



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES
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MEMORANDUM

SUBJECT: **Mefluidide:** Occupational and Residential Exposure and Risk Assessment for the Reregistration Eligibility Decision (RED)
[PC Code 114001, 114002, 114003, DP Barcode D324823]

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Attached is the Occupational and Residential Exposure and Risk Assessment for the Mefluidide RED.

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Table of Contents

Executive Summary	4
1.0 Background Information	6
1.1 Purpose and Criteria for Conducting Exposure Assessments	6
1.2 Toxicological Endpoints	6
1.3 Incident Report	9
1.4 Summary of Use Patterns, Formulations and Application Methods	10
2.0 Occupational Handler/Applicator Exposures & Risks	11
2.1 Exposure Scenarios	11
2.2 Occupational Handler Exposure Assumptions and Data Sources	11
2.3 Occupational Handler Exposure and Risk Estimates	13
2.4 Occupational Handler Risk Characterization	14
3.0 Occupational Post Application Exposure and Risks	14
4.0 Residential Handler Exposures and Risks	14
4.1 Residential Handler Scenarios, Data Sources and Assumptions	15
4.2 Residential Handler Exposure and Risk Estimates	15
4.3 Residential Handler Risk Characterization	16
5.0 Residential Turf Post Application Exposure and Risks	16
5.1 Residential Turf Post Application Exposure Scenarios, Data Sources and Assumptions	16
5.2 Residential Turf Post Application Exposure and Risk Estimates	17
5.3 Residential Turf Post Application Risk Characterization	17
6.0 Residential Turf Granule Ingestion Exposure and Risks	18
7.0 References	18
8.0 Glossary of Terms Used in Occupational/Residential Exposure Assessment	19

Appendices

A - Standard Formulas and Data Resources Used for Calculating Mefluidide Occupational and Residential Exposures

B - Occupational Handler Exposure Data and Risk Calculations for Mefluidide (Excel spreadsheet)

C - Residential Handler Exposure Data and Risk Calculations for Mefluidide (Excel spreadsheet)

D - Residential Turf Post Application Risk Assessment for Mefluidide (Excel spreadsheet)

Executive Summary

Mefluidide Use Description

Based upon the mefluidide Use Closure Memo, there are registered products of mefluidide intended for both occupational and residential uses. 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. 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).

Toxicology Endpoints:

The acute reference dose (RfD) for the general population including infants and children is established based on the LOAEL of 115 mg/kg/day for mortality and clinical signs, and the NOAEL of 58 mg/kg/day from rat developmental study, and an UF of 100X (10- fold for inter-species extrapolation, 10-fold for intra-species variability).

Incidental Oral endpoints were based on 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). The level of concern for residential exposure is for MOEs <100 and for occupational exposure is for MOEs <100.

Inhalation (Short- and Intermediate-Term) endpoints were also from the rat developmental study. NOAEL = 58 mg/kg bw/day, LOAEL = 115 mg/kg bw/day based on mortality and clinical sings. Since an oral study was selected for inhalation exposure assessment, an inhalation-absorption factor of 100% oral equivalent should be used.

The risk assessment team determined that no quantitative dermal assessment is needed. Therefore, no dermal endpoint was selected.

Occupational Handler/Applicator 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 Pesticide Handlers Exposure Database (PHED) and the Outdoor Residential Exposure Task Force (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.

Post-Application Occupational Exposure and Risk Estimates:

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).

Residential Applicator Exposure and Risk Estimates:

None of the labels prohibit use by homeowners. The residential products are typically formulated as granules, liquid concentrates, or ready- to- use spray bottles. Spot and broadcast treatments are both included on the labels. The MOEs for residential handlers were calculated using standard assumptions, maximum label rates and PHED unit exposure data. The MOEs exceed the target MOE of 100 which means the risks are below EPA's level of concern.

Residential Turf Post Application Exposure and Risk Estimates

The residential post- application turf exposures to Children through incidental oral were calculated using the Residential SOPs and maximum label rates. The MOEs were then calculated using the incidental oral endpoint of 58 mg/kg/day and they are >100 . This means that the risks are below EPA's level of concern.

Residential Turf Granule Ingestion Exposure and Risk Estimates

The residential post- application exposures to toddlers from ingesting granules that have been applied to residential turf were assessed using a standard method as outlined in the Residential SOPