from the Kenaga nomogram as modified by Fletcher (Hoerger and Kenaga, 1972; Fletcher et al., 1994). TREX (v.1.3.1) is a simulation model that, in addition to incorporating the nomogram relationship, also includes pesticide degradation in the estimation of EECs. These EEC values from the TREX model are summarized in Appendix D

TREX calculates pesticide residues on each type of food item on a daily interval for one year. A first order decay function is used to calculate the residue concentration at each day based on the concentrations present from both the initial and additional applications. The first-order rate equation is: $C_t = C_i e^{-kt}$ Where C_t is concentration at time t (days; $t=0$ initially), C_i is initial concentration after application, k is the foliar dissipation half-life, and t is time in days. The initial concentration, C_i , is determined by multiplying the application rate by a constant specific to a food item.

For the ornamental turf control application for mefluidide-DEA and mefluidide-K at 1.0 lb a.e. of pesticide per acre the upper-bound, food item concentration (ppm) is: 240.17 for short grass, 110.08 for tall grass, 135.09 for broadleaf plants and small insects, and 15.01 for fruits, pods, and large insects.

The dose-based EECs (mg/kg-bw) derived above are compared with LD_{50} or NOAEL (mg/kg-bw) values from acceptable or supplemental toxicity studies that are adjusted for the size of the animal tested compared with the size of the animal being assessed (e.g., 20-gram bird). These exposure values are presented as mass of pesticide consumed per kg body weight of the animal being assessed (mg/kg-bw). EECs and toxicity values are relative to the animal's body weight (mg residue/kg bw) because consumption of the same mass of pesticide residue results in a higher body burden in smaller animals compared with larger animals. For birds, only acute values (LD_{50} s) are adjusted because dose-based risk quotients are not calculated for the chronic risk estimation. Adjusted mammalian LD_{50} s and reproduction NOAELs (mg/kg-bw) are used to calculate dose-based acute and chronic risk quotients for 15 g, 35 g, and 1000 g mammals. The test weight value for the acute laboratory mouse (20 g), (Lehman,A.J.1975), replaced the (350 g) laboratory rat value in the TREX modeled equations. Equations and calculations for adjusted LD_{50} s (mammals and birds) are summarized in Appendix D.

In many cases, an empirically determined foliar dissipation half-life value is not available, in which case the default value of 35 days is used (Willis and McDowell, 1987). However, a 4 day foliar dissipation half life was estimated from field dissipation studies on

warm-season and cool season grasses (MRID 43276801 and 43276802). The food item concentration on any given day is the sum of all concentrations up to that day taking into account the first-order degradation. The initial application is on day 0 (t = 0) and runs for 365 days. Over the 365 day run, the highest residue concentration is used in calculations of the RQ.

Table 3.3 lists exposure estimates for birds and animals obtained from TREX simulations for all the proposed uses of mefluidide at maximum label rates. Importantly, TREX considers exposure only in the area where mefluidide is applied. The underlying assumption is that most, if not all, of the applied pesticide will settle in the use area. However, depending on weather conditions and type of application, spray drift of pesticides may occur, increasing the likelihood of wildlife exposure outside the use area.

Table 3.3 Estimates of Foliar residues of Mefluidide for proposed uses (dietary based EECs)¹			
Use	Application Rate lbs. ae/A (# app / interval, days)	Food Items	Upper Bound EEC (mg/kg)
Ornamental Turf Ground sprays (Mefluidide salts only)	1.0 3 per season 42 Day interval	Short grass	240.17
		Tall grass	110.08
		Broadleaf plants/small insects	135.09
		Fruits, pods, seeds, and large insects	15.01

¹Predicted maximum residues for specified application rates are based on Hoerger and Kenaga (1972) as modified by Fletcher *et al.* (1994).

The residues or estimated environmental concentrations (EECs) on food items may be compared directly with subacute dietary toxicity data or converted to an ingested whole body dose (single oral dose), as is the case for small mammals and birds. Single-oral dose estimates represent, for many pesticides, an exposure scenario where absorption of the pesticide is maximized over a single ingestion event. Subacute dietary estimates provide for possible effects of the dietary matrix and more extended time of gut exposure on pesticide absorption across the gut. However dietary exposure endpoints are limited in their utility because the current food ingestion estimates are uncertain and may not be directly comparable from laboratory conditions to field conditions. The EEC is converted to an oral dose by multiplying the EEC by the percentage of body weight consumed as estimated through allometric relationships. These consumption-weighted EECs (i.e. EEC equivalent dose) are determined for each food source and body size for mammals (15, 35, and 1000 g) and birds (20, 100, and 1000 g).. The EEC equivalent doses, formulas and calculations for adjusted body weights for birds and mammals based on 1.0 lb ae/A from TREX for turf are summarized in **Appendix D**.

A second approach for calculation of acute RQs for birds and mammals is the LD₅₀ per ft² method. This method is used to address the exposure from granular pesticides (i.e.,

mefluidide). EECs for this approach are calculated from the application rate (lbs ae/acre) and converted to mg ae/sq ft using the formula:

$$\text{lbs ae/acre} * (453590 \text{ mg/lb}) * (\text{acre}/43560 \text{ sq ft}) = \text{mg ae/sq ft.}$$

Because the chemical is not incorporated into the soil immediately after application, it is assumed that 100% of the material is available to birds and mammals (USEPA 1992). For a single application of mefluidide at 0.5 lbs ae/acre, the EEC was calculated at 5.21 mg ae/sq ft. This approach can only be applied for single applications.

Terrestrial Plants

Terrestrial and semi-aquatic plants may be exposed to pesticides from runoff, spray drift or volatilization. Semi-aquatic plants are those that inhabit low-laying wet areas that may be dry at certain times of the year. The runoff scenario in TERRPLANT 1.2.1 is: (1) based on a pesticide's water solubility and the amount of pesticide present on the soil surface and its top one centimeter, (2) characterized as "sheet runoff" (one treated acre to an adjacent acre) for dry areas, (3) characterized as "channel runoff" (10 acres to a distant low-lying acre) for semi-aquatic or wetland areas, and (4) based on percent runoff values of 0.01, 0.02, and 0.05 for water solubilities of <10, 10-100, and >100 ppm, respectively. Spray drift is assumed as (1) 1% for ground application, (2) 5% for aerial, airblast, forced air, and spray chemigation applications, and (3) 0% for granular applications. Currently, EFED derives plant exposure concentrations from a single, maximum application rate only. EECs are calculated using the approach outlined in the text box below. The EECs for terrestrial plants for a single application of Mefluidide at the maximum label rate for ornamental turf are presented in **Table 3.4**

Table 3.4 EECs for Granular and Spray Applications to Terrestrial Plants Near Mefluidide Use Areas from TerrPlant (v 1.2.1)¹.				
Application Rate, lbs a.e./A	Application method	EECs (lbs. a.e A)		
		Total Loading to Adjacent Areas (sheet runoff + drift)	Total Loading to Semi-Aquatic Areas (channelized runoff + drift)	Drift EEC
1.0 lb ae/A Turf	ground spray	0.06	0.51	0.01
0.5 lb ae/A Turf	granular	0.03	0.255	0.0050

¹ For terrestrial plant (seedling emergence and vegetative vigor) toxicity assessments, data evaluating mefluidide-K, mefluidide-DEA and mefluidide toxicity have been bridged. Therefore, the most sensitive Mefluidide endpoint was selected to represent terrestrial plants for all application scenarios.

^a EECs for spray turf applications in this table were calculated for the maximum labeled application rates of (1.2 lbs ae/acre) and (1.0 lbs ae/acre) for mefluidide-DEA and mefluidide-K respectively.

[†]The runoff factor of 0.05 was used based on solubility of 180

Because mefluidide is a spray applied herbicide, a more in-depth spray drift exposure assessment utilizing Tier I AgDRIFT[®] (version 2.01) modeling is also provided to better characterize potential exposure of terrestrial plants. AgDRIFT[®] utilizes empirical data to estimate off-site deposition of aerial and ground applied pesticides, and acts as a tool for evaluating the potential of buffer zones to protect sensitive habitats from undesired exposures. AgDrift provided 90th percentiles estimates based on the distribution of field measurements at 10 to 900, feet distances from the edge of field. **Table 3.5** contains EECs at several distances from the edge of the field for fine to very fine droplet size and medium to course droplet size.

Table 3.5 Estimated environmental concentrations (EECs) Deposition (lb ae./acre) at Specified Buffer Distance From Edge of Field (feet) from off-target terrestrial exposure to Mefluidide through spray drift derived from Tier I AgDRIFT[®] (version 2.01) at varying distance from the edge of field.

Buffer Distance From Edge of Field (feet)	1.0 lb ae/A*	1.0 lb ae/A**
10	0.0923	0.0275
20	0.0437	0.0149
40	0.0218	0.0087
60	0.0149	0.0064
80	0.0115	0.0052
100	0.0095	0.0044
140	0.007	0.0035
180	0.0056	0.0029
200	0.0051	0.0026
250	0.0042	0.0022
500	0.0021	0.0012
900	0.0011	0.0007

* Ground application assumed conditions of low boom, ASAE very fine to fine droplet size, and 90th

** Ground application assumed conditions of low boom, ASAE medium to course droplet size, and 90th

3.3 Ecological Effects Characterization

3.3.1 Aquatic and Terrestrial Effects Characterization

In screening-level ecological risk assessments, effects characterization describes the types of effects a pesticide can produce in an animal or plant. This characterization is based on registrant-submitted studies and an ECOTOX database search that describe acute and chronic effects toxicity information for various aquatic and terrestrial animals and plants. In addition, a review of Ecological Incident Information System (EIIS) was conducted to further refine the characterization of potential ecological effects. **Tables 3.6, 3.7, 3.8**, summarize the most sensitive ecological toxicity endpoints for aquatic organisms, terrestrial organisms, and aquatic and terrestrial plants, respectively, which were used for risk characterization. Discussions of the effects of mefluidide-K, mefluidide-DEA and mefluidide on aquatic and terrestrial taxonomic groups are presented below. Concentrations of mefluidide are expressed in acid equivalence to address the bridging of mefluidide-K, mefluidide-DEA, mefluidide to mefluidide acid.

Acid equivalence was calculated using the following equations:

$$\begin{aligned} \text{Mefluidide-DEA} &= 310 \text{ g/mole (MW mefluidide)} / 415.24 \text{ g/mole (MW mefluidide-DEA)} = 0.75 * \text{concentration of ai} \\ \text{Mefluidide-K} &= 310 \text{ g/mole (MW mefluidide)} / 348.29 \text{ g/mole (MW mefluidide-K)} = 0.89 * \text{concentration of ai} \\ \text{Mefluidide acid} &= 310 \text{ g/mole (MW mefluidide)} / 310 \text{ g/mole (MW mefluidide acid)} = 1.0 * \text{concentration of ai} \end{aligned}$$

Appendix E summarizes the results of all of the registrant-submitted toxicity studies for this risk assessment. Also, a search of the ECOTOX database was completed on mefluidide. Results of Ecotox search are listed in Appendix H. For mammals, toxicity studies are limited to the laboratory rat. Estuarine/marine testing is limited to a crustacean, a mollusk, and a fish. Also, no available data was available for reptiles or amphibians. The risk assessment assumes that avian and reptilian and terrestrial-phase amphibian toxicities are similar. The same assumption is used for fish and aquatic-phase amphibians. The most sensitive ecological toxicity endpoints for aquatic organisms, terrestrial organisms, and aquatic and terrestrial plants were used for risk characterization.

Table 3.6, 3.7 and 3.8 provides a summary of acute and chronic toxicity data used for risk quotient calculation for mefluidide-K, mefluidide-DEA and mefluidide application.

Table 3.6: Summary of endpoints (LC₅₀ or EC₅₀, mg ae/L) for Aquatic Toxicity used in RQ calculations for Mefluidide¹			
TAXONOMIC GROUP	Acute endpoint	Chronic endpoint	MRID/ Estimated value
Acute freshwater fish	>68.47* Rainbow Trout		MRID 418937-02

Chronic freshwater fish		>0.267	Estimated value acute to chronic ratio
Acute freshwater inverts	>77.25* Daphnid		MRID 418937-03
Chronic freshwater inverts		>5.54	Estimated value acute to chronic ratio
Acute estuarine/marine fish	>84.75* Sheepshead minnow		MRID 425623-03
Chronic estuarine/marine fish		>0.267	Estimated value acute to chronic ratio
Acute estuarine/marine inverts	67* Eastern oyster		MRID 425624-01
Chronic estuarine/marine inverts		>5.54	Estimated value acute to chronic ratio

¹ For fish and invertebrates data evaluating mefluidide-K, mefluidide-DEA and mefluidide have been bridged for the runoff risk assessment.

* most sensitive species tested

Table 3.7: Summary of endpoints (LC₅₀ or EC₅₀, mg ae/L) for Plant Toxicity used in RQ calculations for Mefluidide¹

TAXONOMIC GROUP	Acute endpoint	NOAEC or EC ₀₅	
Acute vascular plant	0.515* Lemna		MRID 435266-01 Tier I (8% growth stimulation) Used this value as EC₅₀ ,
Vascular plant(EC ₀₅)		>0.29	Estimated value acute to chronic ratio
Acute non-vascular plant	0.629* Navicula		MRID 435266-05 Tier I (11.5% growth reduction) Used this value as EC₅₀ ,
Non-vascular plant(EC ₀₅)		>0.786	Estimated value acute to chronic ratio
Terrestrial Plant: Vegetative Vigor	Monocot:* Sorghum EC ₂₅ 0.105 lb ae/A Dicot:* Mustard EC ₂₅ 0.0054 lb ae/A	Monocot:* Sorghum NOAEC 0.045 lb ae/A Dicot:* Mustard NOAEC 0.0029 lb ae/A	MRID 435496-01
Terrestrial Plant: Seedling Emergence	Monocot: Sorghum EC ₂₅ 0.105 lb ae/A Dicot:* Mustard EC ₂₅ 0.0054 lb ae/A	Monocot: Sorghum NOAEC 0.045 lb ae/A Dicot:* Mustard NOAEC 0.0029 lb ae/A	Estimated value from vegetative vigor study MRID 435496-01

¹For aquatic and terrestrial plants data evaluating mefluidide-K, mefluidide-DEA and mefluidide have been bridged for the terrestrial and runoff risk assessment.

*most sensitive species tested

Table 3.8: Summary of endpoints (LD₅₀ or LC₅₀ mg ae/kg) for Terrestrial Toxicity data used in RQ calculations for Mefluidide¹

TAXONOMIC GROUP	Acute endpoint	Chronic endpoint	
Acute Avian	>1500* Bobwhite quail		MRID 416019-01 Used this non-definitive endpoint as LD50
Chronic Avian		38	Estimated value acute to chronic ratio based on mammal data
Acute Dietary Avian	>3750*		
Acute mammal	829.8* mouse		MRID 00047116
Chronic mammal		102* rat	MRID 00082748

¹For terrestrial plants data evaluating mefluidide-K, mefluidide-DEA and mefluidide have been bridged for the terrestrial risk assessment.

*most sensitive species tested

3.3.1.1 Aquatic Animals

Acute Toxicity to Freshwater Fish

There are no acute toxicity studies for mefluidide-K or mefluidide for bluegill sunfish (*Lepomis macrochirus*) (warm water species) or cold water species, rainbow trout (*Oncorhynchus mykiss*).

Mefluidide-DEA is practically non-toxic to the cold water species, rainbow trout (*Oncorhynchus mykiss*), with a non-definitive 96-hour LC₅₀ of >68.47 mg ae/L and a NOAEC of 68.47 mg ae/L (MRID 418937-02). No mortalities or sublethal signs of toxicity in rainbow trout were observed with test material in any of the tested concentrations. The mean measured concentrations were 15.2, 12.5, 24.4, 45.2, and 91.3 mg ai /L. (11.4, 9.3, 18.3, 33.9 and 68.4 mg ae/L).

Mefluidide-DEA is practically non-toxic to the warm water species, bluegill sunfish (*Lepomis macrochirus*) with a non-definitive 96-hour LC₅₀ of >70.80 mg ae/L and a NOAEC of 70.80 mg ae/L (MRID 418937-01). No mortalities or sublethal signs of toxicity in bluegill sunfish were observed with test material in any of the tested concentrations. The mean measured concentrations were 14.6, 19.7, 32.4, 58.3 and 94.4 mg ai /L(10.9, 14.7, 24.3, 43.7 and 70.8 mg ae/L).

The most conservative non-definitive LC₅₀ of > 68.47 mg ae/L for mefluidide was determined from the rainbow trout fish study with mefluidide-DEA. Both studies were

classified as acceptable based on guidelines §72-1(a) and §72-1(c) testing requirements. These results are summarized in Table E1.

The non-definitive LC₅₀ of >68.47 mg ae/L was selected for evaluating freshwater fish for the runoff risk assessment of mefluidide-K, mefluidide-DEA and mefluidide.

Acute Toxicity to Estuarine/ Marine Fish

Mefluidide is practically non-toxic to sheepshead minnow (*Cyprinodon variegatus*), with a non-definitive 96-hour LC₅₀ of >130 mg ae/L and a NOAEC of 130 mg ae/L (MRID 425624-03). No mortalities or sublethal signs of toxicity in sheepshead minnow were observed with test material in any of the tested concentrations. The mean measured concentrations were 19, 28, 45, 80, and 130 mg ae /L.

Mefluidide-DEA is practically non-toxic to sheepshead minnow (*Cyprinodon variegatus*), with a non-definitive 96-hour LC₅₀ of >84.75 mg ae/L and a NOAEC of 84.75 mg ae/L (MRID 425623-03). No mortalities or sublethal signs of toxicity in sheepshead minnow were observed with test material in any of the tested concentrations. The mean measured concentrations were 16, 28, 34, 68, and 113 mg ai /L (12, 21, 25.5, 51 and 84.7 mg ae/L).

The non-definitive LC₅₀ of >84.75 mg ae/L was selected for evaluating estuarine marine fish exposed to mefluidide-K, mefluidide-DEA and mefluidide for the runoff risk assessment .

Chronic Toxicity to Freshwater Fish and Estuarine/Marine Fish

No studies evaluating the chronic toxicity of mefluidide to freshwater or estuarine/marine fish have been submitted to the Agency. Due to lack of submitted chronic studies for freshwater fish estimated acute to chronic ratios (ACRs) were derived from the propanil analog. Therefore, the chronic NOAEC of > 0.267 mg ae/L value for freshwater fish was estimated from the propanil analog. Calculations and endpoints used to determine ACRs are summarized in Appendix E

Mefluidide is practically non-toxic to estuarine marine fish and slightly toxic to estuarine marine invertebrates on an acute basis. The lowest acute LC₅₀ values reported for estuarine marine fish and invertebrates are >84.75 and (57.75 and 67 mg ae/L), respectively. There are insufficient data to establish a definitive toxicity endpoint for estuarine/marine fish and invertebrate chronic effects for mefluidide and DEA salt acid equivalents for mefluidide. There is also little available data to compare to other anilide herbicides for this taxonomic group. For the purposes of this risk assessment, it was assumed that estuarine marine fish were at least as sensitive as freshwater fish in terms of chronic toxicity. Therefore, the estimated endpoint for freshwater fish (NOAEC >0.267 mg ae/L) was used to estimate a

chronic effects endpoint for estuarine/marine fish. The multiple assumptions involving extrapolations across species (fathead minnow and rainbow trout), data from a single analog (propanil) and across freshwater and estuarine/marine conditions suggests that this estimate may be highly uncertain. (For more information, please see source data in Appendix E for other anilide herbicide).

Acute Toxicity to Freshwater Invertebrates

Mefluidide-DEA is practically non-toxic to the waterflea (*Daphnia magna*), with a non-definitive 48-hr $EC_{50} > 77.25$ mg ae/L and a NOAEC of 77.25 mg ae/L (MRID 418937-03). Mean measured concentrations were 16.2, 28.0, 41.8, 68.0 and 103 mg ai/L. (12.1, 21, 31.3, 51 and 77.2 mg ae/L). One mortality for freshwater invertebrates occurred at the 51 mg ae/L. This death was not considered treatment related due to 100% survival in the 77.2 mg ae/L concentration. This study is classified as acceptable according to the §72-2 guideline requirements.

The non-definitive LC_{50} of 77.25 mg ae/L was selected for evaluating freshwater invertebrates exposed to mefluidide-K, mefluidide-DEA, and mefluidide for the runoff risk assessment.

The results of these tests are summarized in Appendix E, Table E2.

Acute Toxicity to Estuarine/ Marine Invertebrates

Mefluidide is practically non-toxic to the estuarine marine mysid (*Mysidopsis bahia*), with a 96-hr EC_{50} 133 mg ae/L and a NOAEC of 47 mg ae/L (MRID 425624-02). Mean measured concentrations were 16.2, 28.0, 47, 80 and 133 mg ae/L. One mortality for estuarine marine invertebrates occurred at the 28 mg ae/L treatment level. However, this death was not considered treatment related. By the end of the study 50% mortality had occurred in the 133 mg ae/L treatment group. This study is classified as acceptable according to the §72-3 guideline requirements.

Mefluidide-DEA is practically non-toxic to the estuarine marine mysid (*Mysidopsis bahia*), with a 96-hr $EC_{50} > 94.5$ mg ae/L and a NOAEC of 31.5 mg ae/L (MRID 425623-02). Mean measured concentrations were 15, 26, 42, 75 and 126 mg ai/L (11.25, 19.5, 31.5, 56.2 and 94.5 mg ae/L). One mortality to estuarine marine mysid occurred at the 52.2 mg ae/L treatment level and 2 mortalities occurred in the 94.5 mg ae/L treatment level. No other mortalities or sublethal effects occurred during the test. This study is classified as acceptable according to the §72-3 guideline requirements.

Mefluidide is practically slightly toxic to the estuarine marine eastern oyster (*Crassostrea virginica*) for shell deposition, with a 96-hr EC_{50} 67 mg ae/L and a NOAEC of <12 mg ae/L (MRID 425624-01). Mean measured concentrations were 12, 21, 34, 55 and 99 mg ae/L. There were no mortalities or observations of sublethal effects during the test. The

length measurements indicated shell growth inhibition ranging from 16.7% in the 12 mg ae/L group to 73% in the 99 mg ae/L. This study is classified as acceptable according to the §72-3 guideline requirements.

Mefluidide-DEA is slightly toxic to the estuarine marine eastern oyster (*Crassostrea virginica*) for shell deposition with a 96-hr EC₅₀ 57.75 mg ae/L and a NOAEC of <10.5 mg ae/L (MRID 425623-01). Mean measured concentrations were 14, 23, 37, 61 and 98 mg ai/L (10.5, 17.25, 27.75, 45.75 and 73.5 mg ae/L). The length measurements indicated shell growth inhibition ranging from 11% in the 10.5 mg ae/L group to 71% in the 73.5 mg ae/L. This study had 3 study deficiencies which results in a supplemental study. There was less than the recommended shell growth in the control animals, contamination was present in the control groups and the flow rate in the test chambers was less than recommended. However, adequate dose response occurred in the study. Contamination of the control solutions was evident, but this contamination was intermittent and well below the NOEC. Also the results of the study correlate well with the oyster shell deposition study done with TGAI (MRID 425624-01). This study is classified as supplemental according to the §72-3 guideline requirements.

The EC₅₀ of 67 mg ae/L was selected for evaluating estuarine marine invertebrates exposed to mefluidide-K, mefluidide-DEA and mefluidide for the runoff risk assessment. The most sensitive endpoint EC₅₀ 57.75 mg ae/L was not selected due to study deficiencies as described above.

The results of these tests are summarized in Appendix E, **Table E2**.

Chronic Toxicity to Estuarine/Marine Invertebrates

No studies were submitted to the Agency evaluating the chronic toxicity of mefluidide-DEA, mefluidide-K and mefluidide to freshwater and estuarine marine invertebrates. Due to lack of submitted chronic studies for freshwater invertebrates estimated acute to chronic ratios (ACRs) were derived from the Propanil analog. Therefore, the chronic NOAEC of >5.54 mg ae/L value for freshwater invertebrates was estimated from the propanil analog. Calculations and endpoints used to determine ACRs are summarized in Appendix D. There are insufficient data to establish a definitive toxicity endpoint for estuarine/marine invertebrate chronic effects for the acid and DEA salt acid equivalents for mefluidide. There is also little available data to compare to other anilide herbicides for this taxonomic group. For the purposes of this risk assessment, it was assumed that estuarine marine invertebrates were at least as sensitive as freshwater invertebrates in terms of chronic toxicity. Therefore, the estimated endpoint for freshwater invertebrates (NOAEC >5.54 mg ae/L) was used to estimate a chronic effects endpoint for estuarine/marine invertebrates. The multiple assumptions involving extrapolations with data from a single analog (Propanil) and across freshwater and estuarine/marine conditions suggests that this estimate maybe highly uncertain (see source data in Appendix E for other anilide herbicide).

Aquatic Plant Toxicity

No studies were submitted to the Agency evaluating the acute toxicity of mefluidide-K and mefluidide to aquatic plants. For mefluidide-DEA, the dosage tested for *Lemna gibba* (freshwater vascular plant) was 0.515 mg ae/L with stimulation of 8% frond growth for a Tier I study (MRID 435266-05). The dosage tested for *Selenastrum capricornutum* was 0.561 mg ae/L caused an 8% growth reduction in the exposed algal population for a Tier I study (MRID 435266-03). For the other two species of freshwater non-vascular plants (i.e., *Navicula pelliculosa* and *Anabaena flos-aquae*), Tier I studies resulted in (0.629 mg ae/L) 11.5% growth reduction and (0.543 mg ae/L) 4.3% growth reduction, respectively (MRIDs 435266-01 and 435266-04). For the estuarine/marine non-vascular plant (*Skeletonema costatum*), the dosage tested was 0.575 mg ae/L which resulted in no adverse effects for this Tier I study (MRID 4435266-02). All of the above Tier I studies are classified as acceptable according to the 122-2 guideline requirements.

The experimental procedures and dose calculation procedures for the range finding tests, for the above Tier I studies are basically the same as are those for the final or definitive studies. The results of the definitive or final aquatic plant tests are one order of magnitude more toxic than the range finding tests. The results for both sets of studies do not show any inhibition levels above 50%.

Due to lack of submitted aquatic plant studies for vascular and non-vascular plants, NOAEC or EC₀₅ values were estimated acute to chronic ratios (ACRs) from the propanil analog. An EC₀₅ was estimated at >0.029 value for vascular plants and >0.786 mg ae/L for non-vascular plants. The multiple assumptions involving extrapolations with data from a single analog (propanil) suggests that this estimate maybe highly uncertain. Calculations and endpoints used to determine ACRs are summarized in Appendix E.

Peak EECs from the PRZM/EXAMS turf modeled scenarios ranged from 0.003031 mg ae/L to 0.010573 mg ae/L. The Tier I study for *Navicula pelliculosa* resulted in (0.629 mg ae/L) 11.5% growth reduction. In contrast, the Tier I study for *Lemna gibba* resulted in (0.515 mg ae/L) 8% frond growth.

The results of the above studies and the range-finding tests are provided in **Table E4**.

3.3.1.2 *Terrestrial Animals*

Acute oral gavage bird

For mefluidide, an acute single-dose oral toxicity study was performed using the bobwhite quail (*Colinus virginianus*). The 58.2% ai compound was adjusted to 100% ai at dosing. Thirty birds were used at one dose level of 2000 mg ae/ kg. The LD₅₀ value was >2000mg ae/kg-bw. The results of this study categorize mefluidide as practically non-toxic to birds on a acute oral basis. However, this study is classified as Supplemental for an avian dietary LD₅₀ study because it is unclear what material (TGAI, formulated product, or

formulation intermediate) was tested. No statistics were performed due to lack of mortality and no signs of toxicity were observed. (MRID 416021-01)

For mefluidide-DEA, an acute single-dose oral toxicity study was performed using the bobwhite quail (*Colinus virginianus*). The 21.5% ai compound was adjusted to 100% ai at dosing. Thirty birds were used at one dose level of 1500 mg ae/ kg. The LD₅₀ value was >1500mg ae/kg-bw. The results of this study categorize mefluidide-DEA as practically non-toxic to birds on an acute oral basis. However, this study does not fulfill the requirement in support of registration and is classified as Supplemental for an avian dietary LD₅₀ study because it is unclear what material (TGAI, formulated product, or formulation intermediate) was tested. No statistics were performed due to lack of mortality and no signs of toxicity were observed (MRID 416019-01).

The above studies are summarized in **Table E5**.

Sub acute (dietary) Toxicity to Birds

For mefluidide, one dietary toxicity study was performed using the mallard duck (*Anas platyrhynchos*). The 58.2% ai compound was adjusted to 100% ai at dosing. Thirty birds were used at one dose level of 5000 mg ae/ kg diet. In the mallard duck study, the non-definitive LC₅₀ was >5000 mg ae/kg diet. The results of this study categorize mefluidide as practically non-toxic to birds on a dietary basis. However, this study is classified as Supplemental for an avian dietary LC₅₀ study because it is unclear what material (TGAI, formulated product, or formulation intermediate) was tested. No statistics were performed due to lack of mortality and no signs of toxicity were observed. (MRID416021-03)

For mefluidide, one dietary toxicity study was performed using the bobwhite quail (*Colinus virginianus*). The 58.2% ai compound was adjusted to 100% ai at dosing. Thirty birds were used at one dose level of 5000 mg ae/ kg diet. In the bobwhite quail study, the non-definitive LC₅₀ was >5000 mg ae/kg diet. The results of this study categorize mefluidide as practically non-toxic to birds on a dietary basis. However, this study is classified as Supplemental for an avian dietary LC₅₀ study because it is unclear what material (TGAI, formulated product, or formulation intermediate) was tested. No statistics were performed due to lack of mortality and no signs of toxicity were observed. (MRID 416021-02).

For mefluidide-DEA, one dietary toxicity study was performed using the mallard duck (*Anas platyrhynchos*). The 21.5% ai compound was adjusted to 100% ai at dosing. Thirty birds were used at one dose level of 3750mg ae/ kg diet. In the mallard duck study, the non-definitive LC₅₀ was >3750 mg ae/ kg diet. The results of this study categorize mefluidide as practically non-toxic to birds on a dietary basis. However, this study is classified as Supplemental for an avian dietary LC₅₀ study because it is unclear what material (TGAI, formulated product, or formulation intermediate) was tested. No statistics were performed due to lack of mortality and no signs of toxicity were observed. (MRID416019-03)

For mefluidide-DEA, one dietary toxicity study was performed using the bobwhite quail (*Colinus virginianus*). The 21.5% ai compound was adjusted to 100% ai at dosing. Thirty birds were used at one dose level of 3750 mg ae/ kg diet. In the bobwhite quail study, the non-definitive LC₅₀ was >5000 mg ae/ kg diet. The results of this study categorize mefluidide-DEA as practically non-toxic to birds on a dietary basis. However, this study is classified as Supplemental for an avian dietary LC₅₀ study because it is unclear what material (TGAI, formulated product, or formulation intermediate) was tested. No statistics were performed due to lack of mortality and no signs of toxicity were observed. (MRID416019-02)

The LC₅₀ of 3750 mg ae/kg diet was selected for evaluating birds on a sub acute dietary basis exposed to mefluidide-K, mefluidide-DEA and mefluidide for the terrestrial risk assessment.

The above studies were classified as supplemental according to Guideline §71-2 requirement for subacute avian dietary testing and are summarized in Table E6.

Chronic Toxicity to Birds

No studies were submitted to the Agency evaluating the chronic toxicity of mefluidide-DEA, mefluidide-K and mefluidide to birds. There are insufficient data to establish a definitive toxicity endpoint for chronic effects to birds for the acid and DEA salt acid equivalents for mefluidide. There is also no available chronic avian data from other anilide herbicides for this taxonomic group to extrapolate acute to chronic ratios. For the purposes of this risk assessment, it was assumed that birds are similar in toxicity responses as mammals in terms of chronic toxicity. Therefore, acute to chronic ratios (ACRs) were derived from mefluidide laboratory rat and laboratory mouse data to determine the estimated chronic NOAEC of 38 mg ae/kg value for birds. Calculations and endpoints used to determine ACRs are summarized in Appendix E. The assumptions involving extrapolations with data from different terrestrial species suggests that this estimate maybe highly uncertain.

Acute Oral Toxicity to Mammals

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

An acute oral toxicity study with the laboratory mouse for mefluidide resulted in a LD₅₀ value of 829.8 ae mg/kg bw (MRID 00047116). This study is acceptable and satisfies guideline requirements for acute oral toxicity in rodents (81-1). Mefluidide is toxicity Category II. The data are summarized in **Table E9**.

Additional acute oral toxicity studies with the laboratory mouse and laboratory rat resulted in LD₅₀ values based on mefluidide ranged from 1920.2 ae mg/kg bw to >4000 ae mg/kg bw. Mefluidide toxicity was classified as Category III .

The LD₅₀ of 829.8 mg ae/kg bw was selected for evaluating mammals on a acute dietary basis exposed to mefluidide-K, mefluidide-DEA and mefluidide for the terrestrial risk assessment.

The data are summarized in **Table E9**.

Subchronic and Developmental/Chronic Toxicity to Mammals

Multi-Generation Reproduction Laboratory Rat Toxicity Study

In a three-generation reproduction study (MRID 00082748), MBR 12325 (Mefluidide; 93% a.i., Lot #25) was administered in the diet to 20 male and 40 female Charles River CD® rats/dose group at dose levels of 0, 600, 1800, or 6000 ppm (equivalent to Males/Females - 0/0, 34/60, 102/183, and 346/604 mg ae/kg bw/day)

There were no effects on food consumption, organ weights, gross pathology, or histopathology. Numerous absolute and relative (to bw) organ weights in the 6000 ppm parents were significantly ($p < 0.05$) different from the controls, however, none of these differences were corroborated by any macroscopic or microscopic findings indicating these decreases were most likely not related to treatment. Thus, it is likely that they were attributable to decreased body weights at this dose.

The only deaths included one 6000 ppm F1 female, one 6000 ppm F2 male, and one 1800 ppm F2 female. It was stated that macroscopic and microscopic findings in these animals were unremarkable. Therefore, these deaths were considered incidental and were not treatment related. At 6000 ppm, body weights were decreased by 1-8% in males and 1-12% in females throughout the study in the P generation, attaining significance ($p < 0.05$) at Week 18 in the males and Weeks 8, 18, 19, and 27 in the females. In the F1 generation at this dose, body weights were decreased throughout the study in the males (decr. 13-21%) and females (decr. 10-21%), attaining significance ($p < 0.01$) at Weeks 27, 37, and 56 in both sexes. Similarly in the F2 generation, body weights were decreased throughout the study in the 6000 ppm males (decr. 14-21%) and females (decr. 11-23%), attaining significance ($p < 0.01$) at Weeks 57, 66, and 85 in both sexes. At 1800 ppm, only minor and infrequent decreases in body weights were noted. There were no treatment-related findings at 600 ppm.

The parental systemic LOAEL is 6000 ppm (346/604 mg ae/kg bw/day in males/females), based on decreased body weights in both sexes in all generations. The parental systemic NOAEL is 1800 ppm (102/183 mg ae/kg bw/day in males/females). This study is acceptable/guideline and satisfies the guideline requirement for a three-generation reproductive study (OPPTS 870.3800; OECD 416) in rats.

Developmental Toxicity Study in Laboratory Rats:

In a developmental toxicity study (MRID 42026102), mefluidide-DEA (28.78% a.i. Lot # JB0624)) in distilled water was administered to pregnant Sprague Dawley CrI:CD BR VAF/Plus (25/dose) by gavage at dose levels of 0, 50, 200 or 400 mg/kg bw/day (adjusted doses for 100 % purity were 0, 14, 58, or 115 mg/kg/day, respectively) from days 6 through 15 of gestation. Animals were checked daily for clinical signs, mortality. Body weights were measured on gestation day 0, 6, 9, 12, 16 and 20. Unscheduled deaths, scheduled sacrifice and c-sections were subjected to gross necropsy examination. Each fetus was examined for external/visceral/skeletal anomalies, sexed and then weighed. Evidence of maternal toxicity included transient clinical signs (tremors, dark material around the nose, urine stain and reddish vaginal discharge), decreased body weight gain (11-61%), decreased food consumption and mortality (2/25 females) observed at the 400 mg ai/kg/day levels. No external malformations or developmental variations were observed associated with any fetus. Fetal toxicity was manifested by increase in the number of early resorptions which resulted in increase in mean postimplantation loss at 400 mg ai/kg/day dose.

The maternal NOAEL was 200 mg ai/kg/day (adjusted to 58 mg/kg/day) and the LOAEL at 400 mg ai/kg/day (adjusted to 115 mg/kg/day) based on clinical signs (tremors, dark material around the nose, urine stain and reddish vaginal discharge), decreased body weight gain, decreased food consumption and mortality (2/25 females).

The developmental toxicity NOAEL was 200 mg/kg/day (adjusted to 58 mg/kg/day), the LOAEL was 400 mg ai/kg/day (adjusted to 115 mg/kg/day) based on increase in the number of early resorptions and increase in mean postimplantation loss.

The NOAEC of 102 mg ae/kg bw was selected for evaluating mammals on a chronic/reproductive basis exposed to mefluidide-K, mefluidide-DEA and mefluidide for the terrestrial risk assessment.

This developmental toxicity study is classified acceptable/Guideline and it does satisfy the guideline requirement for a developmental toxicity study (OPPTS 870.3700; OECD 414) in the rat.

Acute Toxicity to Non-target Insects (Honey Bee)

Acute contact toxicity of mefluidide-DEA on the honey bee (*Apis mellifera*) was tested and the data are summarized in Table E8. In the acute contact test, the non-definitive LD₅₀ value was >18.75 µg ae/bee and the NOAEC was 9.37µg ae/bee. Mortality ranged between 6 and 14% with doses 1.6, 3.1, 6.3, 12.5 and 25 ug ai/bee (1.2, 2.3, 4.7, 9.3, and 18.75 ug ae /bee). Mortality at the four lowest test levels was determined to be non-treatment related. Mortality at the highest level was 14%. Mefluidide-DEA is categorized as practically non-toxic to honeybees on an acute contact basis. This study is classified as acceptable according to guideline 141-1 (MRID 425628-01).

Acute contact toxicity of mefluidide-K on the honey bee (*Apis mellifera*) was tested and the data are summarized in Table E8. In the acute contact test, the non-definitive LD₅₀ value was >22.25 µg ae/bee and the NOAEC was 22.25 µg ae/bee. Mortality ranged between 6 and 14% with doses 1.6, 3.1, 6.3, 12.5, 25 µg ai/bee (1.4, 2.7, 5.6, 11.1 and 22.25 µg ae/bee). Mortality at all treatment levels was determined not to be treatment related since clinical observations were similar between control and treated bees and the surviving bees at the lowest dosage appeared normal throughout the test. Mefluidide-K is categorized as practically non-toxic to honeybees on an acute contact basis. This study is classified as acceptable according to guideline 141-1 (MRID 425628-02).

Terrestrial Plant

A Tier II vegetative vigor study was conducted for ten species using mefluidide-DEA and the data are summarized in Tables E12 and E13. For the vegetative vigor study, the most sensitive monocot was sorghum with an EC₂₅ of 0.105 lbs ae/A and a NOAEC of 0.045 lbs ae/A, and the most sensitive dicot was mustard, with an EC₂₅ of 0.00547 lbs ae/A and a NOAEC of 0.0029 lbs ae/acre. For both monocots and dicots, the most sensitive parameter was shoot fresh weight. Symptoms of toxicity included stunting, chlorosis, necrosis and distortion. This study was originally classified as acceptable, however this study will be reviewed for a possible classification of Supplemental because this study was based on fresh weight instead of dry weight which is required according to guideline 123-1 (MRID 435496-01).

Seedling emergence toxicity data was not available for a full review and data was not available from other anilide analogs to derive EC₂₅ values. A preliminary review on a recently submitted seedling emergence study (MRID 471907-01) was conducted. These results are uncertain until a full review of the study is performed. The results of the preliminary review are summarized in Appendix E. Therefore, to estimate possible effects measurement endpoints for seedling emergence, EFED assumed that EC₂₅ toxicity values for vegetative vigor are equal to seedling emergence measurement endpoints for mefluidide, mefluidide-DEA and mefluidide-K. Therefore, the most sensitive seedling emergence EC₂₅ estimated values are 0.105 and 0.0054 lb ae/acre for monocots and dicots, respectively. The NOEC estimated values for seedling emergence are 0.045 and 0.0029 lb ae/acre for monocots and dicots, respectively.

Earthworms

No earthworm studies were submitted to the Agency. However, Ecotox data indicates that mefluidide is non-toxic to earthworms (Ref #39542 Potter DA; Spicer PG; Redmond CT; Powell AJ (1994) Toxicity of Pesticides to Earthworms in Kentucky Bluegrass Turf). Two evaluations were conducted in the spring and the fall of 1992. Earthworm populations were sampled at 1 and 3 weeks after treatment. The application rate of mefluidide applied to the

plots were 0.56 ai/ha of Embark 2S which resulted in 0% and 17 % reduction of earthworms in the spring and fall respectively after the 3 week treatments.

Review of Incident Data

A review of the EIIS database for ecological incidents involving mefluidide, mefluidide-DEA and mefluidide-K was completed on December 28, 2006. There were no incidences reported for mefluidide, mefluidide-DEA and mefluidide-K in the EIIS database.

Incident reports submitted to EPA since approximately 1994 have been tracked by assignment of I #s in an Incident Data System (IDS), microfiched, and then entered to a second database (in EFED), the Ecological Incident Information System (EIIS). An effort has also been made to enter information to EIIS on incident reports received prior to establishment of current databases. Incident reports are often not received in a consistent format (e.g., states and various labs usually have their own formats), may involve multiple incidents involving multiple chemicals in one report, and may report on only part of a given incident investigation (e.g., residues).

It is believed that the EFED database contains reports of only a small portion of plant and animal wildlife incidents that actually occur as a result of pesticide use. Mortality incidents must be seen, reported, investigated, and had investigation reports submitted to EPA to have the potential to get entered into a database. Incidents often are not seen, especially if the affected organisms are inconspicuous or few people are systematically looking, for example. Incidents seen may not get reported to appropriate authorities capable of investigating the incident because the finder may not know of the importance of reporting incidents, may not know who to call, or may not feel they have the time or desire to call, for example. Incidents reported may not be investigated if resources are limited or may not get investigated thoroughly. Reports of investigated incidents often do not get submitted to EPA, since reporting by states is voluntary and some investigators may believe that they don't have the resources to submit incident reports to EPA.

Review of ECOTOX Data

A search of the ECOTOX from a Duluth review was completed on 7/ 5/06 for mefluidide. Six studies were reviewed with reference numbers 39542, 71019, 74741, 82489, 82719 and 82721. Studies with reference numbers 71019, 74741, 82489 were not incorporated in the assessment. The references to the above referenced studies and studies that were not accepted by OPP are posted in Appendix H.

Ecotox data indicates that mefluidide is non-toxic to earthworms (Ref #39542 Potter DA; Spicer PG; Redmond CT; Powell AJ (1994) Toxicity of Pesticides to Earthworms in Kentucky Bluegrass Turf). Two evaluations were conducted in the spring and the fall of 1992. Earthworm populations were sampled at 1 and 3 weeks after treatment. The application rate of mefluidide applied to the plots were 0.56 ai/ha of Embark 2S which resulted in 0% and 17

% reduction of earthworms in the spring and fall respectively after the 3 week treatments. (ref#39542)

Ecotox data indicates that mefluidide is non-toxic to grazing cattle based on weight gain. Twelve Hereford heifers were used in a grazing experiment to determine intake and digestibility of tall fescue forage treated with mefluidide. Additionally, steer and heifer performance were evaluated after grazing tall fescue pastures or consuming hay harvested from pastures treated with mefluidide. Two forage plots were sprayed with 0.28kg ai/ha when tall fescue herbage was 10 cm in height. Steers grazing mefluidide-treated herbage had greater total weight gains than untreated fields during a 168 d study (86 vs 69 kg). Heifers fed hay harvested from mefluidide treated pastures also exhibited similar improvements in gain (49 vs 38 kg) because of increased forage consumption (8.3 vs. 7.3 kg/d) greater forage OM digestibility (65 vs. 61%). Greater weight gains were attributed to a increased nitrogen content, lowered NDF neutral detergent fiber content (NDF) and increased OM digestibility from herbage available(ref#82719) A similar study (ref#82721) for effects of mefluidide on grazing cow-calf performance on smooth brome pastures also resulted in improved calf performance on treated mefluidide fields with 0.28kg ai/ha of mefluidide. Mefluidide sprayed on fields produced 26 kg/ha more cow gain than the controlled smooth brome pastures.

4 RISK CHARACTERIZATION

Risk characterization is the integration of exposure and effects characterization to determine the ecological risk from the use of mefluidide and the likelihood of effects on aquatic life, wildlife, and plants based on varying pesticide-use scenarios. The risk characterization provides a estimation and a description of the risk; articulates risk assessment assumptions, limitations, and uncertainties; synthesizes an overall conclusion; and provides the risk managers with information to support regulatory decision making.

4.1. Risk Estimation - Integration of Exposure and Effects Data

Results of the exposure and toxicity effects data are used to evaluate the likelihood of adverse ecological effects on non-target species. For the assessment of mefluidide risks, the risk quotient (RQ) method is used to compare exposure and toxicity values. Estimated environmental concentrations (EECs) are divided by acute and chronic toxicity values. The resulting RQs are compared to the Agency's levels of concern (LOCs). These LOCs are the Agency's interpretive policy and are used to analyze potential risk to non-target organisms and the need to consider regulatory action. These criteria are used to indicate when a pesticide's use as directed on the label has the potential to cause adverse effects on non-target organisms.

A summary of toxicity values used to calculate RQs is provided in **Table 4.1 and 4.2** and **4.3** more detailed discussion of mefluidide toxicity can be found in section **3.3 and Appendix D**.

Table 4.1: Summary of endpoints (LC₅₀ or EC₅₀, mg ae/L) for Aquatic Toxicity used in RQ calculations for Mefluidide¹

TAXONOMIC GROUP	Acute endpoint	Chronic endpoint	MRID/ Estimated value
Acute freshwater fish	>68.47* Rainbow Trout		MRID 418937-02
Chronic freshwater fish		>0.267	Estimated value acute to chronic ratio
Acute freshwater inverts	>77.25* Daphnid		MRID 418937-03
Chronic freshwater inverts		>5.54	Estimated value acute to chronic ratio
Acute estuarine/marine fish	>84.75* Sheepshead minnow		MRID 425623-03
Chronic estuarine/marine fish		>0.267	Estimated value acute to chronic ratio
Acute estuarine/marine inverts	67* Eastern oyster		MRID 425624-01
Chronic estuarine/marine inverts		>5.54	Estimated value acute to chronic ratio

¹ For fish and invertebrates data evaluating mefluidide-K, mefluidide-DEA and mefluidide have been bridged for the runoff risk assessment.

*most sensitive species

Table 4.2: Summary of endpoints (LC₅₀ or EC₅₀, mg ae/L) for Plant Toxicity used in RQ calculations for Mefluidide¹

TAXONOMIC GROUP	Acute endpoint	NOAEC or EC ₀₅	
Acute vascular plant	0.515* Lemna		MRID 435266-01 Tier I(8% growth stimulation) Used this value as EC₅₀ ,

Vascular plant (EC ₀₅)		>0.29	Estimated value acute to chronic ratio
Acute non-vascular plant	0.629* Navicula		MRID 435266-05 Tier I(11.5% growth reduction) Used this value as EC ₅₀ ,
Non-vascular plant (EC ₀₅)		>0.786	Estimated value acute to chronic ratio
Terrestrial Plant: Vegetative Vigor	Monocot:* Sorghum EC ₂₅ 0.105 lb ae/A Dicot:* Mustard EC ₂₅ 0.0054lb ae/A	Monocot: * Sorghum NOAEC 0.045 lb ae/A Dicot:* Mustard NOAEC 0.0029 lb ae/A	MRID 435496-01
Terrestrial Plant: Seedling Emergence	Monocot: Sorghum EC ₂₅ 0.105 lb ae/A Dicot:* Mustard EC ₂₅ 0.0054lb ae/A	Monocot: Sorghum NOAEC 0.045 lb ae/A Dicot:* Mustard NOAEC 0.0029 lb ae/A	Estimated value from vegetative vigor study MRID 435496-01

¹For terrestrial plants data evaluating mefluidide-K, mefluidide-DEA and mefluidide have been bridged for the terrestrial risk assessment. *most sensitive species tested

Table 4.3: Summary of endpoints (LD₅₀ or LC₅₀ mg ae/kg) for Terrestrial Toxicity data used in RQ calculations for Mefluidide¹			
TAXONOMIC GROUP	Acute endpoint	Chronic endpoint	
Acute Avian	>1500* Bobwhite quail		MRID 416019-01 Used this non-definitive endpoint as LD50
Chronic Avian		38	Estimated value acute to

			chronic ratio based on mammal data
Acute Dietary Avian	>3750*		
Acute mammal	829.8* mouse		MRID 00047116
Chronic mammal		102* rat	MRID 00082748

¹For terrestrial plants data evaluating mefluidide-K, mefluidide-DEA and mefluidide have been bridged for the terrestrial risk assessment. *most sensitive species tested

4.1.1 Non-target Aquatic Animals and Plants

Routes of exposure evaluated in this risk assessment focused on runoff and/or spray drift for mefluidide-K, mefluidide-DEA and mefluidide. Tier II PRZM/EXAM modeling was used to estimate mefluidide acid concentrations in surface water. The runoff assessment considered the maximum label application rates. Because the mefluidide can be used on general turf areas including residential and agricultural areas, the runoff modeling was conducted using the PA turf and FL turf scenarios. More importantly, mefluidide labels allow broadcast applications as well as spot treatments. Application rates, therefore, were expressed on lbs ae/A regardless of the recommend application treatment. This approach is expected to be conservative because it assumes 100% of the watershed is treated with mefluidide. Concentrations of mefluidide are expressed in acid equivalence to address the bridging of mefluidide-K, mefluidide-DEA, mefluidide to mefluidide acid. Foliar dissipation half-lives were incorporated in the modeling to address mefluidide dissipation from the foliage of warm-season and cool season grasses. PRZM /EXAMS input parameters for mefluidide are shown in **Table 3.1**. Estimated environmental concentrations are shown in **Table 3.2**.

The 1-in-10 year peak EECs were compared to acute toxicity endpoints to derive acute RQs for mefluidide. For aquatic vascular and non-vascular plants, 1-in-10 year peak EECs were compared to acute EC₅₀ values to derive acute non-listed species RQs. NOAEC values for vascular and non-vascular plants were estimated to derive listed species RQs for these taxonomic groups. RQs for listed and non-listed aquatic vascular and non-vascular plants are summarized in **Table 4.2**.

4.1.1.1 Freshwater Fish and Invertebrates

Risk quotients for mefluidide-K, mefluidide-DEA and mefluidide were <0.0001 for acute freshwater fish and invertebrates based on the non-definitive EC₅₀ of >68.47 mg ae/L for freshwater fish and >77.25 mg ae/L for freshwater invertebrates. Acute risk quotients for freshwater fish and invertebrates are summarized in **TABLE 4.4**.

Risk quotients for mefluidide-K, mefluidide-DEA and mefluidide were <0.001 for chronic freshwater fish and invertebrates based on the non-definitive estimated NOAEC values of >0.267 mg ae/L for freshwater fish and >5.54 mg ae/L for freshwater invertebrates. Chronic RQs for mefluidide freshwater fish and invertebrates were derived from estimated values due to lack of toxicity data and are summarized in **Appendix D**.

No LOC exceedances occurred for acute and chronic risks to freshwater fish and invertebrates for all application scenarios.

Table 4.4. Aquatic acute freshwater fish and Invertebrate RQs for Mefluidide-K, Mefluidide-DEA and Mefluidide applications by Ground (G) Spray and Granular(GR) for the aquatic runoff assessment^{1,2,3}

Application Scenario				
		Acute EECs mg ae/L	Fresh water Invertebrates Acute RQs (EC50 >77.25 mg ae/L) ²	Freshwater Fish Acute RQs (EC50 >68.47 mg ae/L) ²
Ornamental Turf (FLTurf PRISM scenario) 3 applications per season (interval of 6 weeks apart)	mefluidide (GR)	0.004835	0.0000625	0.0000706
	mefluidide-K and mefluidide-DEA (G)	0.010573	0.0001368	0.0001544
Ornamental Turf (PA Turf PRISM scenario) 3 applications per season (interval of 6 weeks apart)	mefluidide (GR)	0.003031	0.0000392	0.0000442
	mefluidide-K and mefluidide-DEA (G)	0.007054	0.0000913	0.000103

¹ The below notation will be used to denote values that exceed the Levels of Concern (LOC)
 * exceeds LOC for acute risk to listed fish or invertebrate species (RQ ≥ 0.05)
 ** exceeds LOCs for acute risk to listed fish or invertebrate species and restricted use (RQ ≥ 0.1)

4.1.1.2 *Estuarine/Marine Fish and Invertebrates*

Risk quotients for mefluidide-K, mefluidide-DEA and mefluidide were <0.0001 for acute estuarine marine fish aquatic-phase amphibians based on the non-definitive EC₅₀ of >84.75 mg ae/L. No LOC exceedances occurred for acute risks to estuarine/ marine invertebrates with an EC₅₀ of 67 mg ae/L and RQs <0.0001 for all application scenarios. Acute risk quotients for estuarine marine fish and invertebrates are summarized in **TABLE 4.5**.

There are insufficient data to establish a definitive toxicity endpoint for estuarine/marine fish and invertebrate chronic effects for mefluidide and mefluidide-DEA.

For the purposes of this risk assessment, it was assumed that estuarine marine fish were at least as sensitive as freshwater fish in terms of chronic toxicity. Therefore, the estimated endpoint for freshwater fish (NOAEC >0.267 mg ae/L) was used to estimate a chronic effects endpoint for estuarine/marine fish. Therefore, based on the estimated NOAEC of >0.267 mg ae/L no exceedances occurred for chronic estuarine marine fish and invertebrates. These estimated RQ values are summarized in **Appendix D**.

Table 4.5. Aquatic Estuarine Marine fish and Invertebrate RQs for Mefluidide-K, Mefluidide-DEA and Mefluidide applications by Ground (G) Spray and Granular(GR) for the aquatic runoff assessment^{1,2,3}

Application Scenario			E/M Invertebrates	E/M Fish
		Acute EECs mg ae/L	Acute RQs (EC50 67 mg ae/L) ²	Acute RQs (EC50 >84.75 mg ae/L) ²
Ornamental Turf (FL Turf PRISM scenario) 3 applications per season (interval of 6 weeks apart)	mefluidide (GR)	0.004835	0.0000721	0.000057
	mefluidide-K and mefluidide-DEA (G)	0.010573	0.0001578	0.0001247
Ornamental Turf (PA Turf PRISM scenario) 3 applications per season (interval of 6 weeks apart)	mefluidide (GR)	0.003031	0.0000452	0.0000357
	mefluidide-K and mefluidide-DEA (G)	0.007054	0.0001052	0.0000832

¹ The below notation will be used to denote values that exceed the Levels of Concern (LOC)
 * exceeds LOC for acute risk to listed fish or invertebrate species (RQ ≥ 0.05)
 ** exceeds LOCs for acute risk to listed fish or invertebrate species and restricted use (RQ ≥ 0.1)

4.1.1.3 Aquatic Plants

Although no EC₅₀ values were available from aquatic plant studies, RQs were calculated for aquatic plants based on a EC₅₀ values >0.515 mg ae/L for vascular plants and >0.629 mg ae/L for non-vascular plants. RQ values were <0.1 for all modeled scenarios.

Risk quotients for mefluidide-K, mefluidide-DEA and mefluidide were <0.1 for vascular and non-vascular plants based on the non-definitive estimated EC₀₅ values of >0.029 mg ae/L for vascular plants and >0.786 mg ae/L for non-vascular plants.

No LOC exceedances occurred for acute listed and non-listed risks to vascular and non-vascular plants for all application scenarios.

Table 4.6 lists the RQs for aquatic vascular and non-vascular plants potentially exposed to mefluidide-K, mefluidide-DEA and mefluidide. No LOC exceedances (RQs <0.1) occurred for vascular and non-vascular plants.

Table 4.6. Aquatic Plant RQs for Mefluidide-K, Mefluidide-DEA and Mefluidide applications by Ground (G) Spray and Granular(GR) for the aquatic runoff assessment¹

Application Scenario		EECs to calculate Acute RQs mg ae/L	Vascular Plants RQs (EC50 >0.515 mg ae/L)	Vascular Plants (listed) RQs (EC ₀₅ >0.29 mg ae/L)	Non-vascular Plants RQs EC ₅₀ (>0.629 mg ae/L) ²	Non-vascular Plants RQs (EC ₀₅ >0.786 mg ae/L) ²
Ornamental Turf (FLTurf PRZM scenario) 3 applications per season (interval of 6 weeks apart)	mefluidide (GR)	0.004835	0.0093883	0.0166724	0.0076868	0.0061513
	mefluidide-K and mefluidide-DEA (G)	0.010573	0.02053	0.0364586	0.0168092	0.0134516
Ornamental Turf (PA Turf PRZM scenario) 3 applications per season (interval of 6 weeks apart)	mefluidide (GR)	0.003031	0.0058854	0.0104517	0.0048187	0.0038562
	mefluidide-K and mefluidide-DEA (G)	0.007054	0.013697	0.0243241	0.0112146	0.0089745

¹ The below notation will be used to denote values that exceed the Levels of Concern (LOC)
 * exceeds LOC for acute risk to aquatic plant species (RQ ≥ 1.0, calculated as acute EEC /EC50)
 **exceeds LOC for acute risk to listed aquatic plant species (RQ ≥ 1.0, calculated as acute EEC /NOAEC)
 ***exceeds LOC for acute risk to listed aquatic plant species (RQ ≥ 1.0, calculated as acute EEC /NOAEC),
 However, currently there are no listed non-vascular plants.
² EC₅₀ or NOAEC estimated calculations are summarized in Appendix E

4.1.2 Non-target Terrestrial Animals

EECs were calculated for all ornamental turf labeled uses with application rates ranging from 0.5 to 1.0 lb ae/A. Risk quotients are based on the most sensitive studies that yielded the lowest toxicity values. For this assessment, the lowest LD₅₀ and NOAEC values

were used for birds and the lowest LD₅₀ and NOAEL were used for mammals (based on lab rat and mouse studies).

4.1.2.1 Birds

Avian Risk

The EEC's for terrestrial exposure were derived from the Kenaga nomograph, as modified by Fletcher et al. (1994), based on a large set of field residue data. The EECs were calculated by the T-REX Version 1.3.1 model and corresponding avian acute and chronic risk quotients are based on the most sensitive subacute dietary LC₅₀, single oral dose LD₅₀, and NOAEC for birds.

Calculations for single-oral dose risk quotients are based on a Northern bobwhite quail oral acute LD₅₀ of 1500 mg ae/kg-bw. RQs for oral dose-based scenarios are calculated by dividing the consumption-weighted equivalent dose by the body weight-adjusted LD₅₀. The avian LD₅₀ is adjusted for body weight according to the following equation:

$$\text{Adjusted Avian LD}_{50} (\text{mg/kg bw}) = \text{LD}_{50} (\text{mg/kg bw}) * \left(\frac{\text{AW (g)}}{\text{TW (g)}} \right)^{1.15-1}$$

(USEPA, 2006)

The assessed weight (AW) is the body weight of the wildlife species of concern. An adjusted LD₅₀ is calculated for three weight classes of birds (20, 100, and 1000 g). The test weight (TW) is the body weight of the species used in the toxicity study. In this case, the weight of the bobwhite quail is estimated to be 178 g. The adjusted LD₅₀ is 1080, 1375, and 1943 mg ae/kg-bwt for the weight classes 20, 100, and 1000 g birds, respectively.

Foliar Summary for Mefluidide-K and Mefluidide-DEA

1. Acute RQs were calculated for birds based on the non-definitive LD₅₀ value of >1500 mg ae/kg-bw. No mortality occurred at the single dose treatment level (1500 mg ae/kg-bw) for the Tier I Acute Toxicity to Bobwhite quail study MRID 416019-01. RQ values ranged 0 to 0.25 for the 1.0 lb ae/A ornamental turf modeled scenario. RQs are summarized in **Appendix D**, summarizes the avian dietary-based chronic RQs for foliar uses of mefluidide-K and mefluidide-DEA. Chronic RQs were estimated for birds based on the non-definitive LD₅₀ value of 38 mg ae/kg. Chronic dietary-based exceedances occurred for birds for the 1.0 lb ae/A modeled scenario with risk quotients ranging from 2.9 to 6.32. Chronic estimated NOAEC values and calculations are summarized in **Appendix E**.

Table 4.7 summarizes the avian dose-based acute RQs for foliar uses of mefluidide-K and mefluidide-DEA.

For mefluidide-DEA and mefluidide-K, acute restricted use and/or listed species risk LOCs are exceeded for 20 g birds that consume short grass, tall grass, and broadleaf plants and small insects for the 1.0 ae/A application rate modeled scenario with acute RQs of <0.25.

For mefluidide-DEA and mefluidide-K, acute risk to listed species LOCs are exceeded for 20 g birds that consume short grass, tall grass, and broadleaf plants and small insects and 100 g birds that consume short grass for the 1.0 lb ae/A application rate modeled scenario with acute RQs ranging from <0.11 to <0.25.

Table 4.8 summarizes the avian dietary-based chronic RQs for foliar uses of mefluidide-K and mefluidide-DEA. Chronic dietary-based exceedances occurred for birds for the 1.0 lb ae/A modeled scenario with risk quotients ranging from 2.9 to 6.32. Risk quotients based on dietary exposure levels are provided for comparison purposes.

Table 4.7. Avian dose-based acute RQ values for proposed uses of Mefluidide-K, Mefluidide-DEA and Mefluidide based on a bobwhite quail LD₅₀ > 1500 mg ae/kg -bw and upper-bound Kenaga values¹.

Use	Application Rate lbs. ae/A (# app / interval, days)	Body Weight, g	Mammalian Acute Risk Quotients (upper-bound Kenaga residues)			
			Short Grass	Tall Grass	Broadleaf Plants/Small Insects	Fruits/pods/seeds large insects
Ornamental Turf (mefluidide salts only) Ground spray	1.0 3 per season 42 day interval	20	<0.25**	<0.12*	<0.14*	<0.02
		100	<0.11*	<0.05	<0.06	<0.01
		1000	<0.04	<0.02	<0.02	<0.00

¹ For avian toxicity assessments, data evaluating Mefluidide-K, Mefluidide-DEA and Mefluidide toxicity have been bridged because toxicity is expected to come from the benzene ring of mefluidide. Therefore, the most sensitive Mefluidide endpoint was selected to represent avian for all application scenarios.

* exceeds LOC for acute risk to listed species (RQ ≥ 0.1)

** exceeds LOCs for acute risk to listed species and restricted use (RQ ≥ 0.2)

Table 4.8. Avian dietary-based chronic RQ values for Mefluidide-K and Mefluidide-DEA based on an estimated NOAEC of 38.0 mg/ ae kg and upper-bound Kenaga residues¹.

Use	Application Rate lbs. ai/A (# app / interval, days)	Food Items	Upper Bound EEC (mg/kg) ²	Chronic RQ (EEC/ NOAEC)
Ornamental Turf (mefluidide salts only) Ground spray	1.0 3 per season 42 day interval	Short grass	240.17	6.32*
		Tall grass	110.08	2.90*
		Broadleaf plants/small insects	135.09	3.56*

Table 4.8. Avian dietary-based chronic RQ values for Mefluidide-K and Mefluidide-DEA based on an estimated NOAEC of 38.0 mg/ ae kg and upper-bound Kenaga residues¹.

Use	Application Rate lbs. ai/A (# app / interval, days)	Food Items	Upper Bound EEC (mg/kg) ²	Chronic RQ (EEC/ NOAEC)
		Fruits, pods, seeds, and large insects	15.01	0.40

¹ For avian toxicity assessments, data evaluating Mefluidide-K, Mefluidide-DEA and Mefluidide toxicity have been bridged because toxicity is expected to come from the benzene ring of mefluidide. Therefore, the most sensitive Mefluidide endpoint was selected to represent avian for all application scenarios.

* exceeds LOC for chronic risk to listed species (RQ ≥ 1.0)

LD₅₀/sq ft Summary

Mefluidide is the only proposed granular application. Based on one application of mefluidide at 0.5lbs ae/acre, LOC exceedances occurred for small-sized 20 g birds for acute restricted use and/or listed species (RQ=0.24). LD₅₀/sq-ft can be interpreted as the number of lethal doses (LD₅₀) that are available within one square foot immediately after application. EFED does not currently assess chronic risks to birds from granular applications. The acute RQs for LD₅₀/sq ft based on a single application of mefluidide are summarized in **Appendix D**

4.1.2.2 Mammals

Mammalian Risk

EECs and corresponding mammalian acute and chronic RQs for Mefluidide application were determined using the T-REX Version 1.3.1 model. Calculations for mammalian organisms oral dose-based risk quotients were based on an acute laboratory mouse LD₅₀ value of 829.8 mg ae/kg bw and a chronic reproductive effect (NOAEC) observed at 102 mg ae/kg bw/day . Oral dose-based RQ values were calculated by dividing the consumption-weighted equivalent dose by the body weight-adjusted LD₅₀. The mammalian LD₅₀ is adjusted for body weight according the following equation:

$$\text{Adjusted Mammalian LD}_{50} \text{ (mg/kg bw)} = \text{LD}_{50} * \left(\frac{\text{TW (g)}}{\text{AW (g)}} \right)^{0.25}$$

(USEPA, 2006)

The assessed weight (AW) is the body weight of the wildlife species. An adjusted LD₅₀ is calculated for each weight class of mammal (15, 35, and 1000 g). The test weight (TW) is the weight of the species used in the toxicity study. In this case, the average weight of the laboratory mouse was 20 g; however, T-REX assumes the average weight is 350 g. Therefore, the TW was adjusted to a mouse weighing 20 g in the model instead of 350 g rat weight. However, the assumed 350 g TW for the rat was used for the chronic oral dose-based RQ calculations, the NOAEC (102 mg ae/kg bw/day) was converted to a NOAEL (2040 mg ae/kg diet) based on a standard FDA lab rat conversion.

Foliar Summary for Mefluidide-K and Mefluidide-DEA

Table 4.9 summarizes the mammalian dose-based acute RQs for foliar uses of mefluidide-K and mefluidide-DEA.

For mefluidide-DEA and mefluidide-K, acute restricted use and/or listed species acute risk LOCs are exceeded for 15 g and 35 g mammals that consume short grass for the 1.0 lb ae/A application rate modeled scenario with acute RQs ranging from 0.22 to 0.26.

Acute risk to listed species are exceeded for 15 and 35 g sized mammals that consume short grass, tall grass, broadleaf plants and small insects and 1000 g mammals that consume short grass for the 1.0 lb ae/A application rate modeled scenario with acute RQs ranging from 0.10 to 0.26.

Table 4.10 summarizes the mammalian dose-based chronic RQs for foliar uses of mefluidide-K and mefluidide-DEA. The chronic LOC is exceeded for 15 g mammals that consume short grass with an RQ of 1.02 for the 1.0 lb ae/A modeled scenario.

Table 4.11 summarizes the mammalian dietary-based chronic RQs for foliar uses of mefluidide-K and mefluidide-DEA. No chronic dietary-based exceedances occurred for mammals for the 1.0 lb ae/A modeled scenario. Risk quotients based on dietary exposure levels are provided for comparison purposes.

Table 4.9. Mammalian dose-based acute RQ values for proposed uses of Mefluidide-K and Mefluidide-DEA based on a mouse LD₅₀ = 829.8 mg ae/kg -bw and upper-bound Kenaga values¹.

Use	Application Rate lbs. ae/A (# app / interval, days)	Body Weight, g	Mammalian Acute Risk Quotients (upper-bound Kenaga residues)				
			Short Grass	Tall Grass	Broadleaf Plants/Small Insects	Fruits/pods/seeds large insects	Seeds (granivore)
Ornamental Turf (mefluidide)	1.0 3 per season	15	0.26**	0.12*	0.14*	0.02	0.00
	42	35	0.22**	0.10*	0.12*	0.01	0.00

Table 4.9. Mammalian dose-based acute RQ values for proposed uses of Mefluidide-K and Mefluidide-DEA based on a mouse LD₅₀ = 829.8 mg ae/kg -bw and upper-bound Kenaga values¹.

Use	Application Rate lbs. ae/A (# app / interval, days)	Body Weight, g	Mammalian Acute Risk Quotients (upper-bound Kenaga residues)				
			Short Grass	Tall Grass	Broadleaf Plants/Small Insects	Fruits/pods/seeds large insects	Seeds (granivore)
salts only) Ground spray	day interval	1000	0.12*	0.05	0.07	0.01	0.00

¹ For mammal toxicity assessments, data evaluating Mefluidide-K, Mefluidide-DEA and Mefluidide toxicity have been bridged because toxicity is expected to come from the benzene ring of mefluidide. Therefore, the most sensitive Mefluidide endpoint was selected to represent mammals for all application scenarios.

* exceeds LOC for acute risk to listed species (RQ ≥ 0.1)

** exceeds LOCs for acute risk to listed species and restricted use (RQ ≥ 0.2)

Table 4.10. Mammalian dose-based chronic RQ values for proposed uses of Mefluidide-K and Mefluidide-DEA based on a rat reproductive NOAEC of 102 mg ae/kg-bw/day and upper-bound Kenaga residues¹.

Use	Application Rate lbs. ae/A (# app / interval, days)	Body Weight, g	Mammalian Acute Risk Quotients (upper-bound Kenaga residues)				
			Short Grass	Tall Grass	Broadleaf Plants/Small Insects	Fruits/pods/seeds large insects	Seeds (granivore)
Ornamental Turf (mefluidide salts only) Ground spray	1.0 3 per season 42 day interval	15	1.02*	0.47	0.57	0.06	0.01
		35	0.87	0.40	0.49	0.05	0.01
		1000	0.47	0.21	0.26	0.03	0.01

¹ For mammal toxicity assessments, data evaluating Mefluidide-K, Mefluidide-DEA and Mefluidide toxicity have been bridged because toxicity is expected to come from the benzene ring of mefluidide. Therefore, the most sensitive Mefluidide endpoint was selected to represent mammals for all application scenarios.

*exceeds the chronic risk LOC (RQ ≥ 1.0) for non-listed and listed species.

Table 4.11. Mammalian dietary-based chronic RQ values for Mefluidide-K and Mefluidide-DEA based on a rat reproductive NOAEC of 2040 mg/kg-diet and upper-bound Kenaga residues¹.

Use	Application Rate lbs. ai/A (# app / interval, days)	Food Items	Upper Bound EEC (mg/kg) ²	Chronic RQ (EEC/NOAEC)
Ornamental Turf (mefluidide salts only) Ground spray	1.0 3 per season 42 day interval	Short grass	240.17	0.12
		Tall grass	110.08	0.05
		Broadleaf plants/small insects	135.09	0.07

Table 4.11. Mammalian dietary-based chronic RQ values for Mefluidide-K and Mefluidide-DEA based on a rat reproductive NOAEC of 2040 mg/kg-diet and upper-bound Kenaga residues¹.

Use	Application Rate lbs. ai/A (# app / interval, days)	Food Items	Upper Bound EEC (mg/kg) ²	Chronic RQ (EEC/ NOAEC)
		Fruits, pods, seeds, and large insects	15.01	0.01

¹ For mammal toxicity assessments, data evaluating Mefluidide-K, Mefluidide-DEA and Mefluidide toxicity have been bridged because toxicity is expected to come from the benzene ring of mefluidide. Therefore, the most sensitive Mefluidide endpoint was selected to represent mammals for all application scenarios.

² estimated chronic diet concentration equivalent based on reported chronic dose

*exceeds the chronic risk LOC (RQ ≥ 1.0) for non-listed and listed species.

LD₅₀/sq ft Summary

Mefluidide is the only proposed granular application. Based on one application of mefluidide at 0.5lbs ae/acre, acute restricted use and/or listed species acute risk LOC exceedances occurred for the LD₅₀/sq-ft for small and medium-sized mammals. The RQs are 0.39 and 0.21 for small and medium mammals, respectively. LD₅₀/sq-ft can be interpreted as the number of lethal doses (LD₅₀s) that are available within one square foot immediately after application. EFED does not currently assess chronic risks to mammals from granular applications. The acute RQs for LD₅₀/sq ft based on a single application of mefluidide are summarized in **Appendix D**. Calculations for LD₅₀/sq ft are based on the acute laboratory mouse LD₅₀ value of 829.8 mg ae/kg bw, adjusted to an average weight of 20 g. The calculations for food intake for a 20 gram size class mouse are summarized in **Appendix D**. The LD₅₀ approach is only applied to a single application.

4.1.2.3 Plants

Non-target Terrestrial Plants in Dryland and Semi-aquatic Areas

An analysis indicates exceedance of the Acute Risk LOC for listed and non-endangered monocots and dicots in dryland and semi-aquatic areas located adjacent to treated areas, both as a result of combined runoff and spray drift, and from spray drift alone for mefluidide-DEA and mefluidide-K.

For terrestrial plants, only one vegetative vigor toxicity study was submitted for plants based on fresh weight exposed to mefluidide-DEA. These data were bridged with mefluidide and mefluidide-K.

Risk to terrestrial plants from spray drift alone is evaluated by comparing the estimated exposure from drift to the most sensitive EC₂₅ calculated from vegetative vigor laboratory tests. The most sensitive vegetative vigor EC₂₅ values were 0.105 and 0.0054 lb ae/acre for monocots and dicots, respectively. The NOAEC values were 0.045 and 0.0029 lb ae/acre for monocots and dicots, respectively. Wet weight was the most sensitive endpoint for monocots and dicots in the vegetative vigor studies used to evaluate risk to terrestrial plants.

Seedling emergence toxicity data was not available for full review and data was not available from other anilide analogs to derive EC₂₅ values. A preliminary review on a recently submitted seedling emergence study (MRID 471907-01) was conducted. These results are uncertain until a full review of the study is performed. The results of the preliminary review are summarized in Appendix E. Therefore, to estimate possible effects measurement endpoints for seedling emergence, EFED assumed that EC₂₅ toxicity values for vegetative vigor are equal to seedling emergence measurement endpoints for mefluidide, mefluidide-DEA and mefluidide-K. Therefore, the most sensitive seedling emergence EC₂₅ estimated values are 0.105 and 0.0054 lb ae/A for monocots and dicots, respectively. The NOEC estimated values for seedling emergence are 0.045 and 0.0029 lb ae/A for monocots and dicots, respectively. These values are used to calculate risk quotients for exposure from combined runoff and spray drift to adjacent fields.

Because RQs based on the EC₂₅ values exceed the acute LOC, and exposure can be expected which would cause greater than a 25% effect, risk to listed plants is also a concern. Because RQs based on the NOAEC values exceed the acute LOC, and exposure can be expected which would cause potential risks to listed plants. Risk quotients with which to evaluate listed plant risks from a result of combined runoff and spray drift, and from spray drift alone for mefluidide, mefluidide-DEA and mefluidide-K were calculated with the above NOAEC values from the vegetative vigor studies.

Spray applications with 1.0lb ae/A demonstrated the highest RQ exceedances followed by granular applications with 0.5 lb ae/A. Dicots demonstrated more sensitivity than monocots in most application scenarios with exposure to mefluidide, mefluidide-DEA and mefluidide-K.

(Table 4.12) summarizes vegetative vigor and seedling emergence terrestrial plant RQs for foliar and granular uses of mefluidide-K, mefluidide-DEA and mefluidide from a result of combined runoff and spray drift, and from spray drift alone. Risk quotients were exceeded for ground spray (1.0 lb ae/A) and granular applications (0.5 lb ae/A) for monocots and dicots. Dicots demonstrated more sensitivity than monocots in all application scenarios with exposure to mefluidide-K and mefluidide-DEA with all TERR Plant modeled scenarios.

Table 4.12. Summarized Terrestrial Plant Risk Quotients for Mefluidide, Mefluidide-DEA and Mefluidide-K ^{a, b, c, d}						
Scenario	Acute Non-endangered RQs			Acute listed RQs		
	adjacent to treated sites	semi-aquatic areas	drift	adjacent to treated sites	semi-aquatic areas	Drift
Ground spray application (1.0 lbs ae/acre)						
Monocot	0.571	4.86**	0.10	1.33*	11.33*	0.22

Table 4.12. Summarized Terrestrial Plant Risk Quotients for Mefluidide, Mefluidide-DEA and Mefluidide-K^{a, b, c, d}

Scenario	Acute Non-endangered RQs			Acute listed RQs		
	adjacent to treated sites	semi-aquatic areas	drift	adjacent to treated sites	semi-aquatic areas	Drift
Dicot	11.11**	94.44**	1.85*	20.69*	175.86*	3.45*
Granular ground application (0.5 lbs ae/acre)^c						
Monocot	0.24	2.38**	n/a	0.56	5.56*	n/a
Dicot	4.63**	46.3**	n/a	8.62*	86.21*	n/a

¹ For terrestrial plant (seedling emergence and vegetative vigor) toxicity assessments, data evaluating Mefluidide-K, Mefluidide-DEA and Mefluidide toxicity have been bridged. Therefore, the most sensitive Mefluidide endpoint was selected to represent terrestrial plants for all application scenarios.

^a RQs for spray turf applications in this table were calculated for the maximum labeled application rates of (1.2 lbs ae/acre) and (1.0 lbs ae/acre) for mefluidide-DEA and mefluidide-K respectively..

^b Acute non-endangered toxicity thresholds (EC₂₅) were (0.105, 0.0054, 0.105, 0.0054)ae/acre for seedling emergence monocot, seedling emergence dicot, vegetative vigor monocot, and vegetative vigor dicot, respectively. EFED assumed that EC₂₅ toxicity values for terrestrial plants (vegetative vigor) are equal to (seedling emergence) measurement endpoints for Mefluidide, Mefluidide-DEA and Mefluidide-K due to lack of submitted data.

^c Acute listed toxicity thresholds (NOAEC) were (0.045, 0.0029, 0.045, 0.0029) lb ai/acre for seedling emergence monocot, seedling emergence dicot, vegetative vigor monocot, and vegetative vigor dicot, respectively. EFED assumed that NOAEC toxicity values for terrestrial plants (vegetative vigor) are equal to (seedling emergence) measurement endpoints for Mefluidide, Mefluidide-DEA and Mefluidide-K due to lack of submitted data.

* indicates an exceedance of the listed Species Level of Concern (LOC).

**indicates an exceedance of the Acute Risk LOC.

^dRQs for ground granular applications in this table were calculated for the maximum labeled application rate of 0.5lbs ae/acre. Drift RQs are not applicable for granular applications.

Spray drift is an important factor in characterizing the risk of Mefluidide to non-target plants. Spray drift exposure from ground application is assumed to be 1% of the application rate and the EECs and RQs were calculated using EFED’s TerrPlant.xls model (Version 1.2.1). The AgDrift Tier 1 model (ground application, very fine to fine droplet size, medium to course droplet size and low boom height for turf application) was used to determine what conditions are represented by a 1% spray drift exposure from ground application. AgDrift provided 90th percentile estimates based on the distribution of field measurements at 10 to 900 feet distances from the edge of field (Table 3.5). The 90th percentile drift estimates from AgDrift for 1.0 lb ae/A ground application was 0.51% of applied at a distance of 200 ft from the edge of the field for turf applications (very fine to fine droplet size). The 90th percentile drift estimates from AgDrift for 1.0 lb ae/A ground application was 0.26% of applied at a distance of 200 ft from the edge of the field for turf applications (medium to course droplet size). LOC exceedences did not occur with a 80 foot or above buffer size for both listed and non-listed dicots for the 1.0 lb ae/A application scenario with the medium to course droplet size. LOC exceedences did not occur with a 200 foot or above buffer size for both listed and non-listed dicots for the 1.0 lb ae/A application

scenario with the very fine to fine droplet size. RQs were calculated for buffers from 10 to 900 feet are summarized in Appendix D.

4.1.3 RQs Based on Mean Kenaga Residues

For this risk assessment, the RQ that were compared to the LOCs were calculated using maximum EECs derived from the Kenaga nomograph. Risk quotients were also calculated using mean EECs to determine the extent of the risk to mammals. RQs were based on both single oral dose and dietary studies for mammals.

Birds

Acute RQs were calculated for birds based on the non-definitive LD₅₀ value of >1500 mg ae/kg-bwt. No mortality occurred at the single dose treatment level (1500 mg ae/kg-bw) for the Tier I Acute Toxicity to Bobwhite quail study MRID 416019-01. When mean residues were assumed, RQ values ranged from 0 to <0.09 for the 1.0 lb ae/A ornamental turf modeled scenario. Based on the mean kenaga assessment, no acute LOC exceedances occurred for birds for the 1.0 lb ae/A application scenario.

Based on the chronic estimated value of NOAEC of 38 mg/ ae kg diet, when mean residues were assumed, RQ values ranged from 0.18 to 2.23 for the 1.0 lb ae/A ornamental turf modeled scenario. Based on the mean Kenaga assessment, chronic LOC exceedances for birds occurred for the 1.0 lb ae/A ornamental turf modeled scenario. RQs are summarized in APPENDIX D.

Mammals

When mean residues were assumed:

- **Mammalian Acute listed** LOCs were no longer exceeded for the 1 lb ae/A modeled scenario.
- **Mammalian Acute Restricted Use** LOCs were no longer exceeded for 15 g and 35 g mammals for the 1.0 lb ae/A modeled scenario.
- **Mammalian Chronic** LOCs (dose-based) were no longer exceeded for the 15 g and 35 g size mammals for the 1.0 lb ae/A application scenario.

4.2. Risk Description – Interpretation of Direct Effects

4.2.1 *Risks to Aquatic Organisms and Plants*

Based on the risk hypothesis terrestrial organisms (birds, mammals, reptiles, terrestrial-phase amphibians and plants) and aquatic organisms (invertebrates, fish, amphibians and plants) in surface waters (freshwater or saltwater) are subject to adverse effects when exposed to mefluidide residues as a result of labeled use of the pesticide. Routes of exposure evaluated in this risk assessment focused on runoff and spray drift from ground spray with mefluidide applied at application rates of 1.0 lb ae/A (mefluidide-K and mefluidide-DEA) and runoff from granular applications with 0.5 lb ae/A mefluidide.

No LOCs were exceeded for acute effects on freshwater and estuarine marine fish, aquatic invertebrates, non-vascular and vascular aquatic plants in water bodies adjacent to ornamental turf in areas treated with mefluidide DEA, mefluidide K and mefluidide.

No LOC exceedances occurred for chronic freshwater fish, chronic estuarine marine fish, chronic estuarine marine invertebrates, chronic freshwater invertebrates, vascular plants and non-vascular plants.

4.2.2 Risks to Terrestrial Organisms and Plants

Direct application of mefluidide-K, mefluidide-DEA, and mefluidide to the field leads to the conclusion that exposure is likely to terrestrial organisms that are foraging or nesting in or near the treated field. Birds and mammals in treated fields may be exposed to spray and granular applications of pesticides by ingesting material directly with the diet. When pesticides are applied as a granular formulation, the exposure estimate is assumed to account for all methods of exposure. They may also be exposed by other routes, such as incidental ingestion of contaminated soil, dermal contact with treated plant surfaces and soil during activities in the treated areas, direct impingement of sprayed material on the body at the time of application, preening activities, inhalation of pesticide vapor and contaminated particulate, and ingestion of drinking water contaminated by the pesticide.

1. Birds

Six acute dietary studies were considered in determining the risk for birds following applications of mefluidide, mefluidide-K, and mefluidide-DEA to ornamental turf. Also, no mortality occurred at the highest levels for all six dietary studies. No toxic effects were identified for the above studies. Acute RQs were calculated for birds based on the non-definitive LD₅₀ value of >1500 mg ae/kg-bw. RQ values ranged from 0 to <0.25 for the 1.0 ae/A ornamental turf modeled scenario. The available dietary toxicity studies on avian species failed to establish definitive acute LD₅₀ values (i.e., the lethality values exceed the highest dose tested). Therefore, use of this value adds uncertainty and may overestimate risk to avian species. Therefore, when the LD₅₀ value of >1500 mg ae/kg-bw was applied to the TREX model it resulted in LOC exceedances for acute listed for 20 and 100g birds and restricted use for 20 g birds for mefluidide-DEA and mefluidide-K (1.0 lb ae/A at 3 spray applications). The LD₅₀ value of 5000 mg ae/bw if applied to the above modeled scenario would result in no acute LOC exceedances for birds. Based on the mean kenaga assessment, no acute LOC exceedances occurred for birds (1.0 lbae/A at 3 spray applications).

Chronic RQs were estimated for birds based on the non-definitive NOAEC value of 38 mg ae/kg. Chronic dietary-based exceedances occurred for birds for the 1.0 lb ae/A modeled scenario with risk quotient exceedances ranging from 2.90 to 6.32. Chronic estimated NOAEC values and calculations are summarized in **Appendix E**.

Due to the high degree of uncertainty based on the estimated NOAEC value 38 mg ae/kg and the non-definitive LD₅₀ value of >1500 lb ae/A. Acute and chronic avian studies with definitive LD₅₀ and NOAEC values would quantify the uncertainties of avian risk.

LD₅₀/sq ft Summary

Mefluidide is the only proposed granular application. Based on one application of mefluidide at 0.5lbs ae/acre, acute restricted use and/or listed species acute risk LOC exceedances occurred for the LD₅₀s/sq-ft for small and medium-sized mammals. The RQs are 0.39 and 0.21 for small and medium mammals, respectively. LD₅₀s/sq-ft can be interpreted as the number of lethal doses (LD₅₀s) that are available within one square foot immediately after application. EFED does not currently assess chronic risks to birds from granular applications. The acute RQs for LD₅₀/sq ft based on a single application of mefluidide are summarized in **Appendix D**

2. *Mammals*

Two dietary studies were considered in determining the risk for mammals following the application of mefluidide, mefluidide-K and mefluidide-DEA.

Based on this analysis, it is likely that listed and non-listed mammals that feed on grasses and broadleaf plants and small insects are at risk from acute exposure due to spray applications of mefluidide-K and mefluidide-DEA residues for turf modeled scenarios. Also, it is likely that listed and non-listed mammals that feed on grasses and broadleaf plants or small insects are at risk from chronic exposure due to mefluidide-DEA and mefluidide-K residues based on the ornamental turf (1.0 lb ae/A) modeled scenario.

Based on one granular application of mefluidide (0.5 lb ae/A) acute listed and restricted use LOCs were exceeded for small and medium sized mammals.

3. *Non-Target Insects and Earthworms*

EFED currently does not quantify risks to terrestrial non-target insects. Risk quotients, therefore, are not calculated for these organisms. Because mefluidide, mefluidide-K and mefluidide-DEA are practically non-toxic to honey bees (96-hr acute contact LD₅₀ > 18.75 µg ae/bee, MRID 425628-01, LD₅₀ > 22.25 µg ae/bee, MRID 425628-02), the risk are not likely to have adverse effects on pollinators and other beneficial insects.

Ecotox data indicates that mefluidide is non-toxic to earthworms (Ref #39542 Potter DA; Spicer PG; Redmond CT; Powell AJ (1994) Toxicity of Pesticides to Earthworms in Kentucky Bluegrass Turf). Two evaluations were conducted in the spring and the fall of 1992. Earthworm populations were sampled at 1 and 3 weeks after treatment. The application rate

of mefluidide applied to the plots were 0.56 ai/ha of Embark 2S which resulted in 0% and 17 % reduction of earthworms in the spring and fall respectively after the 3 week treatments.

3. *Terrestrial Plants*

Ground spray and granular applications were modeled for both monocots and dicots from combined runoff and drift and drift only scenarios. Only one vegetative vigor toxicity study was submitted for terrestrial plants based on fresh weight basis exposed to mefluidide-DEA. These data were bridged with mefluidide and mefluidide-K. Seedling emergence toxicity data were not available for a full review to evaluate exposure of terrestrial plants to mefluidide from combined runoff and drift. In addition, data were not available from other anilide analogs to derive estimated EC₂₅ values. To estimate possible effects measurement endpoints for seedling emergence, EFED assumed that EC₂₅ toxicity values for vegetative vigor are equal to seedling emergence measurement endpoints for mefluidide, mefluidide-DEA and mefluidide-K.

Levels of concerns are exceeded for acute non-listed and listed monocots and dicots for ground applications for turf modeled scenarios. For the ornamental turf (1.0 lb ae/A) modeled scenario, RQs ranged from 0.10 to 175.86 (ground spray applications) for monocots and dicots from combined runoff and spray drift. For the ornamental turf (0.5 lb ae/A) modeled scenario, RQs ranged from 0.24 to 86.21 (granular applications) for monocots and dicots from runoff.

For the ornamental turf (1.0 lb ae/A) modeled scenario RQs ranged from 0.1 to 3.45 (ground spray applications) for monocots and dicots from spray drift only.

Levels of concerns are exceeded for acute non-listed and listed monocots and dicots from granular turf applications. For the ornamental turf (0.5 lb ae/A) modeled scenario, RQs were 46.3 for non-listed dicots, 86.2 for listed dicots, 2.38 for non-listed monocots and 5.56 for listed monocots.

An analysis of the results indicates exceedance of the Acute Risk LOC for listed and non-listed monocots and dicots in dryland and semi-aquatic areas located adjacent to treated areas, both as a result of combined runoff and spray drift, and from spray drift alone for mefluidide, mefluidide-DEA and mefluidide-K.

Spray applications with 1.0 lb ae/acre demonstrated the highest RQ exceedances followed by granular applications with 0.5 lb ae/A. Dicots demonstrated more sensitivity than monocots in most application scenarios with exposure to mefluidide, mefluidide-DEA and mefluidide-K. A preliminary review on a recently submitted seedling emergence study (MRID 471907-01) was conducted. These results are uncertain until a full review of the study is performed. The results of the preliminary review are summarized in Appendix E.

5. *Endocrine Disruption Assessment*

No studies were submitted for mefluidide-K, mefluidide-DEA and mefluidide that indicated endocrine disruption.

The degradates of mefluidide-K, mefluidide-DEA and mefluidide have not been identified as possessing the potential for endocrine disruption. In addition, the registrant has not submitted, nor has the Agency requested, studies on the potential for endocrine disruption for any of these degradates resulting from the use of mefluidide. Until such time as the Agency determines that any of these degradates have the potential to be an endocrine disruptor, this risk assessment has not included an evaluation of the relative risk of mefluidide-K, mefluidide-DEA and mefluidide, degradates for endocrine disruption and as such is a source of uncertainty in this assessment.

EPA is required under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (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."* Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there were scientific bases 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 the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use The Federal Insecticide, Fungicide, and Rodenticide Act (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 Agency's EDSP have been developed, mefluidide-K, mefluidide-DEA and mefluidide may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

6. *Potential for Avian and Mammalian Exposure in Space and Time*

In order for chemical residues in potential wildlife food items to result in direct adverse effects in a mammalian population, the organisms must be exposed to those food items at locations and at times when the residues are present. There are a number of important questions that must be considered:

1. Are the residues present at locations where wildlife might feed?
2. Are the residues present in food items at times when wildlife might use the areas?
3. Are the residues likely to be around long enough to result in exposure sufficient to trigger the expected adverse responses?

Mefluidide formulations are for use on: agricultural/farm structures/buildings and equipment, agricultural/nonagricultural uncultivated areas/soils, airports/landing fields, commercial industrial lawns, commercial institutional/industrial premises/equipment (indoor/outdoor), golf course turf, hospitals/medical institutions premises (human veterinary), household domestic dwellings outdoor premises, industrial areas (outdoor), nonagricultural outdoor buildings/structures, nonagricultural rights-of-way/fencerows/hedgerows, ornamental and or shade trees, ornamental ground cover, ornamental herbaceous plants, ornamental lawns and turf, ornamental nonflowering plants, ornamental woody shrubs and vines, paths/patios, paved area (private roads/sidewalks), recreational areas, and residential lawns.

One category of ornamental turf that mefluidide is used on is golf courses. Golf courses are recognized as having strong potential for providing quality habitat to many wildlife species (Stangel and Distler 2002). For example, Audubon International has more than 2,200 golf courses enrolled in its Audubon Cooperative Sanctuary System Program for Golf Courses providing education and assistance to golf course managers promoting environmental stewardship, conservation of biological diversity, and sustainable resource management. Audubon International has also been awarded a grant from Wildlife Links to create a database for information on wildlife habitat on golf courses.

Across 24 golf courses in the northern coast of South Carolina, a total of 5,362 birds, 82 species, and 30 neotropical migratory birds species were recorded at 599 point count stations over a two year study (Crum et al. 2003). Crum et al. (2003) report that the majority of birds associated with less developed landscapes (i.e. golf courses with less habitat disturbance) were woodland breeding species, while urban breeding species were found primarily on golf courses in which the majority of native vegetation had either been removed or replaced with ornamental vegetation, or contained a high level of human disturbance including residential and non-residential structures. The large number of species observed on golf courses in this small geographic area of the US indicates that a wide variety of birds will utilize golf courses. Because of the large number of species represented, it is likely that some population of birds will be on the golf course year-round and that bird breeding seasons will be spread throughout much of the year. In another study, Merola-Zwartjes and DeLong (2005) compared a number of golf courses in the Albuquerque, New Mexico, area with paired natural areas to see whether golf courses have the potential of acting as surrogate riparian habitats for Southwestern birds. They concluded that golf courses do have the potential to support riparian bird communities, but that their conservation potential can be enhanced through the addition of habitat complexity and structure utilizing native plants.

Sod farms are also registered for application with mefluidide-K, mefluidide-DEA, mefluidide. One example of a bird species that utilizes sod farms is the mountain plover who is attracted to manmade landscapes (e.g., sod farms and cultivated fields) that mimic their natural habitat associations, or sites with little vegetative cover (e.g., other agricultural lands and alkali flats) (<http://www.epa.gov/fedrgstr/EPA-IMPACT/2002/December/Day-05/i30801.htm>, accessed 01 October 2006). Land management practices on cultivated fields may include periods when fields are fallow, idle, or barren. If these fields remain fallow, idle,

or barren during April and May, mountain plovers may choose these fields for nesting. Sod farms are often listed as popular sites for birding enthusiasts.

(e.g., <http://home.comcast.net/~ehoward24/localbirdingsites.html>, <http://www.crbo.net/SpecialtyBirds.html>, accessed on 01 October 2006).

An example of wildlife use of roadsides is provided by the Minnesota Department of Natural Resources (<http://www.dnr.state.mn.us/roadsidesforwildlife/index.html>, accessed on 01 October 2006). Researchers have found that over 40 species of birds and mammals utilize roadsides for shelter, nesting, and food. Roadsides receive almost continuous nesting use from April through August. Roadsides also provide the right combination of abundant food and cover for birds that nest in cavities or in trees near roads. Examples of birds and mammals documented to use roadsides in Minnesota are: cottontail rabbit, white-tailed jackrabbit, short-tailed shrew, woodchuck, meadow vole, meadow jumping mouse, ring-necked pheasant, gray (Hungarian) partridge, mallard, blue-winged teal, pintail, and upland sandpiper. Disturbance of roadside cover by early mowing, farm tillage, grazing, "blanket" spraying, or vehicle and tractor encroachment during the peak nesting months (May, June, July) will significantly lower production for species that use roadsides for nesting.

Based on a 4 day foliar half-life with LOC exceedances for mammals and birds for the 1.0 and 0.5 lb ae/A application scenarios, residues are likely to result in exposure sufficient to trigger the expected adverse responses.

This analysis suggests that the patterns of mefluidide uses are such that they coincide in time and space to areas frequented by mammalian wildlife. These areas have been of demonstrated use by wildlife as sources of food and cover. Finally, the potentially problematic wildlife food items suggested by the risk assessment of mefluidide are likely to be present in and around the treated areas.

4.2.4 Federally Threatened and Endangered (Listed) Species Concerns

4.2.4.1 Action Area

For listed species assessment purposes, the action area is considered to be the area affected directly or indirectly by the Federal action and not merely the immediate area involved in the action. At the initial screening-level, the risk assessment considers broadly described taxonomic groups and so conservatively assumes that listed species within those broad groups are collocated with the pesticide treatment area. This means that terrestrial plants and wildlife are assumed to be located on or adjacent to the treated site and aquatic organisms are assumed to be located in a surface water body adjacent to the treated site. The assessment also assumes that the listed species are located within an assumed area which has the relatively highest potential exposure to the pesticide, and that exposures are likely to decrease with distance from the treatment area.

4.2.4.2 Taxonomic Groups Potentially at Risk

Based on available screening level information, the greatest concerns for direct Mefluidide ecological risks lie with effects to terrestrial and semi-aquatic plants as well as

acute and chronic effects to birds and mammals. The screening-level risk assessment for Mefluidide has identified potential concerns for direct effects on the following listed species categories: birds, mammals, and terrestrial and semi-aquatic plants (both monocots and dicots). Since birds are used as a surrogate for reptiles and terrestrial phase amphibians, they are also considered to be of concern.

The LOCATES database was not used for this assessment to identify specific listed and threatened species at risk from exposure to Mefluidide. Because of its widespread use on non-crop areas and because it is used throughout the United States, the search of the database could not be restricted by crop or geographic area. Therefore, all species within each of the categories listed above would be identified as being at risk through the LOCATES database.

Probit Slope Analysis

Screening-level acute listed LOCs are exceeded for terrestrial organisms potentially exposed to residues by Mefluidide applications. The Agency uses the dose response relationship from the toxicity study used for calculating the RQ to estimate the probability of acute effects associated with an exposure equivalent to the EEC. This information serves as a guide to establish the need for and extent of additional analysis that may be performed using Services-provided “species profiles” as well as evaluations of the geographical and temporal nature of the exposure to ascertain if a “not likely to adversely affect” determination can be made. The degree to which additional analyses are performed is commensurate with the predicted probability of adverse effects from the comparison of the dose response information with the EECs. The greater the probability that exposures will produce effects on a taxa, the greater the concern for potential indirect effects for listed species dependant upon that taxa, and therefore, the more intensive the analysis on the potential listed species of concern, their locations relative to the use site, and information regarding the use scenario (e.g., timing, frequency, and geographical extent of pesticide application).

The Agency uses the probit dose response relationship as a tool for providing additional information on the listed animal species acute levels of concern. The acute listed Species LOCs of 0.1 and 0.05 are used for terrestrial and aquatic animals, respectively. As part of the risk characterization, an interpretation of acute LOCs for listed species is discussed. This interpretation is presented in terms of the chance of an individual event (i.e., mortality or immobilization) should exposure at the estimated environmental concentration actually occur for a species with sensitivity to Mefluidide on par with the acute toxicity endpoint selected for RQ calculation. To accomplish this interpretation, the Agency uses the slope of the dose response relationship available from the toxicity study used to establish the acute toxicity measurement endpoints for each taxonomic group. The individual effects probability associated with the LOCs is based on the mean estimate of the slope and an assumption of a probit dose response relationship. In addition to a single effects probability estimate based on the mean, upper and lower estimates of the effects, probabilities are also provided to account for variance in the slope. The upper and lower bounds of the effects probability are based on available information on the 95% confidence interval of the slope. Confidence in the applicability of the assumed probit dose response relationship for predicting

individual event probabilities is also relevant. Studies with good probit fit characteristics (i.e., statistically appropriate for the data set) are associated with a high degree of confidence. Conversely, a low degree of confidence is associated with data from studies that do not statistically support a probit dose response relationship. In addition, confidence in the data set may be reduced by high variance in the slope estimate (i.e., large 95% confidence intervals), despite good probit fit characteristics.

The individual effect probabilities for aquatic organisms were calculated based on an Excel spreadsheet tool IECV1.1 (Individual Effect Chance Model Version 1.1) The model allows for such calculations by entering the mean slope estimate (and the 95% confidence bounds of that estimate) as the slope parameter for the spreadsheet. For all species event probability was calculated for the exceeded LOC based on a default slope assumption of 4.5 due to studies that do not statistically support a probit dose response relationship with confidence intervals of 2 and 9 as per original Agency assumptions of typical slope cited in Urban and Cook (1986).

The corresponding estimated chance of individual mortality associated with the terrestrial listed Species LOC 0.10 for terrestrial species located near ornamental turf (1.0 lb ae/A) areas exposed to mefluidide is approximately **1 in 2.94E+05 for mammals**. Probit analysis was not conducted for birds because the LD₅₀ was greater than 1500 mg ae/kg-bw in the Bobwhite quail study (MRID 416019-01) and there were no mortalities reported.

However, based on the screening level assessment, the acute risk quotients for mammals are as high as 0.26, above the acute listed LOC of 0.05. The probability of individual mortality based on the calculated RQs is 1 in 236 for potentially exposed mammals (based on the LD₅₀ study). Table 4.7 summarizes information on the Probability of Individual Mortality for Mammals and Birds.

Species	Type of application	EC50 LD50	RQ	Probit Slope	95% Confidence Interval	Probability of Individual Mortality at the RQ in this Assessment	MRID Source of Probit Slope
Bobwhite quail LD ₅₀	Ornamental Turf	>1500		n/a			416019-01
Lab mouse LD ₅₀	Ornamental Turf	829.8	0.26**	default = 4.5	default 2-9	1 in 236 (95% confidence interval 1 in 8.27 and 1 in 1.43 E+07)	00047116

¹ For terrestrial avian toxicity assessments, data evaluating toxicity data have been bridged. Therefore, the most sensitive mefluidide endpoint for birds was selected to represent all three Mefluidide formulations for birds for all application scenarios. For terrestrial mammal toxicity assessments, data evaluating toxicity data have been bridged. Also the most sensitive mefluidide endpoint for mammals was selected to represent all three Mefluidide formulations for mammals for all application scenarios.

- * exceeds LOC for acute risk to listed species (aquatic LOC = 0.05, terrestrial LOC = 0.10)
- ** exceeds LOCs for acute risk to listed species and restricted use (aquatic LOC = 0.1, terrestrial LOC = 0.20)
- *** exceeds LOCs for acute risk, acute risk to listed species, and restricted use (LOC = 0.5)

The corresponding estimated chance of individual mortality associated with the aquatic species listed Species LOC of 0.05 for potentially exposed **estuarine marine invertebrates** located near ornamental turf (1.0 lb ae/A) is approximately **1 in 4.18E*8**. Probit analysis was not conducted for freshwater fish because the LC₅₀ was greater than 68.47 mg ae/L in the rainbow trout study (MRID 418937-02) and there were no mortalities reported. Probit analysis was not conducted for freshwater invertebrates because the LC₅₀ was greater than 77.25 mg ae/L in the Daphnia study (MRID 418937-03) and there were no mortalities reported. Based on the screening level assessment, the highest acute risk quotient for estuarine marine invertebrates is 0.0001, two orders of magnitude below the acute listed LOC of 0.05. The probability of individual mortality based on the calculated RQs is 1 in 1.03E+72 for potentially exposed invertebrates (based on the LC₅₀ study) Table 4.8 summarizes information on the Probability of Individual Mortality for fish and aquatic invertebrates.

Table 4.8 Probability of Individual Mortality for fish and aquatic invertebrates at the Highest RQs and Application Rate (1.0 ae/A) Mefluidide							
Species	Type of Application	LC50 LD50 EC50	RQ	Probit Slope	95% Confidence Interval	Probability of Individual Mortality at the RQ in this Assessment	MRID Source of Probit Slope
FW Rainbow trout	Ornamental turf	>68.47		n/a			418937-02
FW Daphnid	Ornamental turf	>77.25		n/a			418937-03
EM Sheepshead minnow	Ornamental turf	>84.75		n/a			425623-03
EM Eastern oyster	Ornamental turf	67	0.0001	default = 4.5	default 2-9	1 in 1.03E+72 (95% confidence interval 1 in 1.61E+15 and 1 in 2.39E+283)	425624-01

¹ For terrestrial avian toxicity assessments, data evaluating toxicity data have been bridged. Therefore, the most sensitive mefluidide endpoint for birds was selected to represent all three Mefluidide formulations for birds for all application scenarios. For terrestrial mammal toxicity assessments, data evaluating toxicity data have been bridged. Also the most sensitive mefluidide endpoint for mammals was selected to represent all three Mefluidide formulations for mammals for all application scenarios.

* exceeds LOC for acute risk to listed species (aquatic LOC = 0.05, terrestrial LOC = 0.10)

** exceeds LOCs for acute risk to listed species and restricted use (aquatic LOC = 0.1, terrestrial LOC = 0.20)

*** exceeds LOCs for acute risk, acute risk to listed species, and restricted use (LOC = 0.5)

Indirect Effects Analysis

The Agency acknowledges that pesticides have the potential to exert indirect effects upon the listed organisms by, for example, perturbing forage or prey availability, altering the extent of nesting habitat, etc. In conducting a screen for indirect effects, direct effect LOCs for each taxonomic group are used to make inferences concerning the potential for indirect effects upon listed species that rely upon non-endangered organisms in these taxonomic groups as resources critical to their life cycle. There are acute and chronic direct effects for mammals, birds and acute direct effects for terrestrial plants (monocot and dicot).

Indirect effects are possible for terrestrial animals that are dependent on terrestrial monocots and dicot plants for food and/or shelter. Therefore, there is potential for adverse effects to those species that rely either on a specific plant species or multiple plant species. Also, plant indirect effects may be limited to general habitat modification, host plant loss, and competition. If the available plant material is impacted due to the effects of mefluidide, this may have negative effects not only on the herbivorous animals, but throughout the food chain. Also, depending on the severity of impact to the plant communities (edge and riparian vegetation), community assemblages and ecosystem stability may be altered (i.e. reduced bird and mammal populations in edge habitats; reduced riparian vegetation resulting in increased light penetration and temperature in aquatic habitats).

Acute listed LOCs were exceeded for 20 g and 100 g birds and acute restricted use LOCs were exceeded for 20 g birds that were exposed to and consumed various feed items. Consequently, there may be a concern for potential indirect effects to listed species dependent upon birds that consume feed items (short and tall grasses, broadleaf plants, and small insects) contaminated with mefluidide residues; such as predatory birds and mammals.

Acute listed and acute restricted use LOCs were exceeded for mammals (15 g and 35 g) and acute listed LOCs were exceeded for 1000 g mammals that consumed various feed items. The results of the probit dose analysis for mouse indicated a **1 in 236 for mammals** chance of mortality based on the maximum use scenario and RQ of 0.26 for small mammals consuming mefluidide. Consequently, there may be a concern for potential indirect effects to listed species dependent upon mammals that consume feed items (short and tall grasses, broadleaf plants, and small insects) contaminated with mefluidide residues; such as predatory birds and mammals.

There are potential concerns for indirect effects on aquatic organisms (fish, invertebrates, and plants) due to the potential for changes in the habitat adjacent to water bodies. Shading of water bodies that provides temperature regulation of the water could be

reduced, thus altering the habitat by increasing water temperature. This change in temperature could affect the abundance and/or diversity of aquatic plants and organisms in the adjacent water bodies. Furthermore, the reduction of upstream riparian vegetation that would otherwise supply downstream habitats could result not only in a loss of a significant component of food for aquatic herbivores and detritivores, but also of habitat (i.e. leaf packs, materials for case-building for invertebrates). These concerns are not only for freshwater systems, but also for estuarine/marine systems. As an example, many golf courses are located on or near coastal areas.

Again, the LOCATES database was not used for this assessment to identify specific listed and threatened species at risk from indirect effects to Mefluidide-K, mefluidide-DEA and mefluidide. Because of its widespread use on non-crop areas and because it is used throughout the United States, the search of the database could not be restricted by crop or geographic area. Therefore, further co-location analysis is recommended once the locations of mefluidide use can be identified.

Critical Habitat for Listed Species

In the evaluation of pesticide effects on designated critical habitat, consideration is given to the physical and biological features (constituent elements) of a critical habitat identified by the U.S Fish and Wildlife and National Marine Fisheries Services as essential to the conservation of a listed species and which may require special management considerations or protection. The evaluation of impacts for a screening level pesticide risk assessment focuses on the biological features that are constituent elements and is accomplished using the screening-level taxonomic analysis (RQs) and listed species levels of concern (LOCs) that are used to evaluate direct and indirect effects to listed organisms.

The screening-level risk assessment for mefluidide has identified potential concerns for direct effects on the following listed species categories: small and medium birds, small, medium and large mammals, and terrestrial and semi-aquatic plants (both monocots and dicots). Since birds are used as a surrogate for reptiles and terrestrial phase amphibians, they are also considered to be of concern. In light of the potential for both direct effects, the next step for EPA and the Service(s) is to identify which listed species and critical habitat are potentially implicated.

Analytically, the identification of such species and critical habitat can occur in either of two ways. First, the Agencies could determine whether the action area overlaps critical habitat or the occupied range of any listed species. If so, EPA would examine whether the pesticide's potential impacts on non-endangered species would affect the listed species indirectly or directly affect a constituent element of the critical habitat. Alternatively, the Agencies could determine which listed species depend on biological resources, or have constituent elements that fall into the taxa that may be directly or indirectly impacted by a pesticide. Then EPA would determine whether or not use of the pesticide overlaps the critical habitat or the occupied range of those listed species. At present, the information reviewed by EPA is not sufficient to permit use of either analytical approach to make a definitive

identification of species that are potentially impacted indirectly or critical habitats that are potentially impacted directly by the use of pesticides. EPA and the Service(s) are working together to conduct the necessary analysis.

Because of the large number of species that are potentially impacted, critical habitats will not be analyzed in this assessment. Therefore, it is the continued responsibility of the EPA and the Service(s) to make these assessments before final regulatory decisions are made.

Species with identified critical habitats are listed at:

http://ecos.fws.gov/tess_public/CriticalHabitat.do?listings=0&nmfs=1

(Fish and Wildlife Service)

http://ecos.fws.gov/tess_public/CriticalHabitat.do?listings=0&nmfs=2

(National Oceanic and Atmospheric Administration). A critical habitat mapper for a subset of listed species is available at: <http://ecos.fws.gov/imf/imf.jsp?site=ecos>.

4.3. Description of Assumptions, Limitations, Uncertainties, Strengths and Data Gaps

1. Uncertainties and data gaps associated with the environmental fate and toxicity data

Exposure estimates for this screening level risk assessment focused on the mefluidide, mefluidide-K and mefluidide-DEA. Degradation products were not considered in the exposure assessment. There are no environmental fate data on the degradation products of mefluidide, mefluidide-K and mefluidide-DEA. More importantly, 5-amino-2,4-dimethyltrifluoromethane-sulfonilide is a minor degradation product of mefluidide. Diethanolamine (DEA) degrades rapidly ($t_{1/2}$ = 1.7 to 5.8 days) in aerobic soil and water environments (MRID 43685901, 43685902, 44439401). In contrast, DEA is persistent ($t_{1/2}$ = 990 days) in anaerobic aquatic environments (MRID 43882901). Degradation products of diethanolamine are glycine, ethanolamine, and CO₂. Therefore, the potential mechanisms of transformation (i.e., which degrades may form in the environment, in which media, and how much) must be known, especially for a chemical whose metabolites/degradates such as DEA are of greater toxicological concern.

Additional uncertainty results from the lack of information and/or data in several components of this ecological risk assessment as follows:

Ecotoxicity data for chronic risks to freshwater fish and freshwater invertebrates exposed to mefluidide were not available. However, estimated values were derived from only one anilide (propanil) herbicide to obtain effects measurement endpoints. A range of anilide herbicides was not available to extrapolate endpoints.

- Although propanil has a similar chemical structure as mefluidide, the anilide (propanil) has a different mode of action for plants. Propanil is a photosynthesis inhibitor in contrast to mefluidide which inhibits plant cell division, stem elongation and seed head development. Also propanil has reported sublethal effects in fish and aquatic invertebrates where mefluidide does not at similar or lower concentrations such as; surfacing, loss of equilibrium, quiescent, labored respiration, fish lying on their side, hypersensitivity to disturbances and fish lying on the bottom of test vessel. Even though propanil effects may not be good predictors of mefluidide effects, in the absence of mefluidide data, EFED believes propanil data could be used to estimate the acute to chronic ratio for mefluidide. Note that uncertainties exist with these extrapolated endpoints and propanil data are not considered complete substitutes for missing effects data for mefluidide. Other anilide herbicides such as Chloranocryl, Monalide and Pentanochlor were also considered, however no information was available for these chemicals. Additional information on these estimated values are provided in Appendix E. However, EFED concluded that resulting estimated risk quotients, had they been based on definitive effects measurement endpoints, would not trigger concerns for chronic risks to these taxonomic groups.
- Ecotoxicity data for chronic risks to estuarine marine fish and estuarine marine invertebrates exposed to mefluidide were not available. However, assuming ACRs from the freshwater fish and invertebrates are similar to the estuarine marine species. No chronic exceedances would occur for estuarine marine fish or invertebrates with RQs <0.01. These extrapolated endpoints are uncertain and are not considered complete substitutes for missing effects data. RQ calculations for chronic risks to estuarine marine fish and estuarine marine invertebrates are summarized in Appendix E. However, EFED concluded that resulting estimated risk quotients, had they been based on definitive effects measurement endpoints, would not trigger concerns for chronic risks to these taxonomic groups.
- Ecotoxicity data for chronic risks to birds exposed to mefluidide were not available. Therefore, EFED calculated estimates for measurement endpoints for chronic toxicity to birds by evaluating the available data from mammal toxicity data (acute and chronic) and extrapolating the findings to available data for mefluidide, mefluidide-DEA and mefluidide-K to estimate possible effects measurement endpoints. These extrapolated endpoints are uncertain and are not considered complete substitutes for missing effects data. Additional information on these estimated values are provided in Appendix E. Submission of a chronic bird study would quantify risks associated with exposure of mefluidide to birds.
- The magnitude of toxicity to terrestrial plants is uncertain because only one terrestrial vegetative vigor plant study was available and conducted on fresh weight and not dry weight as required by EPA guidelines. A preliminary review on a recently submitted seedling emergence study (MRID 471907-01) was conducted. These results are uncertain until a full review of the study is performed. The results of the preliminary review are summarized in Appendix E. Ecotoxicity data for terrestrial plants (seedling

emergence) exposed to mefluidide were not available. Therefore, to estimate possible effects measurement endpoints for seedling emergence, EFED assumed that EC₂₅ toxicity values for terrestrial plants (vegetative vigor) are equivalent to (seedling emergence) measurement endpoints for mefluidide, mefluidide-DEA and mefluidide-K. These estimated endpoints are uncertain and are not considered complete substitutes for missing effects data. Additional information on these estimated values are provided in Appendix E.

- NOAEC or EC₀₅ values were not available to calculate (listed) aquatic vascular plants exposed to mefluidide. However, estimated values were derived from only one anilide herbicide to obtain effects measurement endpoints. A range of anilide herbicides was not available to extrapolate endpoints. Although propanil has a similar chemical structure as mefluidide, the anilide (propanil) has a different mode of action for plants. Propanil is a photosynthesis inhibitor in contrast to mefluidide which inhibits plant cell division, stem elongation and seed head development. Therefore, these extrapolated endpoints are uncertain and are not considered complete substitutes for missing effects data. Additional information on these estimated values are provided in Appendix E. However, EFED concluded that resulting estimated risk quotients, had they been based on definitive effects measurement endpoints, would not trigger concerns for chronic risks to these taxonomic groups.
- The available dietary toxicity studies on avian species failed to establish definitive acute LD₅₀ values (i.e., the lethality values exceed the highest dose tested). Therefore, use of this value adds uncertainty and may overestimate risk to avian species. Therefore, when the LD₅₀ value of >1500 mg ae/kg-bw was applied to the TREX model it resulted in LOC exceedances for Acute listed (20 and 100 g birds) and Restricted Use (100 g birds) for mefluidide-DEA and mefluidide-K (1.0 lb ae/A at 3 applications). The LD₅₀ value of 5000 mg ae/bw if applied to the above modeled scenario would result in no acute LOC exceedances for birds.

4.3.1 Assumptions and Limitations Related to Exposure to All Taxa

There are a number of areas of uncertainty in the aquatic and terrestrial risk assessments. The toxicity assessment for terrestrial and aquatic animals is limited by the number of species tested in the available toxicity studies. Use of toxicity data on representative species does not provide information on the potential variability in susceptibility to acute and chronic exposures.

4.3.2 Assumptions and Limitations Related to Exposure to Aquatic Species

PRZM/EXAMS standard runoff model

Although there are uncertainties and limitations with the use of the PRZM/EXAMS standard runoff scenario for a regional aquatic exposure assessment, it is designed to represent pesticide exposure from an agricultural watershed impacting a vulnerable aquatic environment. Extrapolating the risk conclusions from this standard small water body scenario may either underestimate or overestimate the potential risks.

Major uncertainties with the standard runoff scenario are associated with the physical construct of the watershed and representation of vulnerable aquatic environments for different geographic regions. The physico-chemical properties (pH, redox conditions, etc.) of the standard small water body are based on a Georgia farm pond. These properties are likely to be regionally specific because of local hydrogeological conditions. Any alteration in water quality parameters may impact the environmental behavior of the pesticide. The small water body represents a well mixed, static water body. Because the small water body is a static water body (no flow through); it does not account for pesticide removal through flow through or accidental water releases. However, the lack of water flow in the small water body provides an environmental condition for accumulation of persistent pesticides. The assumption of uniform mixing does not account for stratification due to thermoclines (e.g., seasonal stratification in deep water bodies). Additionally, the physical construct of the standard runoff scenario assumes a watershed water body area ratio of 10. This ratio is recommended to maintain a sustainable pond in the Southeastern United States. The use of higher watershed water body ratios (as recommended for sustainable ponds in drier regions of the United States) may lead to higher pesticide concentrations when compared to the standard watershed water body ratio.

The standard small water body scenario assumes uniform environmental and management conditions exist over the standard 10 hectare watershed. Soils can vary substantially across even small areas, and thus, this variation is not reflected in the model simulations. Additionally, the impact of unique soil characteristics (e.g., fragipan) and soil management practices (e.g., tile drainage) are not considered in the standard runoff scenario. The assumption of uniform site and management conditions is not expected to represent some site-specific conditions. Extrapolating the risk conclusions from the standard small water body scenario to other aquatic habitats (e.g., marshes, streams, creeks, and shallow rivers, intermittent aquatic areas) may either underestimate or overestimate the potential risks in those habitats.

Currently, crop sites for PRZM/EXAMS modeling are chosen to represent sites which produce high-end, but not unrealistic or worst-case, EECs for that crop. The EECs in this analysis are accurate only to the extent that the site represents a hypothetical high-end exposure site. It should be remembered that while the standard pond would be expected to generate lower EECs than shallow water bodies near agricultural fields that receive most of their water as runoff from use sites that have been treated with mefluidide.

4.3.3 *Assumptions and Limitations Related to Exposure to Terrestrial Species*

Residue concentration

The data available to support the exposure assessment for mefluidide is substantially complete, with the exception of a chronic bird study, which is an input variable for Tier 1 modeling of risks to birds and mammals (i.e., T-REX Model). EFED is confident that the estimated foliar half-life of 4 days derived from the two field dissipation studies on warm and cool season turf soil are acceptable (MRID 43276802 and 43276801). Therefore, EFED used the 4 day half-life for aquatic and terrestrial modeling in this assessment.

EFED also identified alternative foliar half lives and applications to identify LOC exceedances. To assess risks to terrestrial animals, the Tier I terrestrial model, T-REX, was used with maximum application rates (1 and 3 applications), foliar half-lives (4 day and 35 day) and values derived from upper bound and mean kenaga assessments.

To obtain an upper and lower bound estimates, both the estimated foliar half-life (4 days) and the default foliar half-life (35 days) with 1 and 3 applications resulted in acute LOC exceedances for both mammals and birds from both the upperbound and mean kenaga assessments. Chronic dose based exceedances for mammals did not exceed from the mean kenaga assessment for the 1.0 lb ae/A application scenario. The 35 day foliar half life with 3 applications resulted in RQ values approximately 61% higher than the single application rates for mammals. EFED is confident that the estimated foliar half-life of 4 days derived from the two field dissipation studies on warm and cool season turf soil is acceptable (MRID 43276802 and 43276801). Therefore, EFED will use the 4 day half-life for aquatic and terrestrial modeling in this assessment. Based on acute RQ values for the upper bound kenaga values for mammals, LOC exceedances for acute mammals would occur for the 1.0 lb ae/A modeled scenario. However, acute exceedances for mammals did not exceed from the mean kenaga assessment for the 1.0 lb ae/A application scenario. These RQ values are summarized in Appendix D.

Variation in habitat and dietary requirements

For screening terrestrial risk assessments, a generic bird or mammal is assumed to occupy either the treated field or adjacent areas receiving pesticide at a rate commensurate with the treatment rate on the field. The habitat and feeding requirements of the modeled species and the wildlife species may be different. It is assumed that species occupy, exclusively and permanently, the treated area being modeled. This assumption leads to a maximum level of exposure in the risk assessment.

The acute studies have a fixed exposure period, not allowing for the differences in response of individuals to different durations of exposure. Further, for the acute oral study, Mefluidide is administered in a single dose which does not mimic wild birds' exposure through multiple feedings. Also, it does not account for the effect of different environmental matrices on the absorption rate of the chemical into the animal. Because exposure occurs over several days, both the accumulated dose and elimination of the chemical from the body for the duration of the exposure determine the exact exposure to wildlife, however they are not taken into account in the screening assessment. There was also no assumption of an effect of repeated doses that change the tolerance of an individual to successive doses. EFED is

confident based on the acceptable bird and mammal toxicity studies and conservative modeling procedures that the above assumptions pertaining to variations in habitat and dietary requirements do not effect the certainty of the risk conclusions.

Variation in diet composition

The risk assessment and calculated RQs assume 100% of the diet is relegated to single food types foraged only from treated fields. The assumption of 100% diet from a single food type may be realistic for acute exposures based on this assessment, but diets are likely to be more variable over longer periods of time. This assumption is likely to be conservative and will tend to overestimate potential risks for chronic exposure. These large animals (e.g., deer and geese) will tend to forage from a variety of areas and move on and off of treated fields. Small animals (e.g., mice, voles, and small birds) may have home ranges smaller than the size of a treated area and will have little or no opportunity to obtain foodstuffs that have not been treated with mefluidide. Even if their home range does cover area outside the treated field, mefluidide may have drifted or runoff to areas adjacent to the treated area.

Exposure routes other than dietary

Screening-level risk assessments for spray applications of pesticides consider dietary exposure to terrestrial organisms. Other exposure routes are possible for animals residing in or moving through treated areas. These routes include ingestion of contaminated drinking water, ingestion of contaminated soils, preening/grooming, and dermal contact. Preening exposures, involving the oral ingestion of material from the feathers remains an unquantified, but potentially important, exposure route. If toxicity is expected through any of these other routes of exposure, then the risks of a toxic response to mefluidide is underestimated in this risk assessment. Other routes of exposure, not considered in this assessment, are discussed below:

Incidental soil ingestion exposure

This risk assessment does not consider incidental soil ingestion. Available data suggests that up to 15% of the diet can consist of incidentally ingested soil depending on the species and feeding strategy (Beyer et al, 1994). Because mefluidide is moderately persistent in soils, incidental soil ingestion is a possible exposure pathway.

Inhalation exposure

The screening risk assessment does not consider inhalation exposure however, due to the low Henrys Constant of mefluidide ($2.27E-7$ atm m³/mole) inhalation is not likely to be an

important exposure pathway. Also, mammalian toxicity studies for inhalation exposure to mefluidide indicate low acute toxicity Appendix E.

Based on the acceptable mammal toxicity studies and low Henrys Constant of mefluidide the above assumptions pertaining to inhalation exposure do not effect the certainty of the risk conclusions.

Dermal Exposure

The screening assessment does not consider dermal exposure. Dermal exposure may occur through three potential sources: (1) direct application of spray to terrestrial wildlife in the treated area or within the drift footprint, (2) incidental contact with contaminated vegetation, or (3) contact with contaminated water or soil.

The low octanol/water partitioning coefficient with a Kow value of ($\log Kow=1.97$; $Kow=94.5$) indicates the potential for mefluidide to be absorbed via dermal exposure is not likely to be an important exposure pathway. Also, mammalian toxicity studies for mefluidide indicate low acute toxicity by dermal exposure routes Appendix E.

The available measured data related to wildlife dermal contact with pesticides are extremely limited. The Agency is actively pursuing modeling techniques to account for dermal exposure via direct application of spray and by incidental contact with vegetation. EFED is confident based on the acceptable mammal toxicity studies and low octanol/water partitioning coefficient of mefluidide that the above assumptions pertaining to dermal exposure do not effect the certainty of the risk conclusions.

Drinking Water Exposure

Drinking water exposure to a pesticide active ingredient may be the result of consumption of surface water or consumption of the pesticide in dew or other water on the surfaces of treated vegetation. Given that Mefluidide is soluble in water there exists the potential to dissolve in runoff and puddles on the treated field may contain the chemical. Consumption of drinking water would appear to be inconsequential if water concentrations were equivalent to the concentrations from PRZM/EXAMS; however, concentrations in puddled water sources on treated fields may be higher than concentrations in modeled small water body. Given that this exposure route is not included in the assessment, overall risk may be underestimated.

Dietary Intake - Differences between Laboratory and Field Conditions

There are several aspects of the dietary test that introduce uncertainty into calculation of the LC_{50} value (Mineau, Jobin, and Baril, 1996; ECOFRAM, 1999). The endpoint of this test is reported as the concentration mixed with food that produces a response rather than as the dose ingested. Although food consumption sometimes allows for the estimate of a dose, calculations of the mg/kg/day are confounded by undocumented spillage of feed and how

consumption is measured over the duration of the test. Usually, if measured at all, food consumption is estimated once at the end of the five-day exposure period. Further, group housing of birds undergoing testing only allows for a measure of the average consumption per day for a group; consumption estimates can be further confounded if birds die within a treatment group. The exponential growth of young birds also complicates the estimate of the dose; controls often nearly double in size over the duration of the test. Since weights are only taken at the initiation of the exposure period and at the end, the dose per body weight (mg/kg) is difficult to estimate with any precision. The interpretation of this test is also confounded because the response of birds is not only a function of the intrinsic toxicity of the pesticide, but also the willingness of the birds to consume treated food.

Further, the acute and chronic characterization of risk rely on comparisons of wildlife dietary residues with LC_{50} or NOAEC values expressed in concentrations of pesticides in laboratory feed. These comparisons assume that ingestion of food items in the field occurs at rates commensurate with those in the laboratory. Although the screening assessment process adjusts dry-weight estimates of food intake to reflect the increased mass in fresh-weight wildlife food intake estimates, it does not allow for gross energy and assimilative efficiency differences between wildlife food items and laboratory feed. On gross energy content alone, direct comparison of a laboratory dietary concentration- based effects threshold to a fresh-weight pesticide residue estimate would result in an underestimation of field exposure by food consumption by a factor of 1.25 - 2.5 for most food items. Only for seeds would the direct comparison of dietary threshold to residue estimate lead to an overestimate of exposure.

Differences in assimilative efficiency between laboratory and wild diets suggest that current screening assessment methods do not account for a potentially important aspect of food requirements. Depending upon species and dietary matrix, bird assimilation of wild diet energy ranges from 23 - 80%, and mammal's assimilation ranges from 41 - 85% (U.S. Environmental Protection Agency, 1993). If it is assumed that laboratory chow is formulated to maximize assimilative efficiency (e.g., a value of 85%), a potential for underestimation of exposure may exist by assuming that consumption of food in the wild is comparable with consumption during laboratory testing. In the screening process, exposure may be underestimated because metabolic rates are not related to food consumption.

Finally, the screening procedure does not account for situations where the feeding rate may be above or below requirements to meet free living metabolic requirements. Gorging behavior is a possibility under some specific wildlife scenarios (e.g., bird migration) where the food intake rate may be greatly increased. Kirkwood (1983) has suggested that an upper-bound limit to this behavior might be the typical intake rate multiplied by a factor of 5. In contrast is the potential for avoidance, operationally defined as animals responding to the presence of noxious chemicals in their food by reducing consumption of treated dietary elements. This response is seen in nature where herbivores avoid plant secondary compounds.

In the absence of additional information, the acute oral LD_{50} test provides the best estimate of acute effects for chemicals where exposure can be considered to occur over relative short feeding periods, such as the diurnal feeding peaks common to avian species

(ECOFRAM, 1999). EFED is confident based on the acceptable bird and mammal toxicity studies that the above assumptions pertaining laboratory and field conditions do not effect the certainty of the risk conclusions.

Assumptions and Limitations Related to Effects Assessment

EFED has identified gaps in the effects dataset for mefluidide, mefluidide-DEA and mefluidide-K. These data gaps prevent the establishment of definitive effects measurement endpoints for the following taxonomic groups for mefluidide, mefluidide-DEA and mefluidide-K: Chronic freshwater fish, chronic estuarine marine fish, chronic estuarine marine invertebrates, chronic freshwater invertebrates, vascular plants (EC₀₅ or NOAEC) and non-vascular plants (EC₀₅ or NOAEC). Therefore, EFED calculated estimates for measurement endpoints for these taxonomic groups by evaluating the available data from other anilide herbicides (Propanil) and extrapolating the findings to available data for mefluidide, mefluidide-DEA and mefluidide-K to estimate possible effects measurement endpoints. Other anilide herbicides that were considered for data were Chloranocryl, Monalide and Pentanochlor, however no information was available for these chemicals. Therefore, Propanil was used to estimate acute to chronic ratios for mefluidide. EFED then compared estimated environmental concentrations for surface waters with these endpoints. In all cases, EFED concluded that resulting estimated risk quotients, had they been based on definitive effects measurement endpoints, would not trigger concerns for acute or chronic risks to these taxonomic groups. In fact, the RQ estimates are multiple orders of magnitude below Agency LOCs. However, estimated values were derived from only one anilide herbicides to obtain effects measurement endpoints. A range of anilide herbicides was not available to extrapolate endpoints. Although propanil has a similar chemical structure as mefluidide, the anilide (propanil) has a different mode of action for plants. Propanil is a photosynthesis inhibitor in contrast to mefluidide which inhibits plant cell division, stem elongation and seed head development. Also propanil has reported sublethal effects in fish and aquatic invertebrates where mefluidide does not at similar or lower concentrations such as; surfacing (fish and invertebrates), erratic movement(invertebrates), loss of equilibrium (fish), quiescent (fish), labored respiration (fish), lying on side (fish), hypersensitivity to disturbances (fish) and lying on the bottom of test vessel (fish and invertebrates). Therefore, these extrapolated endpoints are uncertain and are not considered complete substitutes for missing effects data.

EFED has identified gaps in the effects dataset for mefluidide, mefluidide-DEA and mefluidide-K. These data gaps prevent the establishment of definitive effects measurement endpoints for the following taxonomic groups for mefluidide, mefluidide-DEA and mefluidide-K: birds (chronic) and terrestrial plants (seedling emergence). Therefore, EFED calculated estimates for measurement endpoints for chronic toxicity to birds by evaluating the

available data from mammal toxicity data (acute and chronic) and extrapolating the findings to available data for mefluidide, mefluidide-DEA and mefluidide-K to estimate possible effects measurement endpoints.

To estimate possible effects measurement endpoints for seedling emergence, EFED assumed that EC₂₅ toxicity values for terrestrial plants (vegetative vigor) are equivalent to (seedling emergence) measurement endpoints for mefluidide, mefluidide-DEA and mefluidide-K. Therefore, these estimated endpoints are uncertain and are not considered complete substitutes for missing effects data.

Age class and sensitivity of effects thresholds

It is generally recognized that test organism age may have a significant impact on the observed sensitivity to a toxicant. The screening risk assessment acute toxicity data for fish are collected on juvenile fish between 0.1 and 5 grams. Aquatic invertebrate acute testing is performed on recommended immature age classes (e.g., first instar for daphnids, second instar for amphipods, stoneflies and mayflies, and third instar for midges). Similarly, acute dietary testing with birds is also performed on juveniles, with mallard being 5-10 days old and quail 10-14 days old.

Testing of juveniles may overestimate toxicity of older age classes for pesticidal active ingredients, such as Mefluidide, that act directly (without metabolic transformation) because younger age classes may not have the enzymatic systems associated with detoxifying xenobiotics. The screening risk assessment has no current provisions for a generally applied method that accounts for this uncertainty. In so far as the available toxicity data may provide ranges of sensitivity information with respect to age class, the risk assessment uses the most sensitive life-stage information as the conservative screening endpoint. However, EFED is confident based on all the acceptable aquatic and terrestrial toxicity studies that the above assumptions pertaining to age sensitivity does not effect the certainty of the risk conclusions.

Use of the Most Sensitive Species Tested

Although the screening risk assessment relies on a selected toxicity endpoint from the most sensitive species tested, it does not necessarily mean that the selected toxicity endpoint reflect sensitivity of the most sensitive species existing in a given environment. The relative position of the most sensitive species tested in the distribution of all possible species is a function of the overall variability among species to a particular chemical. In the case of listed species, there is uncertainty regarding the relationship of the listed species' sensitivity and the most sensitive species tested.

The Agency is not limited to a base set of surrogate toxicity information in establishing risk assessment conclusions. The Agency also considers toxicity data on non-standard test

species when available. EFED is confident based on the acceptable aquatic and terrestrial toxicity studies that the above assumptions pertaining to the most sensitive species tested does not effect the certainty of the risk conclusions.

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Appendix A Ecological Data Requirements

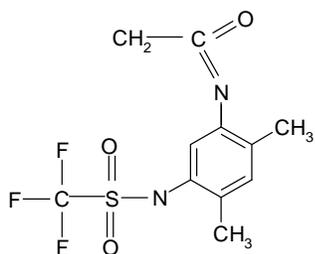
Ecological Effects Data Requirements for Mefluidide ¹				
Guideline #	Data Requirement	Species / MRID	Study Classification	
71-1	850.2100	Avian Oral LD ₅₀	Northern Bobwhite Quail (416019-01) Mallard duck Not submitted	Supplemental
71-2	850.2200	Avian Dietary LC ₅₀	Northern Bobwhite Quail (416019-02)	Supplemental
			Mallard duck (416019-03)	Supplemental
71-4	850.2300	Avian Reproduction	Not submitted	Estimated values
81-1		Acute Mammal	Laboratory mouse (00047116)	Acceptable
83-4		Chronic Mammal	Laboratory rat (00082748)	Acceptable
72-1	850.1075	Freshwater Fish LC ₅₀	Rainbow Trout Coldwater species Freshwater fish (418937-02)	Acceptable
			Bluegill sunfish Warmwater species Freshwater fish (418937-01)	Acceptable
72-2	850.1010	Freshwater Invertebrate Acute LC ₅₀	Water flea Freshwater Invertebrate (418937-03)	Acceptable
72-3(a)	850.1075	Estuarine/Marine Fish LC ₅₀	Sheepshead minnow (425623-03)	Acceptable
72-3(b)	850.1025	Estuarine/Marine Invertebrates EC ₅₀	Eastern Oyster (425624-01)	Acceptable
72-4(a)	850.1400	Fish Early Life-Stage	Not submitted	Estimated values
72-4(b)	850.1300	Aquatic Invertebrate Life-Cycle	Not submitted	Estimated values
	850.1350			
72-5	850.1500	Freshwater Fish Full Life-Cycle	Not submitted	Estimated values
123-1(a)	850.4225	Seedling Emergence	Not submitted	Estimated values
123-1(b)	850.4250	Vegetative Vigor (Tier II)	Most sensitive monocot: Onion Most sensitive dicot: cabbage, lettuce (435496-01)	Supplemental
123-2	850.4400	Aquatic Plant Growth (Tier II)	<i>Navicula pelliculosa</i> Tier I <u>Nonvascular Plant</u> (435266-05)	Acceptable
123-2	850.4400	Aquatic Plant Growth (Tier II)	<i>Lemna gibba</i> Tier I <u>Vascular Plant</u> (435266-01)	Acceptable
141-1	850.3020	Honey Bee Acute Contact LD ₅₀	Honeybee (425628-01)	Acceptable

Appendix B Bibliography for Environmental Fate and Selected Chemical Structures

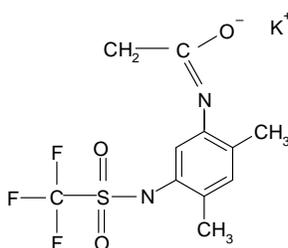
Bibliography

Morrison Robert T. and R. N. Boyd. 1973. *Organic Chemistry* 3rd edition. Allyn and Bacon, Inc., Boston.

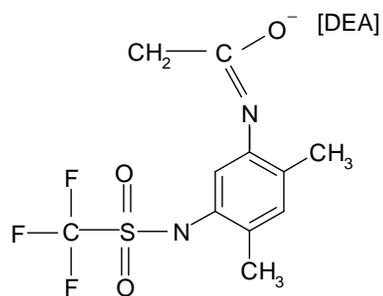
Chemical Structures for Mefluidide



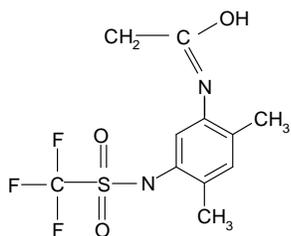
Mefluidide a.i



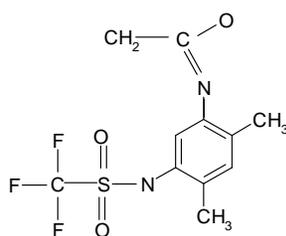
Mefluidide-K a.i



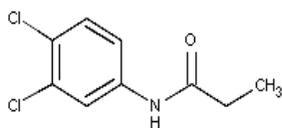
Mefluidide-DEA a.i



Mefluidide acid (Enol form)



Mefluidide (Keto form)



Propanil analog

Appendix C Aquatic Exposure Modeling Assessment PRZM-EXAMS model outputs

PRZM-EXAMS SIMULATIONS

FL TURF mefluidide-DEA

stored as MefluDEA.out

Chemical: Mefluidide

PRZM environment: FLturfC.txt modified Monday, 16 June 2003 at 13:48:06

EXAMS environment: pond298.exv modified Thuday, 29 August 2002 at 16:33:30

Metfile: w12834.dvf modified Wedday, 3 July 2002 at 09:04:28

Water segment concentrations (ppb)

Year	Peak	96 hr	21 Day	60 Day	90 Day	Yearly
1961	6.522	6.393	5.844	4.781	4.142	1.629
1962	2.048	2.006	1.904	1.621	1.473	1.009
1963	10.33	10.1	9.353	7.649	6.617	2.702
1964	3.237	3.164	3.003	2.477	2.159	1.513
1965	1.479	1.45	1.332	1.139	1.112	0.679
1966	16.06	15.7	14.25	11.58	10.03	4.671
1967	3.069	3.035	2.896	2.614	2.409	1.701
1968	8.56	8.38	7.675	6.287	5.45	2.273
1969	5.46	5.357	5.124	4.396	3.892	1.956
1970	2.4	2.345	2.128	1.816	1.765	1.048
1971	6.952	6.81	6.223	5.131	4.881	2.576
1972	2.756	2.706	2.502	2.233	2.031	1.15
1973	2.109	2.069	1.968	1.866	1.792	0.9159
1974	5.179	5.102	4.72	3.909	3.396	1.445
1975	3.035	2.971	2.726	2.251	2.01	1.233
1976	12.62	12.39	11.53	9.825	8.995	4.192
1977	1.88	1.837	1.714	1.619	1.523	1.118
1978	1.602	1.565	1.421	1.337	1.278	0.6743
1979	1.461	1.427	1.304	1.145	1.04	0.5849
1980	5.023	4.929	4.5	3.632	3.132	1.623
1981	1.565	1.529	1.387	1.276	1.222	0.7967
1982	5.846	5.753	5.376	4.844	4.576	2.162
1983	2.743	2.703	2.492	2.398	2.317	1.295
1984	10.6	10.42	9.653	8.537	8.545	3.988
1985	1.841	1.806	1.697	1.559	1.529	1.038
1986	1.867	1.84	1.679	1.404	1.239	0.6823
1987	2.407	2.354	2.14	1.739	1.515	0.7955
1988	1.338	1.309	1.194	1.038	1.003	0.5808
1989	1.267	1.239	1.126	0.9689	0.9342	0.4958
1990	1.281	1.251	1.198	0.9955	0.953	0.5079

Sorted results

Prob.	Peak	96 hr	21 Day	60 Day	90 Day	Yearly
0.032258064516129		16.06	15.7	14.25	11.58	10.03 4.671
0.0645161290322581		12.62	12.39	11.53	9.825	8.995 4.192
0.0967741935483871		10.6	10.42	9.653	8.537	8.545 3.988
0.129032258064516		10.33	10.1	9.353	7.649	6.617 2.702
0.161290322580645		8.56	8.38	7.675	6.287	5.45 2.576
0.193548387096774		6.952	6.81	6.223	5.131	4.881 2.273
0.225806451612903		6.522	6.393	5.844	4.844	4.576 2.162
0.258064516129032		5.846	5.753	5.376	4.781	4.142 1.956
0.290322580645161		5.46	5.357	5.124	4.396	3.892 1.701
0.32258064516129		5.179	5.102	4.72	3.909	3.396 1.629
0.354838709677419		5.023	4.929	4.5	3.632	3.132 1.623
0.387096774193548		3.237	3.164	3.003	2.614	2.409 1.513

0.419354838709677	3.069	3.035	2.896	2.477	2.317	1.445
0.451612903225806	3.035	2.971	2.726	2.398	2.159	1.295
0.483870967741936	2.756	2.706	2.502	2.251	2.031	1.233
0.516129032258065	2.743	2.703	2.492	2.233	2.01	1.15
0.548387096774194	2.407	2.354	2.14	1.866	1.792	1.118
0.580645161290323	2.4	2.345	2.128	1.816	1.765	1.048
0.612903225806452	2.109	2.069	1.968	1.739	1.529	1.038
0.645161290322581	2.048	2.006	1.904	1.621	1.523	1.009
0.67741935483871	1.88	1.84	1.714	1.619	1.515	0.9159
0.709677419354839	1.867	1.837	1.697	1.559	1.473	0.7967
0.741935483870968	1.841	1.806	1.679	1.404	1.278	0.7955
0.774193548387097	1.602	1.565	1.421	1.337	1.239	0.6823
0.806451612903226	1.565	1.529	1.387	1.276	1.222	0.679
0.838709677419355	1.479	1.45	1.332	1.145	1.112	0.6743
0.870967741935484	1.461	1.427	1.304	1.139	1.04	0.5849
0.903225806451613	1.338	1.309	1.198	1.038	1.003	0.5808
0.935483870967742	1.281	1.251	1.194	0.9955	0.953	0.5079
0.967741935483871	1.267	1.239	1.126	0.9689	0.9342	0.4958

0.1 10.573 10.388 9.623 8.4482 8.3522 3.8594
 Average of yearly averages: 1.56783666666667

Inputs generated by pe4.pl - 8-August-2003

Data used for this run:

Output File: MefluDEA

Metfile: w12834.dvf

PRZM scenario: FLturfC.txt

EXAMS environment file: pond298.exv

Chemical Name: Mefluidide

Description	Variable Name	Value	Units	Comments
Molecular weight	mwt	310.6	g/mol	
Henry's Law Const.	henry	2.27E-7	atm-m ³ /mol	
Vapor Pressure	vapr	1E-4	torr	
Solubility	sol	180	mg/L	
Kd	Kd	0.073	mg/L	
Koc	Koc		mg/L	
Photolysis half-life	kdp		days	Half-life
Aerobic Aquatic Metabolism	kbacw	72	days	Halfife
Anaerobic Aquatic Metabolism	kbacs		days	Halfife
Aerobic Soil Metabolism	asm	36	days	Halfife
Hydrolysis:	pH 7		days	Half-life
Method: CAM	2	integer	See PRZM manual	
Incorporation Depth:	DEPI		cm	
Application Rate:	TAPP	1.12	kg/ha	
Application Efficiency:	APPEFF	0.99	fraction	
Spray Drift	DRFT	0.01	fraction of application rate applied to pond	
Application Date	Date	1-4	dd/mm or dd/mm or dd-mm or dd-mmm	
Interval 1	interval	42	days	Set to 0 or delete line for single app.
Interval 2	interval	42	days	Set to 0 or delete line for single app.
Record 17:	FILTRA			
	IPSCND	1		
	UPTKF			
Record 18:	PLVKRT			
	PLDKRT	0.1715		
	FEXTRC	0.5		
Flag for Index Res. Run	IR		Pond	
Flag for runoff calc.	RUNOFF	none	none, monthly or total(average of entire run)	

Value Units Comments

Molecular weight mwt

Henry's Law Const. henry

Vapor Pressure vapr

Solubility sol

Kd Kd

Koc Koc

Photolysis half-life kdp

Aerobic Aquatic Metabolism kbacw

Anaerobic Aquatic Metabolism kbacs

Aerobic Soil Metabolism asm

Hydrolysis: pH 7

Method: CAM 2

Incorporation Depth: DEPI

Application Rate: TAPP

Application Efficiency: APPEFF

Spray Drift DRFT

Application Date Date

Interval 1 interval

Interval 2 interval

Record 17: FILTRA

IPSCND 1

UPTKF

Record 18: PLVKRT

PLDKRT 0.1715

FEXTRC 0.5

Flag for Index Res. Run IR

Flag for runoff calc. RUNOFF

FL TURF mefluidide-K

stored as MefluK.out

Chemical: Mefluidide

PRZM environment: FLturfC.txt modified Monday, 16 June 2003 at 13:48:06

EXAMS environment: pond298.exv modified Thuday, 29 August 2002 at 16:33:30

Metfile: wl2834.dvf modified Wedday, 3 July 2002 at 09:04:28

Water segment concentrations (ppb)

Year	Peak	96 hr	21 Day	60 Day	90 Day	Yearly
1961	6.522	6.393	5.844	4.781	4.142	1.629
1962	2.048	2.006	1.904	1.621	1.473	1.009
1963	10.33	10.1	9.353	7.649	6.617	2.702
1964	3.237	3.164	3.003	2.477	2.159	1.513
1965	1.479	1.45	1.332	1.139	1.112	0.679
1966	16.06	15.7	14.25	11.58	10.03	4.671
1967	3.069	3.035	2.896	2.614	2.409	1.701
1968	8.56	8.38	7.675	6.287	5.45	2.273
1969	5.46	5.357	5.124	4.396	3.892	1.956
1970	2.4	2.345	2.128	1.816	1.765	1.048
1971	6.952	6.81	6.223	5.131	4.881	2.576
1972	2.756	2.706	2.502	2.233	2.031	1.15
1973	2.109	2.069	1.968	1.866	1.792	0.9159
1974	5.179	5.102	4.72	3.909	3.396	1.445
1975	3.035	2.971	2.726	2.251	2.01	1.233
1976	12.62	12.39	11.53	9.825	8.995	4.192
1977	1.88	1.837	1.714	1.619	1.523	1.118
1978	1.602	1.565	1.421	1.337	1.278	0.6743
1979	1.461	1.427	1.304	1.145	1.04	0.5849
1980	5.023	4.929	4.5	3.632	3.132	1.623
1981	1.565	1.529	1.387	1.276	1.222	0.7967
1982	5.846	5.753	5.376	4.844	4.576	2.162
1983	2.743	2.703	2.492	2.398	2.317	1.295
1984	10.6	10.42	9.653	8.537	8.545	3.988
1985	1.841	1.806	1.697	1.559	1.529	1.038
1986	1.867	1.84	1.679	1.404	1.239	0.6823
1987	2.407	2.354	2.14	1.739	1.515	0.7955
1988	1.338	1.309	1.194	1.038	1.003	0.5808
1989	1.267	1.239	1.126	0.9689	0.9342	0.4958
1990	1.281	1.251	1.198	0.9955	0.953	0.5079

Sorted results

Prob.	Peak	96 hr	21 Day	60 Day	90 Day	Yearly
0.032258064516129	16.06	15.7	14.25	11.58	10.03	4.671
0.0645161290322581	12.62	12.39	11.53	9.825	8.995	4.192
0.0967741935483871	10.6	10.42	9.653	8.537	8.545	3.988
0.129032258064516	10.33	10.1	9.353	7.649	6.617	2.702
0.161290322580645	8.56	8.38	7.675	6.287	5.45	2.576
0.193548387096774	6.952	6.81	6.223	5.131	4.881	2.273
0.225806451612903	6.522	6.393	5.844	4.844	4.576	2.162
0.258064516129032	5.846	5.753	5.376	4.781	4.142	1.956
0.290322580645161	5.46	5.357	5.124	4.396	3.892	1.701
0.32258064516129	5.179	5.102	4.72	3.909	3.396	1.629
0.354838709677419	5.023	4.929	4.5	3.632	3.132	1.623
0.387096774193548	3.237	3.164	3.003	2.614	2.409	1.513
0.419354838709677	3.069	3.035	2.896	2.477	2.317	1.445
0.451612903225806	3.035	2.971	2.726	2.398	2.159	1.295
0.483870967741936	2.756	2.706	2.502	2.251	2.031	1.233
0.516129032258065	2.743	2.703	2.492	2.233	2.01	1.15
0.548387096774194	2.407	2.354	2.14	1.866	1.792	1.118
0.580645161290323	2.4	2.345	2.128	1.816	1.765	1.048
0.612903225806452	2.109	2.069	1.968	1.739	1.529	1.038
0.645161290322581	2.048	2.006	1.904	1.621	1.523	1.009
0.67741935483871	1.88	1.84	1.714	1.619	1.515	0.9159
0.709677419354839	1.867	1.837	1.679	1.559	1.473	0.7967
0.741935483870968	1.841	1.806	1.679	1.404	1.278	0.7955
0.774193548387097	1.602	1.565	1.421	1.337	1.239	0.6823

0.806451612903226	1.565	1.529	1.387	1.276	1.222	0.679
0.838709677419355	1.479	1.45	1.332	1.145	1.112	0.6743
0.870967741935484	1.461	1.427	1.304	1.139	1.04	0.5849
0.903225806451613	1.338	1.309	1.198	1.038	1.003	0.5808
0.935483870967742	1.281	1.251	1.194	0.9955	0.953	0.5079
0.967741935483871	1.267	1.239	1.126	0.9689	0.9342	0.4958

0.1 10.573 10.388 9.623 8.4482 8.3522 3.8594
Average of yearly averages: 1.56783666666667

Inputs generated by pe4.pl - 8-August-2003

Data used for this run:

Output File: MefluK

Metfile: w12834.dvf

PRZM scenario: FLturfC.txt

EXAMS environment file: pond298.exv

Chemical Name: Mefluidide

Description	Variable Name	Value	Units	Comments
-------------	---------------	-------	-------	----------

Molecular weight	mwt	310.6	g/mol	
------------------	-----	-------	-------	--

Henry's Law Const.	henry	2.27E-7	atm-m ³ /mol	
--------------------	-------	---------	-------------------------	--

Vapor Pressure vapr	1E-4	torr		
---------------------	------	------	--	--

Solubility	sol	180	mg/L	
------------	-----	-----	------	--

Kd	Kd	0.073	mg/L	
----	----	-------	------	--

Koc	Koc		mg/L	
-----	-----	--	------	--

Photolysis half-life	kdp		days	Half-life
----------------------	-----	--	------	-----------

Aerobic Aquatic Metabolism	kbacw	72	days	Halfife
----------------------------	-------	----	------	---------

Anaerobic Aquatic Metabolism	kbacs		days	Halfife
------------------------------	-------	--	------	---------

Aerobic Soil Metabolism	asm	36	days	Halfife
-------------------------	-----	----	------	---------

Hydrolysis:	pH 7		days	Half-life
-------------	------	--	------	-----------

Method: CAM 2 integer See PRZM manual

Incorporation Depth:	DEPI		cm	
----------------------	------	--	----	--

Application Rate:	TAPP	1.12	kg/ha	
-------------------	------	------	-------	--

Application Efficiency:	APPEFF	0.99	fraction	
-------------------------	--------	------	----------	--

Spray Drift	DRFT	0.01	fraction of application rate applied to pond	
-------------	------	------	--	--

Application Date	Date	1-4	dd/mm or dd/mm/yy or dd-mm or dd-mm/yy	
------------------	------	-----	--	--

Interval 1	interval	42	days	Set to 0 or delete line for single app.
------------	----------	----	------	---

Interval 2	interval	42	days	Set to 0 or delete line for single app.
------------	----------	----	------	---

Record 17: FILTRA

IPSCND 1

UPTKF

Record 18: PLVKRT

PLDKRT 0.1715

FEXTRC 0.5

Flag for Index Res. Run	IR	Pond	
-------------------------	----	------	--

Flag for runoff calc.	RUNOFF	none	none, monthly or total(average of entire run)
-----------------------	--------	------	---

FL TURF mefluidide

stored as Mefluacidi.out

Chemical: Mefluidide

PRZM environment: FLturfC.txt modified Monday, 16 June 2003 at 13:48:06

EXAMS environment: pond298.exv modified Thuday, 29 August 2002 at 16:33:30

Metfile: w12834.dvf modified Wedday, 3 July 2002 at 09:04:28

Water segment concentrations (ppb)

Year	Peak	96 hr	21 Day	60 Day	90 Day	Yearly
1961	2.705	2.623	2.395	1.959	1.697	0.6036
1962	0.4867	0.4819	0.4621	0.4172	0.3845	0.2598
1963	4.628	4.521	4.186	3.424	2.962	1.119
1964	1.063	1.039	0.9768	0.8114	0.7087	0.5198
1965	0.2023	0.2004	0.1923	0.1746	0.1613	0.0877
1966	7.509	7.344	6.666	5.416	4.692	2.106
1967	1.435	1.419	1.354	1.222	1.126	0.6051
1968	3.711	3.633	3.324	2.724	2.361	0.8962
1969	2.254	2.212	2.11	1.748	1.51	0.7417
1970	0.6738	0.6621	0.6153	0.5286	0.4994	0.2943
1971	2.902	2.842	2.597	2.132	1.999	1.053
1972	0.8825	0.8664	0.8012	0.6593	0.5722	0.3381
1973	0.7281	0.7167	0.6819	0.5861	0.5181	0.2195
1974	1.999	1.973	1.825	1.513	1.314	0.4854
1975	0.9183	0.8987	0.8271	0.6841	0.5946	0.3775
1976	5.849	5.746	5.348	4.478	4.143	1.863
1977	0.7792	0.773	0.7472	0.6889	0.6377	0.3198
1978	0.3362	0.3306	0.3074	0.2628	0.2355	0.1042
1979	0.209	0.2042	0.1856	0.1521	0.1322	0.05641
1980	1.927	1.886	1.725	1.393	1.199	0.5759
1981	0.3447	0.3422	0.3319	0.306	0.2846	0.157
1982	2.621	2.58	2.411	2.08	1.908	0.8387
1983	0.9113	0.8994	0.8361	0.7669	0.7557	0.396
1984	4.858	4.774	4.423	3.942	3.914	1.755
1985	0.6437	0.6381	0.615	0.5619	0.5184	0.2808
1986	0.3765	0.3696	0.3383	0.2763	0.2394	0.09841
1987	0.6123	0.5988	0.544	0.4412	0.3805	0.1559
1988	0.1109	0.1099	0.1057	0.09663	0.08981	0.04412
1989	0.02912	0.02866	0.02658	0.02215	0.01923	0.009001
1990	0.08553	0.08355	0.07587	0.0616	0.05313	0.01983

Sorted results

Prob.	Peak	96 hr	21 Day	60 Day	90 Day	Yearly
0.032258064516129			7.509	7.344	6.666	5.416 4.692 2.106
0.0645161290322581			5.849	5.746	5.348	4.478 4.143 1.863
0.0967741935483871			4.858	4.774	4.423	3.942 3.914 1.755
0.129032258064516			4.628	4.521	4.186	3.424 2.962 1.119
0.161290322580645			3.711	3.633	3.324	2.724 2.361 1.053
0.193548387096774			2.902	2.842	2.597	2.132 1.999 0.8962
0.225806451612903			2.705	2.623	2.411	2.08 1.908 0.8387
0.258064516129032			2.621	2.58	2.395	1.959 1.697 0.7417
0.290322580645161			2.254	2.212	2.11	1.748 1.51 0.6051
0.32258064516129			1.999	1.973	1.825	1.513 1.314 0.6036
0.354838709677419			1.927	1.886	1.725	1.393 1.199 0.5759
0.387096774193548			1.435	1.419	1.354	1.222 1.126 0.5198
0.419354838709677			1.063	1.039	0.9768	0.8114 0.7557 0.4854
0.451612903225806			0.9183	0.8994	0.8361	0.7669 0.7087 0.396
0.483870967741936			0.9113	0.8987	0.8271	0.6889 0.6377 0.3775
0.516129032258065			0.8825	0.8664	0.8012	0.6841 0.5946 0.3381
0.548387096774194			0.7792	0.773	0.7472	0.6593 0.5722 0.3198
0.580645161290323			0.7281	0.7167	0.6819	0.5861 0.5184 0.2943
0.612903225806452			0.6738	0.6621	0.6153	0.5619 0.5181 0.2808
0.645161290322581			0.6437	0.6381	0.615	0.5286 0.4994 0.2598
0.67741935483871			0.6123	0.5988	0.544	0.4412 0.3845 0.2195
0.709677419354839			0.4867	0.4819	0.4621	0.4172 0.3805 0.157
0.741935483870968			0.3765	0.3696	0.3383	0.306 0.2846 0.1559
0.774193548387097			0.3447	0.3422	0.3319	0.2763 0.2394 0.1042

0.806451612903226	0.3362	0.3306	0.3074	0.2628	0.2355	0.09841
0.838709677419355	0.209	0.2042	0.1923	0.1746	0.1613	0.0877
0.870967741935484	0.2023	0.2004	0.1856	0.1521	0.1322	0.05641
0.903225806451613	0.1109	0.1099	0.1057	0.09663	0.08981	0.04412
0.935483870967742	0.08553	0.08355	0.07587	0.0616	0.05313	0.01983
0.967741935483871	0.02912	0.02866	0.02658	0.02215	0.01923	0.009001

0.1 4.835 4.7487 4.3993 3.8902 3.8188 1.6914
Average of yearly averages: 0.5460257

Inputs generated by pe4.pl - 8-August-2003

Data used for this run:

Output File: Mefluacidi

Metfile: w12834.dvf

PRZM scenario: FLturfC.txt

EXAMS environment file: pond298.exv

Chemical Name: Mefluidide

Description	Variable Name	Value	Units	Comments
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Molecular weight	mwt	310.6	g/mol	
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Henry's Law Const.	henry	2.27E-7	atm-m ³ /mol	
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Vapor Pressure vapr	1E-4	torr		
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Solubility	sol	180	mg/L	
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Kd	Kd	0.073	mg/L	
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Koc	Koc		mg/L	
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Photolysis half-life	kdp		days	Half-life
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Aerobic Aquatic Metabolism	kbacw	72	days	Halfife
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Anaerobic Aquatic Metabolism	kbacs		days	Halfife
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Aerobic Soil Metabolism	asm	36	days	Halfife
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Hydrolysis:	pH 7		days	Half-life
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Method: CAM 2 integer See PRZM manual

Incorporation Depth:	DEPI		cm	
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Application Rate:	TAPP	0.56	kg/ha	
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Application Efficiency:	APPEFF	1.00	fraction	
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Spray Drift	DRFT	0.0	fraction of application rate applied to pond	
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Application Date	Date	1-4	dd/mm or dd/mm/yy or dd-mm or dd-mm/yy	
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Interval 1	interval	42	days	Set to 0 or delete line for single app.
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Interval 2	interval	42	days	Set to 0 or delete line for single app.
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Record 17: FILTRA

 IPSCND 1

 UPTKF

Record 18: PLVKRT

 PLDKRT 0.1715

 FEXTRC 0.5

Flag for Index Res. Run	IR	Pond	
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Flag for runoff calc.	RUNOFF	none	none, monthly or total(average of entire run)
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PA TURF mefluidide-DEA

stored as MefluDEA.out

Chemical: Mefluidide

PRZM environment: PAturfC.txt modified Saturday, 12 October 2002 at 16:27:02

EXAMS environment: pond298.exv modified Thursday, 29 August 2002 at 16:33:30

Metfile: w14737.dvf modified Wednesday, 3 July 2002 at 09:06:12

Water segment concentrations (ppb)

Year	Peak	96 hr	21 Day	60 Day	90 Day	Yearly
1961	1.508	1.481	1.375	1.288	1.184	0.6653
1962	1.894	1.864	1.74	1.627	1.567	1.027
1963	1.689	1.663	1.549	1.395	1.353	0.9127
1964	1.64	1.616	1.507	1.342	1.309	0.861
1965	1.606	1.582	1.477	1.306	1.277	0.8369
1966	1.618	1.591	1.472	1.321	1.274	0.8173
1967	2.52	2.478	2.31	2.014	1.848	1.149
1968	3.188	3.157	3.052	2.893	2.82	1.641
1969	1.823	1.795	1.677	1.549	1.499	1.083
1970	10.34	10.26	9.907	9.204	8.608	4.205
1971	5.302	5.247	5.022	4.55	4.182	2.656
1972	2.679	2.641	2.464	2.311	2.18	1.537
1973	10.43	10.25	9.455	7.943	7.066	3.655
1974	4.838	4.792	4.605	4.369	4.183	2.896
1975	7.102	7.045	6.814	6.374	5.981	3.199
1976	5.928	5.872	5.64	5.283	4.982	2.834
1977	2.329	2.298	2.172	2.051	2.021	1.455
1978	5.93	5.872	5.592	5.087	4.753	2.412
1979	2.673	2.634	2.47	2.386	2.27	1.662
1980	1.753	1.726	1.601	1.465	1.403	0.9518
1981	2.388	2.359	2.239	2.1	1.963	1.108
1982	2.107	2.078	1.943	1.781	1.701	1.123
1983	1.87	1.84	1.719	1.599	1.527	0.9895
1984	6.622	6.507	6.052	5.134	4.63	2.621
1985	2.641	2.607	2.468	2.323	2.243	1.695
1986	2.182	2.148	2.018	1.904	1.816	1.182
1987	3.103	3.066	2.944	2.855	2.755	1.587
1988	2.9	2.866	2.718	2.551	2.358	1.403
1989	3.313	3.275	3.116	2.887	2.683	1.541
1990	2.244	2.208	2.074	1.949	1.867	1.252

Sorted results

Prob.	Peak	96 hr	21 Day	60 Day	90 Day	Yearly
0.032258064516129			10.43	10.26	9.907	9.204 8.608 4.205
0.0645161290322581			10.34	10.25	9.455	7.943 7.066 3.655
0.0967741935483871			7.102	7.045	6.814	6.374 5.981 3.199
0.129032258064516			6.622	6.507	6.052	5.283 4.982 2.896
0.161290322580645			5.93	5.872	5.64	5.134 4.753 2.834
0.193548387096774			5.928	5.872	5.592	5.087 4.63 2.656
0.225806451612903			5.302	5.247	5.022	4.55 4.183 2.621
0.258064516129032			4.838	4.792	4.605	4.369 4.182 2.412
0.290322580645161			3.313	3.275	3.116	2.893 2.82 1.695
0.32258064516129			3.188	3.157	3.052	2.887 2.755 1.662
0.354838709677419			3.103	3.066	2.944	2.855 2.683 1.641
0.387096774193548			2.9	2.866	2.718	2.551 2.358 1.587
0.419354838709677			2.679	2.641	2.47	2.386 2.27 1.541
0.451612903225806			2.673	2.634	2.468	2.323 2.243 1.537
0.483870967741936			2.641	2.607	2.464	2.311 2.18 1.455
0.516129032258065			2.52	2.478	2.31	2.1 2.021 1.403
0.548387096774194			2.388	2.359	2.239	2.051 1.963 1.252
0.580645161290323			2.329	2.298	2.172	2.014 1.867 1.182
0.612903225806452			2.244	2.208	2.074	1.949 1.848 1.149
0.645161290322581			2.182	2.148	2.018	1.904 1.816 1.123
0.67741935483871			2.107	2.078	1.943	1.781 1.701 1.108
0.709677419354839			1.894	1.864	1.74	1.627 1.567 1.083

0.741935483870968	1.87	1.84	1.719	1.599	1.527	1.027
0.774193548387097	1.823	1.795	1.677	1.549	1.499	0.9895
0.806451612903226	1.753	1.726	1.601	1.465	1.403	0.9518
0.838709677419355	1.689	1.663	1.549	1.395	1.353	0.9127
0.870967741935484	1.64	1.616	1.507	1.342	1.309	0.861
0.903225806451613	1.618	1.591	1.477	1.321	1.277	0.8369
0.935483870967742	1.606	1.582	1.472	1.306	1.274	0.8173
0.967741935483871	1.508	1.481	1.375	1.288	1.184	0.6653

0.1 7.054 6.9912 6.7378 6.2649 5.8811 3.1687
Average of yearly averages: 1.69858333333333

Inputs generated by pe4.pl - 8-August-2003

Data used for this run:

Output File: MefluDEA

Metfile: w14737.dvf

PRZM scenario: PAturfC.txt

EXAMS environment file: pond298.exv

Chemical Name: Mefluidide

Description	Variable Name	Value	Units	Comments
Molecular weight	mwt	310.6	g/mol	
Henry's Law Const.	henry	2.27E-7	atm-m ³ /mol	
Vapor Pressure	vapr	1E-4	torr	
Solubility	sol	180	mg/L	
Kd	Kd	0.073	mg/L	
Koc	Koc		mg/L	
Photolysis half-life	kdp		days	Half-life
Aerobic Aquatic Metabolism	kbacw	72	days	Halfife
Anaerobic Aquatic Metabolism	kbacs		days	Halfife
Aerobic Soil Metabolism	asm	36	days	Halfife
Hydrolysis:	pH 7		days	Half-life
Method: CAM	2	integer	See PRZM manual	
Incorporation Depth:	DEPI		cm	
Application Rate:	TAPP	1.12	kg/ha	
Application Efficiency:	APPEFF	0.99	fraction	
Spray Drift	DRFT	0.01	fraction of application rate applied to pond	
Application Date	Date	1-4	dd/mm or dd/mm ^{mm} or dd-mm or dd-mm ^{mm}	
Interval 1	interval	42	days	Set to 0 or delete line for single app.
Interval 2	interval	42	days	Set to 0 or delete line for single app.
Record 17:	FILTRA			
	IPSCND	1		
	UPTKF			
Record 18:	PLVKRT			
	PLDKRT	0.1715		
	FEXTRC	0.5		
Flag for Index Res. Run	IR		Pond	
Flag for runoff calc.	RUNOFF	none	none, monthly or total(average of entire run)	

PA TURF mefluidide-K

stored as MefluK.out

Chemical: Mefluidide

PRZM environment: PA turfC.txt modified Satday, 12 October 2002 at 15:27:02

EXAMS environment: pond298.exv modified Thuday, 29 August 2002 at 15:33:30

Metfile: w14737.dvf modified Wedday, 3 July 2002 at 08:06:12

Water segment concentrations (ppb)

Year	Peak	96 hr	21 Day	60 Day	90 Day	Yearly
1961	1.508	1.481	1.375	1.288	1.184	0.6653
1962	1.894	1.864	1.74	1.627	1.567	1.027
1963	1.689	1.663	1.549	1.395	1.353	0.9127
1964	1.64	1.616	1.507	1.342	1.309	0.861
1965	1.606	1.582	1.477	1.306	1.277	0.8369
1966	1.618	1.591	1.472	1.321	1.274	0.8173
1967	2.52	2.478	2.31	2.014	1.848	1.149
1968	3.188	3.157	3.052	2.893	2.82	1.641
1969	1.823	1.795	1.677	1.549	1.499	1.083
1970	10.34	10.26	9.907	9.204	8.608	4.205
1971	5.302	5.247	5.022	4.55	4.182	2.656
1972	2.679	2.641	2.464	2.311	2.18	1.537
1973	10.43	10.25	9.455	7.943	7.066	3.655
1974	4.838	4.792	4.605	4.369	4.183	2.896
1975	7.102	7.045	6.814	6.374	5.981	3.199
1976	5.928	5.872	5.64	5.283	4.982	2.834
1977	2.329	2.298	2.172	2.051	2.021	1.455
1978	5.93	5.872	5.592	5.087	4.753	2.412
1979	2.673	2.634	2.47	2.386	2.27	1.662
1980	1.753	1.726	1.601	1.465	1.403	0.9518
1981	2.388	2.359	2.239	2.1	1.963	1.108
1982	2.107	2.078	1.943	1.781	1.701	1.123
1983	1.87	1.84	1.719	1.599	1.527	0.9895
1984	6.622	6.507	6.052	5.134	4.63	2.621
1985	2.641	2.607	2.468	2.323	2.243	1.695
1986	2.182	2.148	2.018	1.904	1.816	1.182
1987	3.103	3.066	2.944	2.855	2.755	1.587
1988	2.9	2.866	2.718	2.551	2.358	1.403
1989	3.313	3.275	3.116	2.887	2.683	1.541
1990	2.244	2.208	2.074	1.949	1.867	1.252

Sorted results

Prob.	Peak	96 hr	21 Day	60 Day	90 Day	Yearly
0.032258064516129			10.43	10.26	9.907	9.204 8.608 4.205
0.0645161290322581			10.34	10.25	9.455	7.943 7.066 3.655
0.0967741935483871			7.102	7.045	6.814	6.374 5.981 3.199
0.129032258064516			6.622	6.507	6.052	5.283 4.982 2.896
0.161290322580645			5.93	5.872	5.64	5.134 4.753 2.834
0.193548387096774			5.928	5.872	5.592	5.087 4.63 2.656
0.225806451612903			5.302	5.247	5.022	4.55 4.183 2.621
0.258064516129032			4.838	4.792	4.605	4.369 4.182 2.412
0.290322580645161			3.313	3.275	3.116	2.893 2.82 1.695
0.32258064516129			3.188	3.157	3.052	2.887 2.755 1.662
0.354838709677419			3.103	3.066	2.944	2.855 2.683 1.641
0.387096774193548			2.9	2.866	2.718	2.551 2.358 1.587
0.419354838709677			2.679	2.641	2.47	2.386 2.27 1.541
0.451612903225806			2.673	2.634	2.468	2.323 2.243 1.537
0.483870967741936			2.641	2.607	2.464	2.311 2.18 1.455
0.516129032258065			2.52	2.478	2.31	2.1 2.021 1.403
0.548387096774194			2.388	2.359	2.239	2.051 1.963 1.252
0.580645161290323			2.329	2.298	2.172	2.014 1.867 1.182
0.612903225806452			2.244	2.208	2.074	1.949 1.848 1.149
0.645161290322581			2.182	2.148	2.018	1.904 1.816 1.123
0.67741935483871			2.107	2.078	1.943	1.781 1.701 1.108

0.709677419354839	1.894	1.864	1.74	1.627	1.567	1.083
0.741935483870968	1.87	1.84	1.719	1.599	1.527	1.027
0.774193548387097	1.823	1.795	1.677	1.549	1.499	0.9895
0.806451612903226	1.753	1.726	1.601	1.465	1.403	0.9518
0.838709677419355	1.689	1.663	1.549	1.395	1.353	0.9127
0.870967741935484	1.64	1.616	1.507	1.342	1.309	0.861
0.903225806451613	1.618	1.591	1.477	1.321	1.277	0.8369
0.935483870967742	1.606	1.582	1.472	1.306	1.274	0.8173
0.967741935483871	1.508	1.481	1.375	1.288	1.184	0.6653

0.1 7.054 6.9912 6.7378 6.2649 5.8811 3.1687
Average of yearly averages: 1.69858333333333

Inputs generated by pe4.pl - 8-August-2003

Data used for this run:

Output File: MefluK

Metfile: w14737.dvf

PRZM scenario: PATurfC.txt

EXAMS environment file: pond298.exv

Chemical Name: Mefluidide

Description	Variable Name	Value	Units	Comments
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Molecular weight	mwt	310.6	g/mol	
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Henry's Law Const.	henry	2.27E-7	atm-m ³ /mol	
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Vapor Pressure	vapr	1E-4	torr	
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Solubility	sol	180	mg/L	
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Kd	Kd	0.073	mg/L	
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Koc	Koc		mg/L	
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Photolysis half-life	kdp		days	Half-life
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Aerobic Aquatic Metabolism	kbacw	72	days	Halfife
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Anaerobic Aquatic Metabolism	kbacs		days	Halfife
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Aerobic Soil Metabolism	asm	36	days	Halfife
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Hydrolysis:	pH 7		days	Half-life
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Method: CAM 2 integer See PRZM manual

Incorporation Depth:	DEPI		cm	
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Application Rate:	TAPP	1.12	kg/ha	
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Application Efficiency:	APPEFF	0.99	fraction	
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Spray Drift	DRFT	0.01	fraction of application rate applied to pond	
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Application Date	Date	1-4	dd/mm or dd/mm or dd-mm or dd-mmm	
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Interval 1	interval	42	days	Set to 0 or delete line for single app.
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Interval 2	interval	42	days	Set to 0 or delete line for single app.
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Record 17: FILTRA

 IPSCND 1

 UPTKF

Record 18: PLVKRT

 PLDKRT 0.1715

 FEXTRC 0.5

Flag for Index Res. Run IR Pond

Flag for runoff calc. RUNOFF none none, monthly or total(average of entire run)

PA TURF mefluidide

stored as Mefluacid.out

Chemical: Mefluidide

PRZM environment: PA turfC.txt modified Satday, 12 October 2002 at 16:27:02

EXAMS environment: pond298.exv modified Thuday, 29 August 2002 at 16:33:30

Metfile: w14737.dvf modified Wedday, 3 July 2002 at 09:06:12

Water segment concentrations (ppb)

Year	Peak	96 hr	21 Day	60 Day	90 Day	Yearly			
1961	0.2013	0.1977	0.1837	0.1572	0.141	0.06874			
1962	0.3033	0.3007	0.291	0.265	0.243	0.1292			
1963	0.06957	0.06934	0.06838	0.06625	0.06425	0.03723			
1964	0.02459	0.0244	0.02365	0.02181	0.0201	0.01287			
1965	0.006556		0.006535		0.006445		0.006245	0.006063	0.003507
1966	0.001198		0.001194		0.001178		0.001142	0.001107	0.0007252
1967	0.5128	0.5042	0.4697	0.4045	0.3667	0.1522			
1968	0.9759	0.9672	0.9291	0.8587	0.7887	0.3996			
1969	0.2438	0.243	0.2397	0.2322	0.2251	0.1299			
1970	4.701	4.666	4.505	4.108	3.775	1.704			
1971	1.972	1.952	1.868	1.635	1.465	0.9264			
1972	0.6406	0.6321	0.5955	0.5166	0.4622	0.3636			
1973	4.493	4.414	4.073	3.421	3.043	1.441			
1974	1.962	1.943	1.868	1.697	1.565	1.058			
1975	3.083	3.059	2.958	2.691	2.461	1.205			
1976	2.504	2.481	2.382	2.164	1.981	1.031			
1977	0.5919	0.5865	0.5663	0.5151	0.5046	0.333			
1978	2.308	2.287	2.179	1.926	1.775	0.8143			
1979	0.6768	0.6705	0.6519	0.6315	0.6109	0.4296			
1980	0.184	0.1834	0.1809	0.1753	0.17	0.09462			
1981	0.5482	0.5415	0.5138	0.4424	0.3929	0.1747			
1982	0.3024	0.2988	0.2824	0.246	0.2211	0.149			
1983	0.21	0.2082	0.2015	0.1855	0.1727	0.09921			
1984	2.558	2.513	2.339	1.984	1.768	0.9311			
1985	0.8114	0.8088	0.7976	0.7681	0.7392	0.4633			
1986	0.4099	0.4043	0.3805	0.3328	0.2998	0.1956			
1987	1.062	1.053	1.014	0.9196	0.8384	0.3995			
1988	0.7952	0.7858	0.7451	0.6441	0.5769	0.3123			
1989	0.9959	0.9843	0.9364	0.8137	0.7298	0.3742			
1990	0.4174	0.4126	0.3863	0.3501	0.3269	0.2328			

Sorted results

Prob.	Peak	96 hr	21 Day	60 Day	90 Day	Yearly			
0.032258064516129			4.701	4.666	4.505	4.108	3.775	1.704	
0.0645161290322581			4.493	4.414	4.073	3.421	3.043	1.441	
0.0967741935483871			3.083	3.059	2.958	2.691	2.461	1.205	
0.129032258064516			2.558	2.513	2.382	2.164	1.981	1.058	
0.161290322580645			2.504	2.481	2.339	1.984	1.775	1.031	
0.193548387096774			2.308	2.287	2.179	1.926	1.768	0.9311	
0.225806451612903			1.972	1.952	1.868	1.697	1.565	0.9264	
0.258064516129032			1.962	1.943	1.868	1.635	1.465	0.8143	
0.290322580645161			1.062	1.053	1.014	0.9196	0.8384	0.4633	
0.32258064516129			0.9959	0.9843	0.9364	0.8587	0.7887	0.4296	
0.354838709677419			0.9759	0.9672	0.9291	0.8137	0.7392	0.3996	
0.387096774193548			0.8114	0.8088	0.7976	0.7681	0.7298	0.3995	
0.419354838709677			0.7952	0.7858	0.7451	0.6441	0.6109	0.3742	
0.451612903225806			0.6768	0.6705	0.6519	0.6315	0.5769	0.3636	
0.483870967741936			0.6406	0.6321	0.5955	0.5166	0.5046	0.333	
0.516129032258065			0.5919	0.5865	0.5663	0.5151	0.4622	0.3123	
0.548387096774194			0.5482	0.5415	0.5138	0.4424	0.3929	0.2328	
0.580645161290323			0.5128	0.5042	0.4697	0.4045	0.3667	0.1956	
0.612903225806452			0.4174	0.4126	0.3863	0.3501	0.3269	0.1747	
0.645161290322581			0.4099	0.4043	0.3805	0.3328	0.2998	0.1522	
0.67741935483871			0.3033	0.3007	0.291	0.265	0.243	0.149	

```

0.709677419354839      0.3024 0.2988 0.2824 0.246 0.2251 0.1299
0.741935483870968      0.2438 0.243 0.2397 0.2322 0.2211 0.1292
0.774193548387097      0.21    0.2082 0.2015 0.1855 0.1727 0.09921
0.806451612903226      0.2013 0.1977 0.1837 0.1753 0.17    0.09462
0.838709677419355      0.184   0.1834 0.1809 0.1572 0.141   0.06874
0.870967741935484      0.06957 0.06934 0.06838 0.06625 0.06425 0.03723
0.903225806451613      0.02459 0.0244 0.02365 0.02181 0.0201 0.01287
0.935483870967742      0.006556      0.006535      0.006445      0.006245      0.006063
      0.003507
0.967741935483871      0.001198      0.001194      0.001178      0.001142      0.001107
      0.0007252

0.1      3.0305 3.0044 2.9004 2.6383 2.413 1.1903
      Average of yearly averages: 0.455540073333333

```

Inputs generated by pe4.pl - 8-August-2003

Data used for this run:

Output File: Mefluacid

Metfile: w14737.dvf

PRZM scenario: PAturfC.txt

EXAMS environment file: pond298.exv

Chemical Name: Mefluidide

Description	Variable Name	Value	Units	Comments
Molecular weight	mwt	310.6	g/mol	
Henry's Law Const.	henry	2.27E-7	atm-m ³ /mol	
Vapor Pressure	vapr	1E-4	torr	
Solubility	sol	180	mg/L	
Kd	Kd	0.073	mg/L	
Koc	Koc		mg/L	
Photolysis half-life	kdp		days	Half-life
Aerobic Aquatic Metabolism	kbacw	72	days	Halfife
Anaerobic Aquatic Metabolism	kbacs		days	Halfife
Aerobic Soil Metabolism	asm	36	days	Halfife
Hydrolysis:	pH 7		days	Half-life
Method: CAM	2	integer		See PRZM manual
Incorporation Depth:	DEPI		cm	
Application Rate:	TAPP	0.56	kg/ha	
Application Efficiency:	APPEFF	1.00	fraction	
Spray Drift	DRFT	0.00	fraction of application rate applied to pond	
Application Date	Date	1-4	dd/mm or dd/mm or dd-mm or dd-mmm	
Interval 1	interval	42	days	Set to 0 or delete line for single app.
Interval 2	interval	42	days	Set to 0 or delete line for single app.
Record 17:	FILTRA			
	IPSCND	1		
	UPTKF			
Record 18:	PLVKRT			
	PLDKRT	0.1715		
	FEXTRC	0.5		
Flag for Index Res. Run	IR	Pond		
Flag for runoff calc.	RUNOFF	none	none, monthly or total(average of entire run)	

Appendix D Terrestrial Exposure Modeling TREX and Terrplant

TREX MODEL OUTPUTS

TREX (Version 1.3.1)

2006

As part of the terrestrial assessment, EFED modeled exposure concentrations of Mefluidide, Mefluidide-K and Mefluidide-DEA to non-target animals following the proposed application rates provided by the registrant. For terrestrial birds and mammals, estimates of initial levels of Mefluidide, Mefluidide-K and Mefluidide-DEA residues on various food items, which may be contacted or consumed by wildlife, were determined using the Kenega-Fletcher nomogram followed by a first order decline model TREX 1.3.1. Upper bound and Mean Kenega-Fletcher values were used for RQ calculations.

T-REX Calculations and Results

Risk Estimation Based on Dietary Residue Concentrations (Foliar Spray)

The methods used by T-REX to estimate risk from consumption of selected contaminated food items is described below. For this analysis, T-REX calculates EECs and risk quotients based on both the upper bound and mean residue concentrations as presented by Hoerger and Kenaga (1972) and modified by Fletcher *et al.* (1994). These concentrations are determined using nomograms that relate application rate of a pesticide to residues remaining on dietary items of terrestrial organisms. The results of the upper bound and mean residue levels are presented in separate tabs (“upper bound Kenega” and “mean Kenega”); however, the methods used to calculate EECs and risk quotients are equivalent. Based on the estimated dietary residue concentrations from the upper bound and mean Kenega values, T-REX calculates the associated doses for various size classes of birds and mammals.

T-REX estimates the following: (1) residue concentrations on selected food items (mg/kg-dietary item); (2) dose-based EECs (mg/kg-bw) from dietary concentrations on selected food items; (3) adjusted toxicity values; and (4) risk quotients.

Calculation of dietary concentrations on selected food items

The spreadsheet calculates the pesticide residue concentrations on each selected food item on a daily interval for one year. When multiple applications are modeled, residue concentrations resulting from the final application and remaining residue from previous applications are summed. The maximum concentration calculated out of the 365 days is returned as the EEC used to estimate potential risk to birds and mammals as described below. Dissipation of a chemical applied to foliar surfaces for single or multiple applications is calculated assuming a first order decay rate from the following first order rate equation:

$$C_t = C_0 e^{-kt}$$

or in log form:

$$\ln(C_t) = \ln(C_0) - kT$$

Where:

C_t = concentration, parts per million (ppm), at time T.

C_0 = concentration (ppm), present initially (on day zero) on the surface of selected food items. C_0 is calculated by multiplying the application rate, in pounds active ingredient per acre, by 240 for short grass, 110 for tall grass, and 135 for broad-leaved plants/small insects and 15 for fruits/pods/large insects for upper bound residue levels. Mean residue levels are derived by multiplying the application rate by 85 for short grass, 36 for tall grass, and 45 for broad-leaved plants/small insects and 7 for fruits/pods/seeds/large insects. Residue levels are based on work by Hoerger and Kenaga (1972) as modified by Fletcher *et al.* (1994). Additional applications are converted from pounds active ingredient per acre to ppm on the plant surface and the additional mass added to the mass of the chemical still present on the surfaces on the day of application.

k = Exponential rate constant = $\ln 2 \div$ foliar dissipation half-life. This value is in cell Q16 of the upper bound and mean Kenaga worksheets of TREX. If the foliar dissipation data submitted to EFED are found scientifically valid and statistically robust for a specific pesticide, the 90% upper confidence limit of the mean half-lives should be used. When scientifically valid, statistically robust data are not available, EFED recommends the using a default foliar dissipation half-life value of 35 days. The use of the 35-day half-life is based on the highest reported value (36.9 days), as reported by Willis and McDowell (1987). However in this assessment a 4 day foliar half life was used.

t = time, in days, since the start of the simulation. The initial application is on day 0. The simulation is designed to run for 365 days.

The dietary concentrations estimated using the above methodology may be used directly to calculate risk quotients, but may also be used to calculate dose-based EECs (mg/kg-bw) for various size classes of mammals and birds .

Calculating EEC Equivalent Doses based on Estimated Dietary Concentrations on Selected Bird and Mammal Food Items

EECs (mg/kg-bw) for various size classes of mammals and birds may be calculated based on the dietary residue concentrations derived using the equations presented above. To allow for this type of analysis, the EECs and toxicity values are adjusted based on food intake and body

weight differences so that they are comparable for a given weight class of animal. The size classes assessed are small (20-gram), medium (100-gram), and large (1000-gram) birds, and small (15-gram), medium (35-gram), and large (1000-gram) mammals. Equations used to calculate food intake (grams/day) and to adjust toxicity values for dose-based risk quotients are presented below.

Calculating Food Intake for Different Size Classes of Birds and Mammals:

Daily food intake (g/day) is assumed to correlate with body weight using the following empirically derived equation (U.S. EPA, 1993):

Avian consumption

$$F = \frac{0.648 * BW^{0.651}}{(1 - W)}$$

where:

F = food intake in grams of fresh weight per day (g/day)

BW = body mass of animal (g)

W = mass fraction of water in the food (EFED value = 0.8 for birds and herbivorous mammals, 0.1 for granivorous mammals)

Based on this equation, a 20-gram bird would consume 22.8 grams of food daily (114% of its body weight), a 100-gram bird would consume 65 grams of food daily (65% of its body weight daily), and 1000-gram bird would consume 290 grams of food daily (29% of its body weight). These data, together with the residue concentrations (mg/kg-food item) on selected food items calculated from the Kenaga nomogram, are used to estimate the dose (mg/kg-bw) of residue consumed by the three size classes of birds as discussed below. Using a small (20-gram) bird as an example, a dietary concentration of 100 mg/kg-diet (ppm) x 1.14 kg diet/kg bw (114%) would result in an equivalent dose-based EEC of 114 mg/kg-bw. T-REX calculates food intake based on dry weight and wet weight of food items. The dose-based assessment uses the wet weight food consumption values by assuming that dietary items are 80% water by weight. However, if dietary items of a species being assessed are known, then a refined dose-based EEC can be calculated using appropriate water fractions of the food items.

A similar relationship between body weight and food intake has been derived for mammals (U.S. EPA 1993):

Mammalian food consumption (g/day)

$$F = \frac{0.621 * BW^{0.564}}{(1 - W)}$$

where:

F = food intake in grams of fresh weight per day (g/day)

BW = body mass of animal (g)

W = mass fraction of water in the food (EFED value = 0.8 for birds and herbivorous mammals, 0.1 for granivorous mammals)

The scaling factors result in a percent body weight consumed presented in the following table for each weight class of mammal. These values are used in the same manner described for birds to calculate dose-based EECs (mg/kg-bw). Note the difference in food intake of granivores compared with herbivores and insectivores. This is caused by the difference in the assumed mass fraction of water in their diets.

Organism and body weight	Food intake (g day ⁻¹) ^a	Percent body weight consumed (day ⁻¹) ^a
15 g	14.3 / 3.2	95 / 21
35 g	23 / 5.1	66 / 15
1000 g	150 / 34	15 / 3

^a The first number in this column is specific to herbivores/insectivores. The second number is for granivores. These groups have markedly different consumption requirements.

T-REX calculates food intake based on dry weight and wet weight of food items (wet weight is used for RQ calculations). The dose-based assessment uses the wet weight food consumption values by assuming that dietary items are 80% water by weight (10% for granivores). However, if dietary items of a species being assessed are known, then a refined dose-based EEC can be calculated using appropriate water fractions of the food items.

Calculating Adjusted Toxicity Values

The dose-based EECs (mg/kg-bw) derived above are compared with LD₅₀ or NOAEL (mg/kg-bw) values from acceptable or supplemental toxicity studies that are adjusted for the size of the animal tested compared with the size of the animal being assessed (e.g., 20-gram bird). These exposure values are presented as mass of pesticide consumed per kg body weight of the animal being assessed (mg/kg-bw). EECs and toxicity values are relative to the animal's body weight (mg residue/kg bw) because consumption of the same mass of pesticide residue results in a higher body burden in smaller animals compared with larger animals. For birds, only acute values (LD₅₀s) are adjusted because dose-based risk quotients are not calculated for the chronic risk estimation. Adjusted mammalian LD₅₀s and reproduction NOAELs (mg/kg-bw) are used to calculate dose-based acute and chronic risk quotients for 15-, 35-, and 1000-gram mammals. The following equations are used for the adjustment (U.S. EPA 1993):

$$\text{Adjusted avian LD}_{50}: \text{Adj. LD}_{50} = \text{LD}_{50} \left(\frac{AW}{TW} \right)^{(x-1)}$$

where:

Adj. LD₅₀ = adjusted LD₅₀ (mg/kg-bw) calculated by the equation
 LD₅₀ = endpoint reported from bird study (mg/kg-bw)
 TW = body weight of tested animal (178g bobwhite; 1580g mallard; 350g rat)
 AW = body weight of assessed animal (avian: 20g, 100g, and 1000g)
 x = Mineau scaling factor for birds; EFED default 1.15

Adjusted mammalian NOAELs and LD₅₀s (note that the same equation is used to adjust the NOAEL): $Adj. NOAEL \text{ or } LD_{50} = NOAEL \text{ or } LD_{50} \left(\frac{TW}{AW} \right)^{(0.25)}$

where:

Adj. NOAEL or LD₅₀ = adjusted NOAEL or LD₅₀ (mg/kg-bw)
 NOAEL or LD₅₀ = endpoint reported from animal study (mg/kg-bw)
 TW = body weight of tested animal (350g for chronic mammal based on the rat) TREX does not incorporate in the model different mammal TW. Therefore, the above calculation was used and incorporated in model (replaced the 350 g to 20 g in the formula equations) with the TW of 20 g for acute mammal based on the laboratory mouse with 829.8mg ae/kg bw LD₅₀ to derive the adjusted toxicity values for acute mammals for each body weight class.
 AW = body weight of assessed animal (15g, 35g, 1000g)

Calculating Risk Quotients

Two types of risk quotients are calculated by T-REX based on the estimated dietary residue concentrations determined from the Kenaga nomogram: (1) dietary based RQs; and (2) dose based RQs. These RQs are not equivalent. Dietary risk quotients are calculated by directly comparing the concentration of a pesticide administered (or estimated to be administered) to experimental animals in the diet in a toxicity study to the concentration estimated to be on selected food items. These risk quotients do not account for the fact that smaller-sized animals need to consume more food relative to their body weight than larger animals or that differential amounts of food are consumed depending on the water content and nutritive value of the food. The dose-based risk quotients do account for these factors. The dose-based RQs incorporate the ingestion rate-adjusted exposure from the various food items to the different weight classes of birds and the weight class-scaled toxicity endpoints. Formulas presented in Table 1 are used to calculate dose-based and dietary based risk quotients:

Duration	Dose or Dietary RQ	Surrogate Organism	Equation
Acute	Dose-based	Birds and mammals	Acute Daily Exposure (mg/kg-bw) / adjusted LD ₅₀ (mg/kg-bw)
	Dietary-	Birds	Kenaga EEC (mg/kg-food item) / LC ₅₀ (mg/kg-

	based		diet)
Chronic	Dietary-based	Birds and mammals	EEC (mg/kg-food item) / NOAEC (mg/kg-diet)
	Dose-based	Mammals only	EEC (mg/kg-bw) / Adjusted NOAEL (mg/kg-bw)

These risk quotients are compared to the Agency's LOCs to determine if risk is greater than EFED's concern level.

Granular LD50 per square foot

Mammalian LD50 per Square Foot 0.5 lbs ae A	
Based on acute mouse LD ₅₀ 829.8 mg /kg bw, 4 day half life, 42 day interval and 3 applications per season	
Size Class (grams)	Broadcast LD50 per Square Foot
15	0.39
35	0.21
1000	0.02

Upper Bound and Mean Kenaga 1.0 lbs ae/A application Rate based on acute mouse LD₅₀ 829.8 mg/kg bw, 4 day half life, 42 day interval and 3 applications per season

Upper 90th Percentile Kenaga, Acute Mammalian Dose-Based Risk Quotients 1.0 Lbs ae/A											
Based on acute mouse LD ₅₀ 829.8, 4 day half life, 42 day interval and 3 applications per season											
Size Class (grams)	Adjusted LD50	EECs and RQs									
		Short Grass		Tall Grass		Broadleaf Plants/ Small Insects		Fruits/Pods/ Seeds/ Large Insects		Granivore	
		EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ
15	891.68	228.98	0.26	104.95	0.12	128.80	0.14	14.31	0.02	3.18	0.00
35	721.46	158.26	0.22	72.53	0.10	89.02	0.12	9.89	0.01	2.20	0.00
1000	312.05	36.69	0.12	16.82	0.05	20.64	0.07	2.29	0.01	0.51	0.00

Mean Kenega, Acute Mammalian Dose-Based Risk Quotients 1.0 Lbs ae/A											
Based on acute mouse LD ₅₀ 829.8, 4 day half life, 42 day interval and 3 applications per season											
Size Class (grams)	Adjusted LD50	EECs and RQs									
		Short Grass		Tall Grass		Broadleaf Plants/ Small Insects		Fruits/Pods/ Seeds/ Large Insects		Granivore	
		EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ
15	891.68	80.81	0.091	34.22	0.038	42.78	0.048	6.65	0.007	1.47	0.00
35	721.46	56.14	0.078	23.78	0.033	29.72	0.041	4.62	0.006	1.05	0.00
1000	312.05	12.76	0.041	5.40	0.017	6.75	0.022	1.05	0.003	0.21	0.00

Upper Bound and Mean Kenega 1.0 lbs ae/A application Rate based on Chronic rat NOAEL 102 mg ae/A, 4 day half life, 42 day interval and 3 applications per season

Upper 90th Percentile Kenega, Chronic Mammalian Dietary Based Risk Quotients									
1.0 lbs ae/A application Rate based on Chronic rat NOAEL 102 mg ae/A, 4 day half life, 42 day interval and 3 applications per season									
NOAEC (ppm)	EECs and RQs								
	Short Grass		Tall Grass		Broadleaf Plants/ Small Insects		Fruits/Pods/ Seeds/ Large Insects		
	EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ	
2040	240.17	0.12	110.08	0.05	135.09	0.07	15.01	0.01	

Size class not used for dietary risk quotients

Upper 90th Percentile Kenega, Chronic Mammalian Dose-Based Risk Quotients											
1.0 lbs ae/A application Rate based on Chronic rat NOAEL 102 mg ae/A, 4 day half life, 42 day interval and 3 applications per season											
Size Class (grams)	Adjusted NOAEL	EECs and RQs									
		Short Grass		Tall Grass		Broadleaf Plants/ Small Insects		Fruits/Pods/ Seeds/ Large Insects		Granivore	
		EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ
15	224.18	228.98	1.02	104.95	0.47	128.80	0.57	14.31	0.06	3.18	0.01
35	181.38	158.26	0.87	72.53	0.40	89.02	0.49	9.89	0.05	2.20	0.01
1000	78.45	36.69	0.47	16.82	0.21	20.64	0.26	2.29	0.03	0.51	0.01

Mean Kenega, Chronic Mammalian Dietary Based Risk Quotients								
1.0 lbs ae/A application Rate based on Chronic rat NOAEL 102 mg ae/A, 4 day half life, 42 day interval and 3 applications per season								
NOAEC (ppm)	EECs and RQs							
	Short Grass		Tall Grass		Broadleaf Plants/ Small Insects		Fruits/Pods/ Seeds/ Large Insects	
	EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ
2040	85.06	0.04	36.02	0.018	45.03	0.022	7.00	0.003

Size class not used for dietary risk quotients

Mean Kenega, Chronic Mammalian Dose-Based Risk Quotients											
1.0 lbs ae/A application Rate based on Chronic rat NOAEL 102 mg ae/A, 4 day half life, 42 day interval and 3 applications per season											
Size Class (grams)	Adjusted NOAEL	EECs and RQs									
		Short Grass		Tall Grass		Broadleaf Plants/ Small Insects		Fruits/Pods/ Seeds/ Large Insects		Granivore	
		EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ
15	224.18	80.81	0.36	34.22	0.153	42.78	0.191	6.65	0.030	1.47	0.01
35	181.38	56.14	0.31	23.78	0.131	29.72	0.164	4.62	0.025	1.05	0.01
1000	78.45	12.76	0.163	5.40	0.069	6.75	0.086	1.05	0.013	0.21	0.00

Avian Granular LD50 per square foot

Avian LD50 per Square Foot 0.5 lbs ae A		
Based on acute bird LD ₅₀ >1500 mg ae /kg bw, 4 day half life, 42 day interval and 3 applications per season		
Size Class (grams)	Adjusted LD50	Broadcast LD50 per Square Foot
20	1080.64	0.24
100	1375.71	0.04
1000	1943.25	0.00

Upper Bound and Mean Kenega 1.0 lbs ae/A application Rate based on acute avian LD₅₀ >1500 mg/kg bw, 4 day half life, 42 day interval and 3 applications per season

Upper 90th Percentile Kenega, Acute Avian Dose-Based Risk Quotients
1.0 lbs ae/A application Rate based on acute bird LD ₅₀ >1500 mg ae/kg bw, 4 day half life, 42 day interval and 3 applications per season

Size Class (grams)	Adjusted LD50	EECs and RQs							
		Short Grass		Tall Grass		Broadleaf Plants/ Small Insects		Fruits/Pods/ Seeds/ Large Insects	
		EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ
20	1080.64	273.52	0.25	125.37	0.12	153.86	0.14	17.10	0.02
100	1375.71	155.98	0.11	71.49	0.05	87.74	0.06	9.75	0.01
1000	1943.25	69.83	0.04	32.01	0.02	39.28	0.02	4.36	0.00

Upper 90th Percentile Kenega, Subacute Avian Dietary Based Risk Quotients									
1.0 lbs ae/A application									
LC50	EECs and RQs								
	Short Grass		Tall Grass		Broadleaf Plants/ Small Insects		Fruits/Pods/ Seeds/ Large Insects		
	EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ	
3750	240.17	0.06	110.08	0.03	135.09	0.04	15.01	0.00	

Mean Kenega, Acute Avian Dose-Based Risk Quotients									
1.0 lbs ae/A application Rate based on acute bird >1500 mg ae/kg bw, 4 day half life, 42 day interval and 3 applications per season									
Size Class (grams)	Adjusted LD50	EECs and RQs							
		Short Grass		Tall Grass		Broadleaf Plants/ Small Insects		Fruits/Pods/ Seeds/ Large Insects	
		EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ
20	1080.64	96.97	0.090	41.07	0.038	51.34	0.048	7.99	0.007
100	1375.71	55.29	0.040	23.42	0.017	29.27	0.021	4.55	0.003
1000	1943.25	24.67	0.013	10.45	0.005	13.06	0.007	2.03	0.001

Mean Kenega, Subacute Avian Dietary Based Risk Quotients									
1.0 lbs ae/A application									
LC50	EECs and RQs								

	Short Grass		Tall Grass		Broadleaf Plants/ Small Insects		Fruits/Pods/ Seeds/ Large Insects	
	EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ
3750	85.06	0.023	36.02	0.010	45.03	0.012	7.00	0.002

Upper Bound and Mean Kenega 1.0 lbs ae/A application Rate based on Chronic bird NOAEL= 38 mg ae/kg, 4 day half life, 42 day interval and 3 applications per season

Upper 90th Percentile Kenega, Chronic Avian Dietary Based Risk Quotients								
1.0 lbs ae/A application Rate based on chronic bird = 38 mg ae/kg , 4 day half life, 42 day interval and 3 applications per season								
NOAEC (ppm)	EECs and RQs							
	Short Grass		Tall Grass		Broadleaf Plants/ Small Insects		Fruits/Pods/ Seeds/ Large Insects	
	EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ
38	240.17	6.32	110.08	2.90	135.09	3.56	15.01	0.40

Mean Kenega, Chronic Avian Dietary Based Risk Quotients								
1.0 lbs ae/A application Rate based on Chronic bird = 38 mg ae/A, 4 day half life, 42 day interval and 3 applications per season								
NOAEC (ppm)	EECs and RQs							
	Short Grass		Tall Grass		Broadleaf Plants/ Small Insects		Fruits/Pods/ Seeds/ Large Insects	
	EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ
38	85.06	2.238	36.02	0.948	45.03	1.185	7.00	0.184

TERRPLANT MODEL

(November 9, 2005; version 1.2.1)

Terrestrial plant exposure characterization employs runoff and spray drift scenarios contained in OPP's Terrplant model. Exposure calculations are based on a pesticide's water solubility and the amount of pesticide present on the surface soil within the first inch of depth. For dry areas, the loading of pesticide active ingredient or acid equivalent from runoff to an adjacent non-target area is assumed to occur from one acre of treatment to one acre of non-target area. For terrestrial plants inhabiting semi-aquatic (wetland) areas, runoff is considered to occur from a larger source area with active ingredient loading originating from 10 acres of treated area to a single acre of non-target wetland. Default spray drift assumptions are 1% for ground applications and 5% for aerial, forced air (i.e., air pressure within a spray tank that forces the spray liquid through the boom nozzles), and chemigation applications. Predicted EECs resulting from spray drift and aerial applications are derived for non-granular applications only.

**TERRPLANT
MEFLUIDIDE-K, MEFLUIDIDE-DEA (1.0 lbs ae/A)
GROUND SPRAY ONLY**

**Terrestrial Plant EECs and Acute Non Endangered RQs
(November 9, 2005; version 1.2.1)**

Input
Values

Application Rate (lb a.e./acre)	1.0	Estimated Environmental Concentrations (EECs) for NON-GRANULAR formulation applications (lbs a.i./acre)				Risk Quotients (RQs) for NON-GRANULAR formulation applications		
Runoff Value (0.01, 0.02, or 0.05 if chemical solubility <10, 10-100, or >100 ppm, respectively)	0.05	Applica tion Method	Total Loading to Adjacent Areas (EEC = Sheet Runoff +Drift)	Total Loading to Semi- aquatic Areas (EEC = Channelized Runoff + Drift)	DRIFT EEC*	Emergence RQs, Adjacent Areas RQ = EEC/Seedling Emergence EC25	Emergence RQs, Semi-aquatic Areas RQ = EEC/Seedling Emergence EC25	Drift RQs RQ = Drift EEC/ Vegetative Vigor EC25

Minimum Incorporation Depth (cm)	0	Ground Unincorp.	0.600	0.5100	0.100	Monocot	Dicot	Monocot	Dicot	Monocot	Dicot
						0.571	11.11	4.86	94.44	0.10	1.85
Seed Emerg Monocot EC25 (lb a.e./acre)	0.105	Ground Incorp	0.600	0.5100	0.100	0.571	11.11	4.86	94.44	0.10	1.85
Seed Emerg Dicot EC25 (lb a.e./acre)	0.0054										
Veg Vigor Monocot EC25 (lb a.e./acre)	0.105										
Veg Vigor Dicot EC25 (lb a.e./acre)	0.0054										

**TERRPLANT
MEFLUIDIDE-K, MEFLUIDIDE-DEA (1.0 lbs ae/A)
GROUND SPRAY ONLY**

**Terrestrial Plant EECs and Acute Endangered RQs
(November 9, 2005; version 1.2.1)**

Input
Values

Application Rate (lb a.e./acre)	1.0	Estimated Environmental Concentrations (EECs) for NON-GRANULAR formulation applications (lbs a.i./acre)				Risk Quotients (RQs) for NON-GRANULAR formulation applications					
Runoff Value (0.01, 0.02, or 0.05 if chemical solubility <10, 10-100, or >100 ppm, respectively)	0.05	Applica tion Method	Total Loading to Adjacent Areas (EEC = Sheet Runoff +Drift)	Total Loading to Semi- aquatic Areas (EEC = Channelized Runoff + Drift)	DRIFT EEC*	Emergence RQs, Adjacent Areas RQ = EEC/Seedling Emergence EC05 or NOAEC		Emergence RQs, Semi-aquatic areas RQ = EEC/Seedling Emergence EC05 or NOAEC		Drift RQs RQ = EEC/ Vegetative Vigor EC05 or NOAEC	
Minimum Incorporation Depth (cm)	0					Ground Unincorp.	0.600	0.5100	0.100	Monocot	Dicot
Seed Emerg Monocot EC05 or NOAEC (lb a.e./acre)	0.105	Ground Incorp	0.600	0.5100	0.100	1.333	20.69	11.33	175.86	0.22	3.45

Seed Emerg Dicot EC05 or NOAEC (lb a.e./acre)	0.0054
Veg Vigor Monocot EC05 or NOAEC (lbs a.e./acre)	0.105
Veg Vigor Dicot EC05 or NOAEC (lb a.e./acre)	0.0029

**TERRPLANT
MEFLUIDIDE (0.5 lbs ae/A) GRANULAR
APPLICATION ONLY**

**Terrestrial Plant EECs and Acute Non Endangered RQs
(November 9, 2005; version 1.2.1)**

Input
Values

Application Rate (lb a.e./acre)	0.5	Estimated Environmental Concentrations (EECs) for NON-GRANULAR formulation applications (lbs a.i./acre)				Risk Quotients (RQs) for NON-GRANULAR formulation applications					
Runoff Value (0.01, 0.02, or 0.05 if chemical solubility <10, 10-100, or >100 ppm, respectively)	0.05	Applica tion Method	Total Loading to Adjacent Areas (EEC = Sheet Runoff)	Total Loading to Semi- aquatic Areas (EEC = Channelized Runoff)	DRIFT EEC*	Emergence RQs, Adjacent Areas RQ = EEC/Seedling Emergence EC25		Emergence RQs, Semi-aquatic Areas RQ = EEC/Seedling Emergence EC25		Drift RQs RQ = Drift EEC/ Vegetative Vigor EC25	
Minimum Incorporation Depth (cm)	0	Ground Unincor p-	0.0250	0.2500	N/A	Monocot	Dicot	Monocot	Dicot	Monocot	Dicot
Seed Emerg Monocot EC25 (lb a.e./acre)	0.105										
Seed Emerg Dicot EC25 (lb a.e./acre)	0.0054										
Veg Vigor Monocot EC25 (lb a.e./acre)	0.105										
Veg Vigor Dicot EC25 (lb a.e./acre)	0.0054										

**TERRPLANT
MEFLUIDIDE (0.5 lbs ae/A) GRANULAR
APPLICATION ONLY**

**Terrestrial Plant EECs and Acute Endangered RQs
(November 9, 2005; version 1.2.1)**

Input
Values

Application Rate (lb a.e./acre)	0.5	Estimated Environmental Concentrations (EECs) for NON-GRANULAR formulation applications (lbs a.i./acre)				Risk Quotients (RQs) for NON-GRANULAR formulation applications					
Runoff Value (0.01, 0.02, or 0.05 if chemical solubility <10, 10-100, or >100 ppm, respectively)	0.05	Application Method	Total Loading to Adjacent Areas (EEC = Sheet Runoff)	Total Loading to Semi-aquatic Areas (EEC = Channelized Runoff)	DRIFT EEC*	Emergence RQs, Adjacent Areas RQ = EEC/Seedling Emergence EC05 or NOAEC		Emergence RQs, Semi-aquatic areas RQ = EEC/Seedling Emergence EC05 or NOAEC		Drift RQs RQ = EEC/ Vegetative Vigor EC05 or NOAEC	
Minimum Incorporation Depth (cm)	0	Ground Unincorp.	0.0250	0.2500	N/A	Monocot	Dicot	Monocot	Dicot	Monocot	Dicot
	0.56					8.62	5.56	86.21	N/A	N/A	
Seed Emerg Monocot EC05 or NOAEC (lb a.e./acre)	0.105										
Seed Emerg Dicot EC05 or NOAEC (lb a.e./acre)	0.0054										
Veg Vigor Monocot EC05 or NOAEC (lbs a.e./acre)	0.105										
Veg Vigor Dicot EC05 or NOAEC (lb a.e./acre)	0.0029										

**DRIFT RQs for Buffers from 10 to 900 ft RQs= (EEC/EC₂₅)
EECs derived from AGDRIFT Table 3.5 for very fine to fine droplet size***

Buffer distance	1.0 lb ae/A	RQs Monocot (EC25 0.105)	RQs Dicot (EC25 0.0054)
10	0.0923	0.879	17.093

20	0.0437	0.416	8.093
40	0.0218	0.208	4.037
60	0.0149	0.142	2.759
80	0.0115	0.110	2.130
100	0.0095	0.905	1.759
140	0.007	0.067	1.296
180*	0.0056	0.053	1.037
200	0.0051	0.049	0.944
250	0.0042	0.040	0.778
500	0.0021	0.020	0.389
900	0.0011	0.011	0.204

* dicots exceed LOCs for spray drift (very fine to fine droplet size)

**DRIFT RQs for Buffers from 10 to 900 ft RQs= (EEC/EC₂₅)
EECs derived from AGDRIFT Table 3.5 for medium to course droplet size***

Buffer distance	1.0 lb ae/A	RQs Monocot (EC ₂₅ 0.105)	RQs Dicot (EC ₂₅ 0.0054)
10	0.0275	0.262	4.8
20	0.0149	0.142	2.8
40	0.0087	0.083	1.61
60*	0.0064	0.061	1.18
80	0.0052	0.05	0.96
100	0.0044	0.042	0.82
140	0.0035	0.033	0.65
180	0.0029	0.028	0.54
200	0.0026	0.025	0.481
250	0.0022	0.021	0.41
500	0.0012	0.011	0.22
900	0.0007	0.006	0.13

* dicots exceed LOCs for spray drift (medium to course droplet size)

Appendix E

APPENDIX E. Ecological Effects Characterization for Mefluidide, Mefluidide-DEA and Mefluidide-K

310=Molecular Weight of Mefluidide acid

415.24 = Molecular Weight of Mefluidide-DEA

348.29=Molecular Weight of Mefluidide-K

The following tables present measures of effect both in terms of active ingredient and acid equivalents. Conversion from active ingredient to acid equivalents was made in accordance with molecular weight differences (MW acid/ MW salt = AE). One gram mole of Mefluidide acid has a mass of 310.0 and one gram mole of **Mefluidide-DEA** has a mass of 415.24 grams; therefore one unit of salt would be equivalent to 0.75 units of the acid. Hence, the LC50 values from the toxicity tests with **Mefluidide-DEA** were converted to acid equivalents by multiplying the values by 0.75. The same conversion scenario was made Mefluidide-K with one gram mole of Mefluidide-K equal to 348.29. Therefore, 310 MW acid/348.29MW potassium salt is equivalent to 0.89. Hence, the LC50 values from the toxicity tests with Mefluidide-K were converted to acid equivalents by multiplying the values by 0.89.

Table E-1: Acute Toxicity of Mefluidide to Freshwater Fish

Species	% a.i. / %ae	96-hr LC ₅₀ , mg/L (confid. int.)		NOEC (mg/L)		Study Properties ^a	Toxicity Classification (based on a.e.)	MRID	Status
		a.i.	a.e.	a.i.	a.e.				
<p>Freshwater fish studies were submitted for 114001-Mefluidide and are in review MRIDs 73635, 80027, 80028 , 87475, 41893801 and 41893802 with LC50s ranging from > 96.4 mg/L to 1720 mg/L</p> <p>No freshwater fish studies were submitted for 114003 -Mefluidide potassium salt</p>									
114002- Mefluidide-DEA									
Rainbow trout	28.8	>91.3	>68.47	91.3	68.47	F-T, M	Slightly-toxic	418937-02	Acceptable
Bluegill sunfish	28.8	>94.4	>70.80	94.4	70.80	F-T, M	Slightly-toxic	418937-01	Acceptable

Table E-2: Acute Toxicity of Mefluidide to Freshwater Invertebrates

Species	% a.i.	48-hr EC ₅₀ , mg/L (confid. int.)		NOEC (mg/L)		Study Properties ^a	Toxicity Classification (based on a.e.)	MRID	Status
		a.i.	a.e.	a.i.	a.e.				
Freshwater invertebrate study was submitted for 114001-Mefluidide and is in review with MRID 41893803 with and EC ₅₀ of >111									
No freshwater invertebrate studies were submitted for 114003 -Mefluidide potassium salt									
114002- Mefluidide-DEA									
Daphnia	28.8%	>103	>77.25	103	77.25	F-T, M	Slightly-toxic	418937-03	Acceptable

^a M=mean-measured chemical concentrations, N=nominal chemical concentrations; F-T=flow-through; S=static.

Table E-3: Chronic (Early-life) Toxicity of Mefluidide to Invertebrates									
Species	% a.i.	NOEC (mg/L)		LOEC (mg/L)		Study Properties ^a	Most sensitive parameter	MRID	Status
		a.i.	a.e.	a.i.	a.e.				
No Chronic invertebrate studies were submitted for 114001-Mefluidide , 114002 Mefluidide-DEA and 114003 - Mefluidide-K									

^a M=mean-measured chemical concentrations, N=nominal chemical concentrations; F-T=flow-through; S=static.

Table E-1: Acute Toxicity of Mefluidide to Estuarine marine Fish									

Species	% a.i. / %ae	96-hr LC ₅₀ , mg/L (confid. int.)		NOEC (mg/L)		Study Properties ^a	Toxicity Classification (based on a.e.)	MRID	Status
		a.i.	a.e.	a.i.	a.e.				
114001-Mefluidide									
Sheepshead minnow	58.2	>130	>130	130	130	F-T, M	Practically non-toxic	425624-03	Acceptable
114002- Mefluidide-DEA									
Sheepshead minnow	28.8	>113	>84.75	113	84.75	F-T, M	Slightly-toxic	425623-03	Acceptable

Table E-2: Acute Toxicity of Mefluidide to Estuarine marine Invertebrates

Species	% a.i.	EC ₅₀ , mg/L (confid. int.)		NOEC (mg/L)		Study Properties ^a	Toxicity Classification (based on a.e.)	MRID	Status
		a.i.	a.e.	a.i.	a.e.				
114001-Mefluidide									
Mysid (<i>Mysidopsis bahia</i>) (96 HR)	58.2	133 (113-204)	133	47	47	F-T, M	Practically non-toxic	425624-02	Acceptable
Eastern Oyster (<i>Crassostrea virginica</i>)(96 HR)	58.2	67	67	<12	<12	F-T, M	Slightly toxic	425624-01	Acceptable
114002- Mefluidide-DEA									
Mysid (<i>Mysidopsis bahia</i>) (96 HR)	28.8	>126	>94.5	42	31.5	F-T, M	Practically non-toxic	425623-02	Acceptable

Table E-2: Acute Toxicity of Mefluidide to Estuarine marine Invertebrates									
Species	% a.i.	EC ₅₀ , mg/L (confid. int.)		NOEC (mg/L)		Study Properties ^a	Toxicity Classification (based on a.e.)	MRID	Status
		a.i.	a.e.	a.i.	a.e.				
Eastern Oyster (<i>Crassostrea virginica</i>)	28.8	77	57.75	<14	<10.5	F-T, M	Slightly toxic	425623-01	Supplemental

^a M=mean-measured chemical concentrations, N=nominal chemical concentrations; F-T=flow-through; S=static.

Table E-3: Acute Toxicity of Mefluidide to Aquatic Plants

Species	%a.i.	Definitive test		Most sensitive parameter	Initial/mean measured concentrations	MRID	Status
		a.i.	a.e.				
114002- Mefluidide-DEA							
<i>Navicula pelliculosa</i> Tier I (120 Hr)	28.8	831 ug ai/L	.629mg ae/L	11.5% growth reduction	mean	435266-01	Acceptable
<i>Skeletonema costatum</i> Tier I (120 Hr)	28.8	767ug ai/L	.575 mg ae/L	no adverse effects	mean	435266-02	Acceptable
<i>Lemna gibba</i> Tier I (14 day)	28.8	687 ug ai/L (8% growth stimulation)	0.515 mg ae/L	8% growth stimulation	mean	435266-05	Acceptable
<i>Anabaena flos-aquae</i> Tier I (120 Hr)	28.8	725 ug ai/L	0.543 mg ae/L	4.3% growth reduction	mean	435266-04	Acceptable
<i>Selenastrum capricornutum</i> Tier I (120 Hr)	28.8	749 ug ai/L	0.561 mg ae/L	8% growth reduction	mean	435266-03	Acceptable

Table E-4: Acute Toxicity of Mefluidide to Aquatic Plants			
Species			MRID
	Endpoints definitive tests	Endpoints range finding tests	
114002- Mefluidide-DEA Definitive and Range finding Tessts for Tier I studies for aquatic plants			
<i>Navicula pelliculosa</i> Tier I (120 Hr)	831 ug ai/L 11.5% growth reduction	1131 ug ai/L 5.10% growth stimulation	435266-01
<i>Skeletonema costatum</i> Tier I (120Hr)	767ug ai/L no adverse effects	1117 ugai/L 2.5% growth stimulation	435266-02
<i>Lemna gibba</i> Tier I (14day)	687 ug ai/L 8% growth stimulation	1084 ug ai/L 2.6% growth reduction	435266-05
<i>Anabaena flos-aquae</i> Tier I (120 Hr)	725 ug ai/L 4.3% growth reduction	1077 ug ai/L 26.5% growth stimulation	435266-04

Table E-4: Acute Toxicity of Mefluidide to Aquatic Plants			
Species			MRID
	Endpoints definitive tests	Endpoints range finding tests	
<i>Selenastrum capricornutum</i> Tier I (120 Hr)	749 ug ai/L 4.3% growth reduction	1117 ug ai/L 8.5% growth stimulation	435266-03

Table E-5: Acute Toxicity of Mefluidide to Birds (oral administration)									
Species	% a.i.	LD ₅₀ , mg ai/kg-bw (conf. interval)		NOEC, mg ai/kg-diet		Effects	Toxicity Classification (based on a.e.)	MRID	Status
		a.i.	a.e.	a.i.	a.e.				
114001-Mefluidide*									
Bobwhite quail Tier I	58.2	>2000	>2000	>2000	>2000		Practically non-toxic	416021-01	Supplemental
114002- Mefluidide_DEA									
Bobwhite quail Tier I	28.8	>2000	>1500	>2000	>1500		Practically non-toxic	416019-01	Supplemental

*Avian acute oral studies were submitted for 114001-Mefluidide and are in review MRIDs 7362 with LD₅₀ 4640 mg/kg bw

Table E-6: Acute Toxicity of Mefluidide to Birds (dietary administration)

Species	% a.i.	LC ₅₀ , mg ai/kg-diet (conf. interval)		NOEC, mg ai/kg-diet		Effects	Toxicity Classification (based on a.e.)	MRID	Status
		a.i.	a.e.	a.i.	a.e.				
114001-Mefluidide*									
Mallard duck (Tier I or limit test)	58.2% (adjusted to 100%ai)	>5000	>5000	>5000	>5000	No mortality	Practically non-toxic	416021-03	Supplemental
Bobwhite quail (Tier I or limit test)	58.2% (adjusted to 100%ai)	>5000	>5000	>5000	>5000	No mortality	Practically non-toxic	416021-02	Supplemental
114002- Mefluidide Diethanolamine salt									
Mallard duck (Tier I or limit test)	28.8% (adjusted to 100%ai)	>5000	>3750	>5000	>3750	No mortality	Practically non-toxic	416019-03	Supplemental
Bobwhite quail (Tier I or limit test)	28.8% (adjusted to 100%ai)	>5000	>3750	>5000	>3750	No mortality	Practically non-toxic	416019-02	Supplemental

***Avian acute dietary studies were submitted for 114001-Mefluidide and are in review MRIDs, 7633 and 7634 with LC₅₀s of >10,000 mg/kg diet**

Table E-7: Chronic Toxicity of Mefluidide to Birds

Table E-7: Chronic Toxicity of Mefluidide to Birds							
Species	NOEC (mg ai/kg-diet)		LOEC (mg ai/kg-diet)		Effects	MRID	Status
	% a.i.	a.i.	a.e.	a.e.			
No Chronic bird studies were submitted for 114001-Mefluidide , 114002 Diethanolamine salt and 114003 -Mefluidide potassium salt							

Table E-8: Acute Contact Toxicity of Mefluidide to Non-target Insects							
Species	% a.i.	Toxicity endpoint		NOEL	Toxicity classification (based on a.e.)	MRID	Status
		a.i.	a.e.				
114002- Mefluidide Diethanolamine salt							
Honey bee	28.8	>25	>18.75	12.5	Practically non-toxic	425628-01	Acceptable
114003- Mefluidide Potassium salt							
Honey bee	28.8	>25	>22.25	25	Practically non-toxic	425628-02	Acceptable

Table E 9 Acute Toxicity of Mefluidide ^a				
Guideline No.	Study Type	MRID	Results (LD ₅₀ /LC ₅₀)	Toxicity Category
870.1100 (81-1)	Acute Oral (female rat) Mefluidide tech		>4000 mg/kg MRID 00047118	III
870.1100 (81-1)	Acute Oral (mouse) Mefluidide tech		1920.2 mg/kg MRID 00047117	III
870.1100 (81-1)	Acute Oral (mouse) Mefluidide tech		829.8 mg/kg MRID 00047116	III

^a Status (acceptability) based on HEDs guidelines.

Table E 10 Toxicity Profile of Mefluidide sub chronic and developmental toxicity and its salts (114001, 114002, 114003) ^a

Guideline No./ Study type	MRID No.(year)/Doses/ classification	Results
870.3200 82-2 21-Day Dermal toxicity - rabbit	00082073, (1977) 0, 1, 3, 10 ml of 2S formulation/kg/day (Formulation containing 24% a.i., equivalent to 0, 240, 720, or 2400 mg mefluidide/kg/day) (4 rabbits/sex/dose) Acceptable/Non-guideline (NOAEL was not observed) Note: This study assessed the dermal toxicity of 24 % formulation mefluidide	Dermal LOAEL = 240 mg/kg/day, based on irritation, inflammation and necrosis at test sites. Dermal a NOAELs were not established.
870.3700a 83-3(a) Developmental Toxicity Gavage [rat]	42097201 (range finding), 1991 42097701 (teratology), 1991 Range finding: 0, 100, 200, 400, 600 or 800 mg a.i./kg/d Teratology study: 0, 50, 200 or 400 mg a.i./kg/d Mefluidide technical 58.2% a.i. Acceptable/Guideline	Maternal LOAEL = 400 mg/kg/d based on reduced gain and food consumption. Higher dose in the range finding study of 600 mg/kg/day produced excessive mortality. Maternal NOAEL = 200 mg/kg/d Developmental LOAEL = 400 mg/kg/d based on slight fetal toxicity as indicated by a slight nonstatistical increase in 14 th rtb. Developmental NOAEL = 200 mg/kg/d
870.3700a 83-3(a) Developmental Toxicity, gavage [rat]	42026102, (1991) 0, 50, 200 400 mg diethanolamine salt of mefluidide (28.78%)/kg/d (25 females/dose) Doses adjusted for 100 % purity were 0, 14, 58, or 115 mg/kg/day. Acceptable/guideline	Maternal LOAEL = 115 mg a.i./kg/day based on mortality, clinical signs (tremors, stained nose, urine and vaginal discharge), decreased body weight and weight gain. Maternal NOAEL = 58 mg a.i./kg/day), Developmental LOAEL = 115 mg a.i./kg/day based on increased number of early resorptions and mean post- implantation loss. Developmental NOAEL : 200 mg/kg/day (adjusted to 58 mg/kg/day),
Non-guideline 14-Day Oral gavage [rabbit]	00047138, (1975) 0, 100, 200, 400, 800 mg/kg/d Vistar tech, 93% a.i. 4 females/dose range finding Acceptable/non-guideline	LOAEL = < 100 mg/kg/day (females), based on mortality (1/3 deaths) at 100 mg/kg/d. Tremors and 100% mortality were noted at the levels of 200 mg/kg/d and above. Histopathology not reported. NOAEL : not established
870.3700b 83-3(b) Developmental	00047139, (1975) 0, 15, 30, 60 mg technical MBR 12325/kg/d	Maternal LOAEL = not established. Maternal NOAEL = 60 mg/kg/day, Developmental LOAEL = not

Table E 10 Toxicity Profile of Mefluidide sub chronic and developmental toxicity and its salts (114001, 114002, 114003) ^a

Guideline No./ Study type	MRID No.(year)/Doses/ classification	Results
Toxicity, gavage [rabbit]	Unacceptable by itself, however, if combined with the 14-day oral study (00047138), it is acceptable.	established. Developmental NOAEL = 60 mg/kg/day,
870.1300 (81-3)	Acute inhalation – rat DEA salt of Mefluidide	>5.2 mg/L MRID 41888801
870.1300 (81-3)	Acute inhalation – rat Mefluidide tech.	>5.4 mg/L MRID 41964601
870.3800 (83-4) 3-generation reproduction [rat]	00082748, (1979) 0, 600, 1800, 6000 ppm, 93% a.i. (M/F: 0/0, 34/60, 102/183, 346/604 mg/kg/d) Acceptable/guideline	The parental systemic LOAEL = 346/604 mg/kg bw/day (M/F), based on decreased body weights. The parental systemic NOAEL = 102/183 mg/kg bw/day in males/females. The offspring LOAEL = 346/604 mg/kg bw/day in males/females, based on decreased body weights in both sexes and both litters in all generations. The offspring NOAEL = 102/183 mg/kg bw/day in males/females. The reproductive LOAEL was not observed. The reproductive NOAEL = 346/604 mg/kg bw/day in males/females.

M = Males; F = Females

^a Status (acceptability) based on HEDs guidelines.

Table E-11: Toxicity of Mefluidide to Terrestrial Plants (vegetative vigor)¹

Most Sensitive Species	% a.i.	EC ₂₅ , lbs ai/acre		NOEC (lbs ai/acre)		Most sensitive parameter	MRID	Status
		a.i.	a.e.	a.i.	a.e.			
114002- Mefluidide Diethanolamine salt								
<i>Monocot - Sorghum</i>	29.5	0.14		0.06		Shoot fresh weight	435496-01	Supplemental

Table E-11: Toxicity of Mefluidide to Terrestrial Plants (vegetative vigor) ¹								
Most Sensitive Species	% a.i.	EC ₂₅ , lbs ai/acre		NOEC (lbs ai/acre)		Most sensitive parameter	MRID	Status
		a.i.	a.e.	a.i.	a.e.			
<i>Dicot - Mustard</i>	29.5	0.0073		0.0039		<u>Shoot fresh weight</u>		

¹ Seedling emergence studies were not available for Mefluidide formulations

Additional preliminary reviews were conducted on the following submitted studies to determine the most sensitive species for endpoint selection. The results of the preliminary reviews concluded that the most sensitive endpoints will remain the same in all cases as well as in all risk conclusions.

MRID 73633 Fink, Robert. 1975. Final Report: Acute Dietary LC₅₀ of MBR 12325 in Mallard Ducks. Unpublished study performed by Truslow Farms, Incorporated, Chestertown, MD. Laboratory report number 136-102. Study sponsored by Riker Laboratories, Inc., Sterling, VA. Study completed April 3, 1975.

MRID 73634 Fink, Robert. 1975. Final Report: Acute Dietary LC₅₀ of MBR 12325 in Bobwhite Quail. Unpublished study performed by Truslow Farms, Incorporated, Chestertown, MD. Laboratory report number 136-101. Study sponsored by Riker Laboratories, Inc., Sterling, VA. Study completed April 3, 1975.

MRID 73632 Fink, Robert. 1975. Final Report: Acute Oral LD₅₀ of MBR 12325 in Mallard Ducks. Unpublished study performed by Truslow Farms, Incorporated, Chestertown, MD. Laboratory report number 136-103. Study sponsored by Riker Laboratories, Inc., Sterling, VA. Study completed April 3, 1975.

MRID 73635 Rausima, Gary. 1975. Four-Day Static Aquatic Toxicity Studies with MBR 12325 Technical and MBR 12325-4S in Rainbow Trout and Bluegills. Unpublished study performed by Industrial Bio-Test Laboratories, Inc. Laboratory report number 621-07032. Study submitted by Riker Laboratories, Inc. Final report issued July 21, 1975.

MRID 80027 Rhuberick, John C. 1980. Acute Toxicity of MBR 12325 (Technical) to the Rainbow Trout (*Salmo gairdneri*). Unpublished study conducted by Biospherics Incorporation, Rockville, MD. Study sponsored by Agrichemicals 3M Company, St. Paul, MN. Study completed on February 23, 1980.

MRID 87475 Rhuberick, John C. 1980. Acute Toxicity of MBR 12325 (Technical) to the Bluegill Sunfish (*Lepomis macrochirus*). Unpublished study conducted by Biospherics Incorporation, Rockville, MD. Laboratory report number 80-PL-14-AQ. Study sponsored by Agrichemicals 3M Company, St. Paul, MN. Study completed on March 12, 1980.

MRID 41893801 Murphy, Daniel and G.T. Peters. 1991. Mefluidide: A 96-Hour Flow-Through Toxicity Test with the Bluegill (*Lepomis macrochirus*). Unpublished study performed by Wildlife International, Ltd., Easton, Maryland. Laboratory report number 281A-112. Study sponsored by PBI Gordon, Kansas City, Missouri. Study completed May 23, 1991.

MRID 41893802 Murphy, Daniel and G.T. Peters. 1991. Mefluidide: A 96-Hour Flow-Through Toxicity Test with the Rainbow Trout (*Oncorhynchus mykiss*). Unpublished study performed by Wildlife International, Ltd., Easton, Maryland. Laboratory report number 281A-111. Study sponsored by PBI Gordon, Kansas City, Missouri. Study completed May 23, 1991

MRID 41893803 Holmes, Catherine M. and G.T. Peters. 1991. Mefluidide: A 48-Hour Flow-Through Acute Toxicity Test with the Cladoceran (*Daphnia magna*). Unpublished study performed by Wildlife International, Ltd., Easton, Maryland. Laboratory report number 281A-110. Study sponsored by PBI Gordon, Kansas City, Missouri. Study completed May 23, 1991.

Seedling emergence test (MRID 471907-01) preliminary review results

A preliminary review was conducted on the submitted seedling emergence test MRID 471907-01 to determine if LOC exceedences would decrease with additional toxicity data. Based on the reported results of the author the most sensitive dicot is mustard with an EC25 of 0.0625 and a NOEC of 0.0625. The most sensitive monocot is oat with an EC25 of 0.034 and a NOEC of 0.031. It is unclear however the determination of the EC25 of 0.0625 and a NOEC of 0.0625 for dicots since 30 percent inhibition occurred at 0.0078 and 20 percent inhibition occurred at 0.0039. In addition, results were reported using pooled controls. The blank or solvent controls were not clearly identified in the raw data. Therefore, control -1.00000 and 0.00000 need to be identified as to which one is the solvent and blank control. In reported controls there are differences of one order of magnitude. If the identified blank controls in this study have magnitudes of order differences in the reported responses, this study would be considered unacceptable.

Therefore, EFED used the nuthatch statistical program on mustard dry weight using the assumed blank control with response values of 0.88, 0.55, 0.58 and 0.33 which resulted in an EC25 of 0.0032 and a NOEC of 0.0156 for the most sensitive dicot (mustard).

EFED also used the nuthatch statistical program on oat dry weight using the assumed blank control with response values of 1.09, 1.14, 0.83 and 1.15 which resulted in an EC25 of 0.080 and a NOEC of 0.03125 for the most sensitive monocot (oat).

After a full review of the above seedling emergence study for validity and review of statistics, higher LOC exceedences may result for granular and ground spray applications based on EC25 and NOEC values than in existing estimated values in the assessment. Based on EC25 of 0.0032 and a NOEC of 0.0156 for dicots (mustard) the highest RQs were 159 (ground spray) nonlisted species, 33 (ground spray) listed species 78 (granular) nonlisted species and 16 (granular) for listed species.

Dicots continued to show more sensitivity than monocots. Based on EC25 of 0.080 and a NOEC of 0.03125 for monocots (oat), RQ exceedences for monocots ranged from 1.65 to 8.06 for granular and spray applications. Refer to Appendix D for all calculations from the preliminary review of the seedling emergence test.

After full review of the above seedling emergence test if considered acceptable, the following risk conclusion remains the same in the assessment based on preliminary review of the seedling emergence test:

Terrestrial and Semi-aquatic Plants (Listed Species and Non-Listed Species) LOCs were exceeded for monocots and dicots with the 1.0 lb ae/A spray applications of mefluidide-K and mefluidide-DEA. LOCs were exceeded for dicots and monocots (granular applications) with 0.5 lb ae/acre of mefluidide. Dicots demonstrated more sensitivity than monocots in all application scenarios.

Acute Non- Endangered granular and spray applications (preliminary review of seedling emergence test)

**TERRPLANT
MEFLUIDIDE-K, MEFLUIDIDE-DEA (1.0 lbs ae/A)
GROUND SPRAY ONLY**

**Terrestrial Plant EECs and Acute Non Endangered RQs
(November 9, 2005; version 1.2.1)**

Input Values

Application Rate (lb a.e./acre)	1.0	Estimated Environmental Concentrations (EECs) for NON-GRANULAR formulation applications (lbs a.i./acre)				Risk Quotients (RQs) for NON-GRANULAR formulation applications			
Runoff Value (0.01, 0.02, or 0.05 if chemical solubility <10, 10-100, or >100 ppm, respectively)	0.05	Application Method	Total Loading to Adjacent Areas (EEC = Sheet Runoff + Drift)	Total Loading to Semi-aquatic Areas (EEC = Channelized Runoff + Drift)	DRIFT EEC*	Emergence RQs, Adjacent Areas RQ = EEC/Seedling Emergence EC25		Emergence RQs, Semi-aquatic Areas RQ = EEC/Seedling Emergence EC25	
Minimum Incorporation Depth (cm)	0					Monocot	Dicot	Monocot	Dicot
Seed Emerg Monocot EC25 (lb a.e./acre)	0.08	Ground Unincorp	0.06	0.51	0.01	0.750	18.75	6.38	159.38
Seed Emerg Dicot EC25 (lb a.e./acre)	0.0032	Ground Incorp	0.06	0.51	0.01	0.75	18.75	6.38	159.38

EECs for GRANULAR formulation applications (lbs a.i./acre) 0.5lb ae/A Terrestrial Plant EECs and Acute Non Endangered RQs (November 9, 2005; version 1.2.1)			RQs for GRANULAR formulation applications			
Application Method	Total Loading to Adjacent Areas (EEC = Sheet Runoff)	Total Loading to Semiaquatic Areas (EEC = Channelized Runoff)	Emergence RQs, Adjacent Areas RQ = EEC/Seedling Emergence EC25		Emergence RQs, Semiaquatic Areas RQ = EEC/Seedling Emergence EC25	
			Monocot	Dicot	Monocot	Dicot
Unincorp.	0.0250	0.2500	0.31	7.81	3.13	78.13
Incorp.	0.0250	0.02500	0.31	7.81	0.31	7.81

Acute Endangered granular and spray applications (preliminary review of seedling emergence test)

TERRPLANT

**MEFLUIDIDE-K, MEFLUIDIDE-DEA (1.0 lbs ae/A)
GROUND SPRAY ONLY**

**Terrestrial Plant EECs and Acute Endangered RQs
(November 9, 2005; version 1.2.1)**

Input
Values

Application Rate (lb a.e./acre)	1.0	Estimated Environmental Concentrations (EECs) for NON-GRANULAR formulation applications (lbs a.i./acre)				Risk Quotients (RQs) for NON-GRANULAR formulation applications			
Runoff Value (0.01, 0.02, or 0.05 if chemical solubility <10, 10-100, or >100 ppm, respectively)	0.05	Application Method	Total Loading to Adjacent Areas (EEC = Sheet Runoff + Drift)	Total Loading to Semi-aquatic Areas (EEC = Channelized Runoff + Drift)	DRIFT EEC*	Emergence RQs, Adjacent Areas RQ = EEC/Seedling Emergence EC25		Emergence RQs, Semi-aquatic Areas RQ = EEC/Seedling Emergence EC25	
Minimum Incorporation Depth (cm)	0					Monocot	Dicot	Monocot	Dicot
Monocot NOAEC	0.31	Ground Unincorp.	0.06	0.51	0.01	0.194	3.85	1.65	32.69
Divot NOAEC	0.0156	Ground Incorp	0.06	0.51	0.01	0.19	3.85	1.65	32.69

EECs for GRANULAR formulation applications (lbs a.i./acre) 0.5lb ae/A Terrestrial Plant EECs and Acute Endangered RQs (November 9, 2005; version 1.2.1)			RQs for GRANULAR formulation applications			
Application Method	Total Loading to Adjacent Areas (EEC = Sheet Runoff)	Total Loading to Semiaquatic Areas (EEC = Channelized Runoff)	Emergence RQs, Adjacent Areas RQ = EEC/Seedling Emergence EC25		Emergence RQs, Semiaquatic Areas RQ = EEC/Seedling Emergence EC25	
			Monocot	Dicot	Monocot	Dicot
Unincorp.	0.0250	0.2500	0.81	1.60	8.06	16.03

Calculations for Estimated Endpoints

Seedling emergence toxicity data was not available for full review and data was not available from other anilide analogs to derive EC₂₅ values. To estimate possible effects measurement endpoints for seedling emergence, EFED assumed that EC₂₅ toxicity values for vegetative vigor are equal to seedling emergence measurement endpoints for Mefluidide, Mefluidide-DEA and Mefluidide-K. Therefore, the most sensitive seedling emergence EC₂₅ estimated values are 0.105 and 0.0054 lb ae/acre for monocots and dicots, respectively. The NOEC estimated values for seedling emergence are 0.045 and 0.0029 lb ae/acre for monocots and dicots, respectively. These values are used to calculate risk quotients for exposure from combined runoff and spray drift to adjacent fields.

There are insufficient data to establish a definitive toxicity endpoint for freshwater fish chronic effects for the acid and DEA salt acid equivalents for mefluidide. To estimate a potential chronic freshwater fish endpoint for mefluidide the relationship between established acute and chronic endpoints for mefluidide and propanil were considered (see source data in Appendix E). A ratio was determined between the 96h acute freshwater fish endpoints and the chronic freshwater fish endpoints used for RQ calculation for mefluidide (>68.47 mg/L acute freshwater fish) and propanil ($2.3\text{mg /L}/0.009$ mg /L = 256 mg/L). The largest ratio between acute endpoint and chronic endpoint was applied to the Mefluidide acute freshwater fish value to derive an estimated chronic endpoint of 0.267 mg/L ($>68.47\text{mg/L}/256 = >0.267$ mg/L).

There are insufficient data to establish a definitive toxicity endpoint for freshwater invertebrate chronic effects for the acid and DEA salt acid equivalents for mefluidide. To estimate a potential chronic freshwater fish endpoint for mefluidide the relationship between established acute and chronic endpoints for mefluidide and propanil were considered (see source data in Appendix E). A ratio was determined between the 48 h acute freshwater invertebrate endpoints and the chronic freshwater invertebrate endpoints used for RQ calculation for mefluidide (>77.25 mg/L acute freshwater invertebrate) and propanil ($1.2\text{mg /L acute freshwater invertebrate}/0.086$ mg /L chronic freshwater invertebrate = 13.95). The largest ratio between acute endpoint and chronic endpoint was applied to the Mefluidide acute freshwater fish value to derive an estimated chronic endpoint of 5.54 mg/L (>77.25 mg/L/ $13.95 = >5.54$ mg/L).

There are insufficient data to establish a definitive toxicity endpoint for estuarine/marine fish and invertebrate chronic effects for the acid and DEA salt acid equivalents for mefluidide. There is also little available data to compare to other anilide herbicides for this taxonomic group. For the purposes of this risk assessment, it was assumed that estuarine marine fish and invertebrates were at least as sensitive as freshwater fish and invertebrates in terms of chronic toxicity. Therefore, the estimated endpoint for freshwater invertebrates (>5.54 mg/L) was used to estimate a chronic effects endpoint for estuarine/marine invertebrates and >0.267 mg/L was used to estimate chronic effect endpoint for estuarine marine fish.

There are insufficient data to establish a definitive toxicity endpoint for a NOAEC or EC₀₅ value for vascular plant effects for the acid and DEA salt acid equivalents for mefluidide. To estimate a potential EC₀₅ endpoint for mefluidide the relationship between established acute and EC₀₅ endpoints for mefluidide and propanil were considered (see source data in Table 1 Appendix E). Comparisons were made between the acute mefluidide endpoint and the propanil EC₀₅ endpoint for vascular plant RQ calculation for mefluidide (>0.515 mg/L acute vascular plant) and propanil

(0.11mg /L acute vascular plant/0.0063 mg /L EC05 vascular plant= 17.46). The largest ratio between acute endpoint and EC₀₅ was applied to the Mefluidide acute vascular plant value to derive an estimated EC05 endpoint of >0.029 mg/L (>5.15 mg/L/17.46= >0.029 mg/L).

There are insufficient data to establish a definitive toxicity endpoint for a chronic (NOAEC) value for bird effects for the acid and DEA salt acid equivalents for mefluidide. To estimate a potential chronic endpoint for mefluidide the relationship between established acute and chronic endpoints for mefluidide mammals were considered (see source data in Appendix E). Chronic NOAEC values for the most sensitive mammal (mouse) were not available. Therefore, to derive a chronic value for the mouse the acute mefluidide endpoint and the chronic mefluidide endpoint from rat toxicity endpoints were used to derive a chronic mouse value for mefluidide (829.8 mg ae/kg acute mouse) and mefluidide (>4000mg ae /kg acute (rat)/102 mg ae /kg chronic (rat)) = 39.2). The largest ratio between acute endpoint and chronic endpoint was applied to the mefluidide acute mouse value to derive an estimated chronic mouse endpoint of NOAEC>21 mg ae/kg bw (829.8 mg ae/kg bw /39.2= NOAEC >21mg ae/kg bw (mouse)). The acute mefluidide endpoint for bird and the acute and chronic endpoints for the mouse were used to derive a ratio for the chronic bird RQ calculation for mefluidide (>1500 mg ae/kg acute bird) and mefluidide (829.8 mg ae /kg acute (mouse)/ >21mg ae /kg chronic (mouse) = 39.5). The largest ratio between acute endpoint and chronic endpoint was applied to the mefluidide acute bird value to derive an estimated chronic endpoint of NOAEC 38 mg ae/kg bw (>1500mg/L/39.5= NOAEC 38 mg ae/kg bw).

Calculations for Estimated Endpoints

Table #1 <u>Summary of Calculations for Estimated Endpoints</u>				
ENDPOINT DESIRED For Mefluidide	Acute/Chronic mefluidide =ratio	Acute/Chronic Propanil =ratio	Acute Endpoint Mefluidide/ratio= endpoint	Estimated Endpoint
Chronic Fish		2.3/0.009=256	>68.47/256=>0.267	
Chronic Invertebrate		1.2/0.086=13.95	>77.25/13.95=>5.54	
Chronic Bird (used mammal rat and mouse toxdata body weight)	>4000 mefluidide rat /102mefluidide rat =39.2 (829.8 mg ae/kg bw (mouse) /39.2= NOAEC >21mg ae/kg bw (mouse)). 829.8 mg ae /kg acute (mouse)/ >21mg ae /kg chronic (mouse) = 39.5		>1500/39.5=38	
EC05 vascular plant		0.11/0.0063=17.46	>0.515/17.46=>0.029	

EC05 non-vascular plant		0.016/0.02=0.80	>0.629/0.80=>0.786
Seedling emergence EC05 and EC25			EC05 and EC25 values are equal to vegetative vigor values

Due to data gaps for chronic studies for freshwater and estuarine marine fish and invertebrates and chronic studies for birds EFED reviewed the analog Propanil to obtain estimated LD50 and LC50 values for Mefluidide from acute to chronic ratios

Also for the most sensitive estuarine marine invertebrate Propanil is 2 orders more toxic than Mefluidide and no chronic estuarine marine studies were available for Propanil.

No chronic studies for birds were submitted for Propanil.

Tables #2 to #4 summarize endpoints from mefluidide and propanil considered for estimated values. Bolded values were used in endpoint selection for acute and chronic ratios.

Table#2 Summary of Aquatic and Terrestrial Plant Toxicity Data used for Risk Quotient Calculation Mefluidide and Propanil Application (bolded values were used in acute to chronic ratios)

Species	Mefluidide	Propanil
Aquatic Plant: <i>Navicula</i> Tier I <u>Nonvascular</u>	EC₅₀ = >0.629 mg ae/L NOAEC N/A due to Tier one study	
Freshwater diatom		0.016 mgai/L EC05 0.02
Aquatic Plant: <i>Lemna gibba</i> Tier I <u>Vascular</u>	EC₅₀ = 0.515 mg ae/L NOAEC N/A due to Tier one study	.11 mg ai/L EC05 0.0063
Terrestrial Plant: Vegetative Vigor	Most sensitive endpoint: (N/Afor Propanil) Fresh Weight Most sensitive monocot: Sorghum NOAEC 0.045 lb ae/A; EC₂₅ 0.105 lb ae/A Most sensitive dicot: Mustard NOAEC 0.0029 lb ae/A; EC₂₅ 0.0054lb ae/A	N/A for Propanil
Terrestrial Plant: Seedling Emergence	(No studies submitted) Vegetative Vigor endpoints from mefluidide were used for this data gap.	EC25 1.4 lb ai/A for Propanil

Table#3 Summary of Terrestrial Acute and Chronic Toxicity Data used for Risk Quotient Calculation for Mefluidide and Propanil Application (bolded values were used in acute to chronic ratios)

Species	Acute Toxicity				Chronic Toxicity	
	Mefluidide LD₅₀ mg ae/kg-bw	Propanil LD₅₀ mg ae/kg-bw	Mefluidide LC₅₀	Propanil LC₅₀	Mefluidide NOAEC	Propanil NOAEC
Laboratory rat	>4000 Rat Used to calculate chronic bird endpoint	1080			102 Used to calculate chronic bird endpoint	300
Laboratory mouse	829.8 Used to calculate chronic bird endpoint					

Table#4 Summary of Acute and Chronic Aquatic Toxicity Data used for Risk Quotient Calculation for Mefluidide and Propanil Application (bolded values were used in acute to chronic ratios)

Species	Acute Toxicity				Chronic Toxicity	
	Mefluidide 96-hr LC ₅₀ (mg/L ae)	Mefluidide 48-hr EC ₅₀ (mg/L ae)	Propanil 96-hr LC ₅₀ (mg ai/L)	Propanil 48-hr EC ₅₀ (mg ai/L)	Mefluidide NOAEC / LOAEC (mg/L)	Propanil NOAEC / LOAEC (mg/L)
Rainbow Trout <i>Oncorhynchus mykiss</i> Coldwater species Freshwater fish	>68.47		2.3		No studies submitted	No studies submitted
Fathead minnow Freshwater fish					No studies submitted	.009
Water flea <i>Daphnia magna</i> Freshwater Invertebrate		>77.25		1.2	No studies submitted	.086
Sheepshead minnow Estuarine marine fish	>84.75		4.6		No studies submitted	No studies submitted
Mysid shrimp Estuarine marine invertebrate				.400	No studies submitted	No studies submitted
Eastern oyster Estuarine marine Invertebrate		67			No studies submitted	No studies submitted
Northern Bobwhite Quail (<i>Colinus virginianus</i>) Limit study(Tier I)	>1500 Used to calculate chronic bird endpoint		>3750	2311	No studies submitted	No studies submitted

Summary of Endpoints (LC₅₀ or EC₅₀, mg ae/L) for Aquatic and Terrestrial Toxicity used in RQ calculations for Mefluidide¹

Summary of endpoints (LC₅₀ or EC₅₀, mg ae/L) for Aquatic Toxicity used in RQ calculations for Mefluidide¹			
TAXANOMIC GROUP	Acute endpoint	Chronic endpoint	MRID/ Estimated value
Acute freshwater fish	>68.47* Rainbow Trout		MRID 418937-02
Chronic freshwater fish		>0.267	Estimated value acute to chronic ratio
Acute freshwater inverts	>77.25* Daphnid		MRID 418937-03
Chronic freshwater inverts		>5.54	Estimated value acute to chronic ratio
Acute estuarine/marine fish	>84.75* Sheepshead minnow		MRID 425623-03
Chronic estuarine/marine fish		>0.267	Estimated value acute to chronic ratio
Acute estuarine/marine inverts	67* Eastern oyster		MRID 425624-01
Chronic estuarine/marine inverts		>5.54	Estimated value acute to chronic ratio

¹ For fish and invertebrates data evaluating Potassium Mefluidide, Diethanolamine Mefluidide and Mefluidide have been bridged for the runoff risk assessment.

Summary of endpoints (LC₅₀ or EC₅₀, mg ae/L) for Plant Toxicity used in RQ calculations for Mefluidide¹			
TAXONOMIC GROUP	Acute endpoint	EC05 and NOAEC	
Acute vascular plant	0.515* Lemna		MRID 435266-01 Tier I(8% growth stimulation)

			Used this value as EC₅₀ ,
Vascular plant (EC05)		>0.29	Estimated value acute to chronic ratio
Acute non-vascular plant	0.629* Navicula		MRID 435266-05 Tier I(11.5% growth reduction) Used this value as EC₅₀ ,
Non-vascular plant(EC05)		>0.786	Estimated value acute to chronic ratio
Terrestrial Plant: Vegetative Vigor	Monocot:* Sorghum EC ₂₅ 0.105 lb ae/A Dicot:* Mustard EC ₂₅ 0.0054lb ae/A	Monocot:* Sorghum NOAEC 0.045 lb ae/A Dicot:* Mustard NOAEC 0.0029 lb ae/A	MRID 435496-01
Terrestrial Plant: Seedling Emergence			N/A
Summary of endpoints (LD₅₀ mg ae/L) for Terrestrial Toxicity data used in RQ calculations for Mefluidide¹			
TAXONOMIC GROUP	Acute endpoint	Chronic endpoint	
Acute Avian	>1500* Bobwhite quail		MRID 416019-01 Used this non-definitive endpoint as LD50
Chronic Avian		38	Estimated value acute to chronic ratio based on mammal data
Acute mammal	829.8* mouse		MRID 00047116
Chronic mammal		102* rat	MRID 00082748

¹For terrestrial plants data evaluating Potassium Mefluidide, Diethanolamine Mefluidide and Mefluidide have been bridged for the terrestrial risk assessment.

*most sensitive species tested

Summary of Mammal and Avian RQS with both 35 day and 4 day half lives

Mammalian dose-based acute RQ values for proposed uses of Mefluidide K and Mefluidide DEA based on a mouse LD₅₀ = 829.8 mg/kg -bw and upper-bound Kenaga values¹. 35day half life (A 4day half life with either 1 and 3 applications = 1 application at 35 day)

Use	Application Rate lbs. ae/A (# app / interval, days)	Mammalian Acute Risk Quotients (upper-bound Kenaga residues)						
		Body Weight, g	Short Grass (1app)	Short Grass (3 app)	Tall Grass(1app)	Tall Grass(3app)	Broadleaf Plants/Small Insects(1app)	Broadleaf Plants/Small Insects(3 app)
Ornamental Turf (mefluidide salts only) Ground spray	1.0	15	0.26	0.42	0.12	0.19	0.14	0.23
		35	0.22	0.36	0.10	0.16	0.12	0.20
		1000	0.12	0.19	0.05	0.09	0.07	0.11

¹ For mammal toxicity assessments, data evaluating Potassium Mefluidide, Diethanolamine Mefluidide and Mefluidide toxicity have been bridged because toxicity is expected to come from the benzene ring of mefluidide. Therefore, the most sensitive Mefluidide endpoint was selected to represent mammals for all application scenarios.

Mammalian dose-based chronic RQ values for proposed uses of MefluidideK and Mefluidide DEA based on a rat reproductive NOAEC of 102 mg ae/kg-bw/day and upper-bound Kenaga residues¹ based on a 35day half life (4day half life with 1 and 3 application rates)= 1 application 35 day)

Use	Application Rate lbs. ae/A (# app / interval, days)	Mammalian Acute Risk Quotients (upper-bound Kenaga residues)						
		Body Weight, g	Short Grass (1app)	Short Grass (3 app)	Tall grass(1app)	Tall grass (3 app)	Broadleaf Plants/Small Insects(1app)	Broadleaf Plants/Small Insects(3 app)
Ornamental Turf (mefluidide salts only) Ground spray	1.0 3 per season 42 day interval	15	1.02	1.66	0.47	0.76	0.57	0.93
		35	0.87	1.42	0.40	0.65	0.49	0.80
		1000	0.47	0.76	0.21	0.35	0.26	0.43

¹ For mammal toxicity assessments, data evaluating Potassium Mefluidide, Diethanolamine Mefluidide and Mefluidide toxicity have been bridged because toxicity is expected to come from the benzene ring of mefluidide. Therefore, the most sensitive Mefluidide endpoint was selected to represent mammals for all application scenarios.

Avian dose-based acute RQ values for proposed uses of MefluidideK and Mefluidide DEA based on a bobwhite quail LD₅₀ >1500 mg/kg -bw and upper-bound Kenaga values¹. 35day half life (4day half life with 1 and 3 application rates)= same as 1 application 35 day)

Use	Application	Body	Avian Acute Risk Quotients (upper-bound Kenaga residues)				
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			Short Grass (1app)	Short Grass (3 app)	Tall Grass(1app)	Tall Grass(3app)	Broadleaf Plants/Small Insects((1app)	Broadleaf Plants/Small Insects(3 app)
Ornamental Turf (mefluidide salts only) Ground spray	1.0	20	0.25	0.41	0.12	0.19	0.14	0.23
		100	0.11	0.18	0.05	0.08	0.06	0.10
		1000	0.04	0.06	0.02	0.03	0.02	0.03

¹ For mammal toxicity assessments, data evaluating Potassium Mefluidide, Diethanolamine Mefluidide and Mefluidide toxicity have been bridged because toxicity is expected to come from the benzene ring of mefluidide. Therefore, the most sensitive Mefluidide endpoint was selected to represent mammals for all application scenarios.

Appendix F Guideline Sequence Bibliographies for Ecological Effects

PC 14001--Mefluidide

Guideline: 71-1 Avian Single Dose Oral Toxicity

MRID: 41602101

Culotta, J.; Campbell, S.; Hoxter, K.; et al. (1990) Mefluidide: An Acute Oral Toxicity Study with the Northern Bobwhite: Wildlife Int. Project No. 281-106. Unpublished study prepared by Wild- life International Ltd. 17 p.

Guideline: 71-2 Avian Dietary Toxicity

MRID: 41602102

Foster, J.; Driscoll, C.; Hoxter, K.; et al. (1990) Mefluidide: A Dietary LC50 Study with the Northern Bobwhite: Lab Project Number: 281-104. Unpublished study prepared by Wildlife Inter- national Ltd. 17 p.

MRID: 41602103

Foster, J.; Driscoll, C.; Hoxter, K.; et al. (1990) Mefluidide: A Dietary LC50 Study with the Mallard: Lab Project No: 281-105. Unpublished study prepared by Wildlife International Ltd. 19 p.

Guideline: 72-3 Acute Toxicity to Estuarine/Marine Organisms

MRID 425624-01

Graves, W.C. and J.P. Swigert. (1992) Technical Mefluidide: A 96-Hour shell deposition Test with Eastern Oyster Project No. 281A-121 Prepared by Wildlife International Ltd

MRID 425624-02

Graves, W.C. and J.P. Swigert. (1992) Technical Mefluidide: A 96-Hour flow through acute toxicity test with the salt water mysid. Project No. 281A-122a Prepared by Wildlife International Ltd

PC 114002—Mefluidide-DEA

Guideline: 71-1 Avian Single Dose Oral Toxicity

MRID: 41601901

Culotta, J.; Campbell, S.; Smith, G. (1990) Diethanolamine Salt of Mefluidide: An Acute Oral Toxicity Study with the Northern Bob- white: Lab Project Number: 281-103. Unpublished study prepared by Wildlife International Ltd. 17 p.

Guideline: 71-2 Avian Dietary Toxicity

MRID: 41601902

Foster, J.; Driscoll, C.; Hoxter, K.; et al. (1990) Diethanolamine Salt of Mefluidide: A Dietary LC 50 Study with the Northern Bob- white: Lab Project Number: 281-101. Unpublished study prepared by Wildlife International Ltd. 17 p.

MRID: 41601903

Foster, J.; Driscoll, C.; Hoxter, K.; et al. (1990) Diethanolamine Salt of Mefluidide: A Dietary LC50 Study with the Mallard: Lab Project Number: 281-102. Unpublished study prepared by Wildlife International Ltd. 19 p.

Guideline: 72-1 Acute Toxicity to Freshwater Fish

MRID: 41893701

Murphy, D.; Peters, G. (1991) Diethanolamine Salt of Mefluidide: A 96-Hour Flow-Through Acute Toxicity Test with the Bluegill (*Lepomis macrochirus*): Final Report: Lab Project Number: 281A-114. Unpublished study prepared by Wildlife International Ltd. 56 p.

MRID: 41893702

Murphy, D.; Peters, G. (1991) Diethanolamine Salt of Mefluidide: A 96-Hour Flow-Through Acute Toxicity Test with the Rainbow Trout (*Oncorhynchus mykiss*): Final Report: Lab Project Number: 281A- 1113. Unpublished study prepared by Wildlife International Ltd. 56 p.

Guideline: 72-2 Acute Toxicity to Freshwater Invertebrates

MRID: 41893703

Holmes, C.; Peters, G. (1991) Diethanolamine Salt of Mefluidide: A 48-Hour Flow-Through Toxicity Test with the Cladocern (*Daphnia magna*): Final Report: Lab Project Number: 281A-109. Unpublished study prepared by Wildlife International Ltd. 54 p.

Guideline: 72-3 Acute Toxicity to Estuarine/Marine Organisms

MRID: 42562301

Graves, W.; Swigert, J. (1992) Diethanolamine Salt of Mefluidide: A 96-hour Shell Deposition Test with the Eastern Oyster (*Crassostrea virginica*): Final Report: Lab Project Number: 281A-124A. Unpublished study prepared by Wildlife International Ltd. 46 p.

MRID: 42562302

Graves, W.; Swigert, J. (1992) Diethanolamine Salt of Mefluidide: A 96-hour Flow-through Acute Toxicity Test with Saltwater Mysid (*Mysidopsis bahia*): Final Report: Lab Project Number: 281A-125. Unpublished study prepared by Wildlife International Ltd. 45 p.

MRID: 42562303

Graves, W.; Swigert, J. (1992) Diethanolamine Salt of Mefluidide: A 96-hour Flow-through Acute Toxicity Test with the Sheepshead Minnow (*Cyprinodon variegatus*): Final Report: Lab Project Number: 281A-126. Unpublished study prepared by Wildlife International Ltd. 45 p.

Guideline: 122-2 Aquatic plant growth

MRID: 43526601

Hughes, J.; Alexander, M.; Conder, L. (1995) The Toxicity of Diethanolamine (DEA) Salt of Mefluidide to *Navicula pelliculosa*: Lab Project Number: 15-01-3. Unpublished study prepared by Carolina Ecotox, Inc. 58 p.

MRID: 43526602

Hughes, J.; Alexander, M.; Conder, L. (1995) The Toxicity of Diethanolamine (DEA) Salt of Mefluidide to *Skeletonema costatum*: Lab Project Number: 15-01-4. Unpublished study prepared by Carolina Ecotox, Inc. 60 p.

MRID: 43526603

Hughes, J.; Alexander, M.; Conder, L. (1995) The Toxicity of Diethanolamine (DEA) Salt of Mefluidide to *Selenastrum capricornutum*: Lab Project Number: 15-01-1. Unpublished study prepared by Carolina Ecotox, Inc. 60 p.

MRID: 43526604

Hughes, J.; Alexander, M.; Conder, L. (1995) The Toxicity of Diethanolamine (DEA) Salt of Mefluidide to *Anabaena flos-aquae*: Lab Project Number: 15-01-2. Unpublished study prepared by Carolina Ecotox, Inc. 62 p.

MRID: 43526605

Hughes, J.; Alexander, M.; Conder, L. (1995) The Toxicity of Diethanolamine (DEA) Salt of Mefluidide to *Lemna gibba*: Lab Project Number: 15-01-5. Unpublished study prepared by Carolina Ecotox, Inc. 59 p.

Guideline: 123-1 Seed germination/seedling emergence and vegetative vigor

MRID: 43549601

Crosby, K. (1995) Effect of DEA Mefluidide on Vegetative Vigor of Plants: Lab Project Number: 6272-92-0223-BE-001. Unpublished study prepared by Ricerca, Inc. 213 p.

Guideline: 141-1 Honey bee acute contact

MRID: 42562801

Hoxter, K.; Bernard, W.; Smith, G. (1992) An Acute Contact Toxicity Study with the Honey Bee: Diethanolamine Salt of Mefluidide: Final Report: Lab Project Number: 281-111A. Unpublished study prepared by Wildlife Int'l Ltd. 16 p.

PC 114003 Mefluidide-K

Guideline: 141-1 Honey bee acute contact

MRID: 42562802

Hoxter, K.; Bernard, W.; Smith, G. (1992) An Acute Contact Toxicity Study with the Honey Bee: Potassium Salt of Mefluidide: Final Report: Lab Project Number: 281-112A. Unpublished study prepared by Wildlife Int'l Ltd. 16 p.

Appendix G: The Risk Quotient Method and Levels of Concern

The Risk Quotient Method is the means used by EFED to integrate the results of exposure and ecotoxicity data. For this method, risk quotients (RQs) are calculated by dividing exposure estimates by ecotoxicity values (i.e., $RQ = EXPOSURE/TOXICITY$), both acute and chronic. These RQs are then compared to OPP's levels of concern (LOCs). These LOCs are criteria used by OPP to indicate potential risk to non-target organisms and the need to consider regulatory action. EFED has defined LOCs for acute risk, potential restricted use classification, and for endangered species.

The criteria indicate that a pesticide used as directed has the potential to cause adverse effects on nontarget organisms. LOCs currently address the following risk presumption categories:

- (1) acute - there is a potential for acute risk; regulatory action may be warranted in addition to restricted use classification;
- (2) acute restricted use - the potential for acute risk is high, but this may be mitigated through restricted use classification
- (3) acute endangered species - the potential for acute risk to endangered species is high, regulatory action may be warranted, and
- (4) chronic risk - the potential for chronic risk is high, regulatory action may be warranted.

Currently, EFED does not perform assessments for chronic risk to plants, acute or chronic risks to non-target insects, or chronic risk from granular/bait formulations to mammalian or avian species.

The ecotoxicity test values (i.e., measurement endpoints) used in the acute and chronic risk quotients are derived from required studies. Examples of ecotoxicity values derived from short-term laboratory studies that assess acute effects are: (1) LC_{50} (fish and birds), (2) LD_{50} (birds and mammals), (3) EC_{50} (aquatic plants and aquatic invertebrates), and (4) EC_{25} (terrestrial plants). Examples of toxicity test effect levels derived from the results of long-term laboratory studies that assess chronic effects are: (1) LOAEL (birds, fish, and aquatic invertebrates), and (2) NOAEL (birds, fish and aquatic invertebrates). The NOAEL is generally used as the ecotoxicity test value in assessing chronic effects.

Risk presumptions, along with the corresponding RQs and LOCs are summarized in Table E.

Table F: Risk Presumptions and LOCs		
Risk Presumption	RQ	LOC
Birds ¹		
Acute Risk	EEC/LC ₅₀ or LD ₅₀ /sqft or LD ₅₀ /day	0.5
Acute Restricted Use	EEC/LC ₅₀ or LD ₅₀ /sqft or LD ₅₀ /day (or LD ₅₀ < 50 mg/kg)	0.2
Acute Endangered Species	EEC/LC ₅₀ or LD ₅₀ /sqft or LD ₅₀ /day	0.1
Chronic Risk	EEC/NOAEC	1
Wild Mammals ¹		
Acute Risk	EEC/LC ₅₀ or LD ₅₀ /sqft or LD ₅₀ /day	0.5
Acute Restricted Use	EEC/LC ₅₀ or LD ₅₀ /sqft or LD ₅₀ /day (or LD ₅₀ < 50 mg/kg)	0.2
Acute Endangered Species	EEC/LC ₅₀ or LD ₅₀ /sqft or LD ₅₀ /day	0.1
Chronic Risk	EEC/NOAEC	1
Aquatic Animals ²		
Acute Risk	EEC/LC ₅₀ or EC ₅₀	0.5
Acute Restricted Use	EEC/LC ₅₀ or EC ₅₀	0.1
Acute Endangered Species	EEC/LC ₅₀ or EC ₅₀	0.05
Chronic Risk	EEC/NOAEC	1
Terrestrial and Semi-Aquatic Plants		
Acute Risk	EEC/EC ₂₅	1
Acute Endangered Species	EEC/EC ₀₅ or NOAEC	1
Aquatic Plants ²		
Acute Risk	EEC/EC ₅₀	1
Acute Endangered Species	EEC/EC ₀₅ or NOAEC	1

¹ LD₅₀/sqft = (mg/sqft) / (LD₅₀ * wt. of animal)
 LD₅₀/day = (mg of toxicant consumed/day) / (LD₅₀ * wt. of animal)

² EEC = (ppb or ug/L) in water

Appendix H ECOTOX Results

MEFLUIDIDE
Papers that were accepted for ECOTOX

Acceptable for ECOTOX and OPP

Agnello, A. M., Bradley, J. R. Jr., and Van Duyn, J. W. (1986). Plant-Mediated Effects of Postemergence Herbicides on *Epilachna varivestis* (Coleoptera: Coccinellidae). *Environ.Entomol.* 15: 216-220.

EcoReference No.: 71019

Chemical of Concern: MFD,FZFB,SXD; Habitat: T; Effect Codes: REP,GRO,BEH,ENV; Rejection Code: LITE EVAL CODED(SXD,MFD),OK(ALL CHEMS).

Griffin, J. L. and Harger, T. J. (1990). Red Rice (*Oryza sativa*) Control Options in Soybeans (*Glycine max*). *Weed Technol.* 4 : 35-38.

EcoReference No.: 74045

User Define 2: WASH

Chemical of Concern: MTL,BT,FZFP,ACR,SXD,HFP,MFD,FZF,QZF; Habitat: T; Effect Codes: POP; Rejection Code: NO CONTROL,TARGET(SXD).

Kwon, S. L., Smith, R. J. Jr., and Talbert, R. E. (1991). Red Rice (*Oryza sativa*) Control and Suppression in Rice (*O. sativa*). *Weed Technol.* 5: 811-816.

EcoReference No.: 74741

Chemical of Concern: MLT,FNP,AMC,SXD,MFD; Habitat: A; Effect Codes: PHY,POP; Rejection Code: LITE EVAL CODED(MFD),OK(ALL CHEMS).

Marini, R. P., Byers, R. E., and Sowers, D. L. (1989). Growth Regulators and Herbicides for Delaying Apple Fruit Abscission. *Hortscience* 24: 957-959.

EcoReference No.: 76104

Chemical of Concern: BZO,TPR,DMB,PBZ,DMZ,FXP,PDM,MFD; Habitat: T; Effect Codes: GRO; Rejection Code: OK(FXP,DMZ,PBZ),OK TARGET(DMB),NO ENDPOINT(MFD,PDM,BZO,TPR).

Potter, D. A., Spicer, P. G., Redmond, C. T., and Powell, A. J. (1994). Toxicity of Pesticides to Earthworms in Kentucky Bluegrass Turf. *Bull.Environ.Contam.Toxicol.* 52: 176-181.

EcoReference No.: 39542

Chemical of Concern:

24DXY,AZD,BFT,BMY,CPZ,CYF,DTP,EP,FNF,FPD,FSTAI,FVL,MFD,MYC,PRM,TEZ,TPM; Habitat: T; Effect Codes: POP; Rejection Code: LITE EVAL CODED(AZD,FVL,BFT,CYF),OK(ALL CHEMS).

Potter, D. A., Spicer, P. G., Redmond, C. T., and Powell, A. J. (1994). Toxicity of Pesticides to Earthworms in Kentucky Bluegrass Turf. *Bull. Environ. Contam. Toxicol.* 52: 176-181.

EcoReference No.: 39542

Chemical of Concern:

24DXY,AZD,BFT,BMY,CPZ,CYF,DTP,EP,FNF,FPD,FSTAI,FVL,MFD,MYC,PRM,TEZ,TPM; Habitat: T; Effect Codes: POP; Rejection Code: LITE EVAL CODED(MFD,AZD,FVL,BFT,CYF),OK(ALL CHEMS).

Smith, R. J. Jr. (1989). Cropping and Herbicide Systems for Red Rice (*Oryza sativa*) Control. *Weed Technol.* 3: 414-419.

EcoReference No.: 73748

User Define 2: WASH

Chemical of Concern: MTL,TFN,PAQT,ACR,BT,MFD

Endpoint: POP; Habitat: T; Rejection Code: OK.

Storey, G. K. and Gardner, W. A. (1986). Sensitivity of the Entomogenous Fungus *Beauveria bassiana* to Selected Plant Growth Regulators and Spray Additives. *Appl. Environ. Microbiol.* 52: 1-3.

EcoReference No.: 82489

Chemical of Concern: MFD,PBZ,FPD; Habitat: T; Effect Codes:

POP,MOR,REP; Rejection Code: LITE EVAL CODED(MFD),OK(ALL CHEMS).

Turner, K. E., Paterson, J. A., Kerley, M. S., and Forwood, J. R. (1990). Mefluidide Treatment of Tall Fescue Pastures: Intake and Animal Performance. *J. Anim. Sci.* 68: 3399-3405.

EcoReference No.: 82719

Chemical of Concern: MFD; Habitat: T; Effect Codes: PHY,BEH,GRO;

Rejection Code: LITE EVAL CODED(MFD).

Wimer, S. K., Ward, J. K., Anderson, B. E., and Waller, S. S. (1986). Mefluidide Effects on Smooth Brome Composition and Grazing Cow-Calf Performance. *J. Anim. Sci.* 63: 1054-1062.

EcoReference No.: 82721

Chemical of Concern: MFD; Habitat: T; Effect Codes: BCM,POP; Rejection Code: LITE EVAL CODED(MFD).

Acceptable for ECOTOX but not OPP

Agnello, A. M., Van Duyn, J. W., and Bradley, J. R. Jr. (1986). Influence of Postemergence Herbicides on Populations of Bean Leaf Beetle, *Cerotoma trifurcata* (Coleoptera: Chrysomelidae) and Corn Earworm, *Heliothis zea* (Lepidoptera: Noctuidae), in Soybeans. *J.Econ.Entomol.* 79: 261-265.

EcoReference No.: 72071

Chemical of Concern: MFD,SXD,FZFB; Habitat: T; Effect Codes: POP; Rejection Code: NO MIXTURE(SXD,MFD,FZFB),CONTROL(ACR).

Arnold, C. E., Aldrich, J. H., and Martin, F. G. (1983). Vegetative and Flowering Response of Peach to Mefluidide. *Act Horti* 137: 145-152.

EcoReference No.: 44149

Chemical of Concern: MFD; Habitat: T; Effect Codes: GRO; Rejection Code: NO ENDPOINT(MFD).

Atkin, J. C. (1984). The Use of Mefluidide to Control Grass Growth in Amenity Areas. *Asp App Biol* 6: 45-53.

EcoReference No.: 31485

Chemical of Concern: MFD; Habitat: T; Rejection Code: TARGET(MFD).

Banko, T. J. (1985). Evaluation of Growth Regulator Effects of Embark, Atrinal, Blazer, and Bayleton on Container-Grown Azaleas . *J. Environ. Horti*. 3: 149-152.

EcoReference No.: 31450

Chemical of Concern: TDF,ACF,DKGNa,MFD; Habitat: T; Effect Codes: GRO; Rejection Code: OK(ACF),NO ENDPOINT(TDF,TARGET-DKGNa,MFD).

Belander, G. and Winch, J. E. (1985). Herbicides for Sod-Seeding Legumes on Shallow Soil Pastures. *Can.J.Plant Sci.* 65: 1049-1055.

EcoReference No.: 44163

Chemical of Concern: GYP,MFD,FZFB,PAQT; Habitat: T; Effect Codes: POP,BCM; Rejection Code: OK(ALL CHEMS),OK TARGET(MFD).

Chappell, W. E., Coartney, J. S., and Link, M. L. (1977). Plant Growth Regulators for Highway Maintenance. *Proc.South.Weed Sci.Soc.* 30: 300-305.

EcoReference No.: 40596

Chemical of Concern: MFD,MLH; Habitat: T; Effect Codes: GRO,REP; Rejection Code: OK(ALL CHEMS),OK TARGET(MFD).

Elkins, D. M., Vandeventer, J. W., and Briskovich, M. A. (1977). Effect of Chemical Growth Retardants on Turfgrass Morphology. *Agron J* 69: 458-461.

EcoReference No.: 43015

Chemical of Concern: MFD,MLH; Habitat: T; Effect Codes: GRO,MOR;
Rejection Code: OK(ALL CHEMS),OK TARGET(MFD).

Field, R. J. and Whitford, A. R. (1983). Response of Perennial Ryegrass, Prairie Grass, and Browntop to the Growth Retardant, Mefluidide. *Nz J Exp Ag* 11: 199-203 .

EcoReference No.: 44162

Chemical of Concern: MFD; Habitat: T; Effect Codes: BCM,GRO; Rejection Code: NO ENDPOINT(ALL CHEMS).

Gerrish, J. R. and Dougherty, C. T. (1983). Tall Fescue Sward Response to Mefluidide and Nitrogen. *Agron J* 75(6): 895-898.

EcoReference No.: 32345

Chemical of Concern: MFD; Habitat: T; Rejection Code: TARGET(MFD).

Griffin, J. L. and Harger, T. J. (1990). Red Rice (*Oryza sativa*) Control Options in Soybeans (*Glycine max*). *Weed Technol.* 4 : 35-38.

EcoReference No.: 74045

Chemical of Concern: MTL,BT,FZFP,ACR,SXD,HFP,MFD,FZF,QZF; Habitat: T; Effect Codes: POP; Rejection Code: NO CONTROL(TARGET-SXD,MFD) .

Ivie, G. W. (1980). Fate of the Plant Growth Regulator Mefluidide [N-[2,4-Dimethyl-5-[[trifluoromethyl)sulfonyl]amino]phenyl]acetamide] in A Cow and Sheep. *J.Agric.Food Chem.* 28: 1286-1288.

EcoReference No.: 37270

Chemical of Concern: MFD; Habitat: T; Effect Codes: PHY; Rejection Code: NO ENDPOINT(MFD).

Marini, R. P., Byers, R. E., and Sowers, D. L. (1989). Growth Regulators and Herbicides for Delaying Apple Fruit Abscission. *Hortscience* 24: 957-959.

EcoReference No.: 76104

Chemical of Concern: BZO,TPR,DMB,PBZ,DMZ,FXP,PDM,MFD; Habitat: T; Effect Codes: GRO; Rejection Code: OK(FXP,DMZ,PBZ),OK TARGET(DMB),NO ENDPOINT(MFD,PDM,BZO,TPR).

McWhorter, C. G. and Barrentine, W. L. (1979). Weed Control in Soybeans (*Glycine max*) with Mefluidide Applied Postemergence. *Weed Sci.* 27: 42-47.

EcoReference No.: 42763

Chemical of Concern: GYP,BT,MFD,24DB; Habitat: T; Effect Codes: POP,PHY; Rejection Code: OK(ALL CHEMS),OK TARGET(MFD).

McWhorter, C. G. and Wills, G. D. (1978). Factors Affecting the Translocation of 14C-Mefluidide in Soybeans (*Glycine max*), Common Cocklebur (*Xanthium pensylvanicum*) and Johnson Grass (*Sorghum halapense*). *Weed Sci.* 26: 382-388.

EcoReference No.: 29602

Chemical of Concern: MFD; Habitat: T; Rejection Code: TARGET(MFD).

Parups, E. V. and Cordukes, W. E. (1977). Growth of Turfgrass As Affected by Atrinal and Embark. *Hortscience* 12: 258-259.

EcoReference No.: 28947

Chemical of Concern: DKGNa,MFD; Habitat: T; Rejection Code: TARGET(DKGNa,MFD).

Slade, J. J. and Reynolds, J. H. (1985). Plant Growth Regulator Effects on Forage Quality of Tall Fescue and Bermudagrass. *Tenn.Farm Home Sci.* 134: 19-23.

EcoReference No.: 44106

Chemical of Concern: EDT,CQTC,EPH,MFD; Habitat: T; Effect Codes: GRO,BCM,POP; Rejection Code: OK(ALL CHEMS),OK TARGET(MFD,CQTC).

Smith, R. J. Jr. (1989). Cropping and Herbicide Systems for Red Rice (*Oryza sativa*) Control. *Weed Technol.* 3: 414-419.

EcoReference No.: 73748

Chemical of Concern: MTL,TFN,PAQT,ACR,BT,MFD; Habitat: A; Effect Codes: POP; Rejection Code: OK(MTL,TFN,ACR,PAQT),NO MIXTURE(MFD,BT).

Sterrett, J. P. (1979). Injection Methodology for Evaluating Plant Growth Retardants. *Weed Sci.* 27: 688-690.

EcoReference No.: 44029

Chemical of Concern: DKGNa,MFD; Habitat: T; Effect Codes: GRO,BCM; Rejection Code: OK TARGET(MFD,DKGNa).

Truelove, B., Davis, D. E., and Pillai, C. G. P. (1977). Mefluidide Effects on Growth of Corn (*Zea mays*) and the Synthesis of Protein by Cucumber (*Cucumis sativus*) Cotyledon Tissue. *Weed Sci.* 25: 360-363.

EcoReference No.: 43005

Chemical of Concern: MFD; Habitat: T; Effect Codes: POP,GRO,BCM; Rejection Code: OK TARGET(MFD).

MEFLUIDIDE

Papers that were excluded from ECOTOX

2001). Bolster quality efforts by developing effective PI (performance improvement)

- infrastructure. *Hospital Peer Review* 26: 45-47.
- 1996). Four TDR diseases can be "eliminated". *TDR News* 1-2.
- 1992). Pesticide chemicals manufacturing category effluent limitations guidelines, pretreatment standards, and new source performance standards. *Federal Register* 57: 12560-601.
- Productivity in the '90s. The outsourcing source book. *The Journal Of Business Strategy* 14: 52-56.
- Abert, James G. and Vancil, Ronald M. (1977). A graphical approach to determine the economics of recovering resources from municipal solid waste. *Conservation & Recycling* 1: 299-300.
- Abramov, V V, Mustafin, A G, Iarygin, V N, and Kozlov, V A (1991). Immunogenesis and axoplasmic transport in Wistar rats. *Biulleten' Eksperimental'Noi Biologii i Meditsiny* 112: 621-623.
- Abramson, D (1987). Hadley Regional Medical Center embarks on laundry savings plan. *Laundry News* 13: 6.
- Adamczewsk, A M and Morris, S (2001). Metabolic status and respiratory physiology of *Gecarcoidea natalis*, the Christmas Island red crab, during the annual breeding migration. *The Biological Bulletin* 200: 321-335.
- Afanas'ev, Iu I and Bobova, L P (1976). Histophysiology of the thymus gland. *Arkhiv Patologii* 38: 3-17.
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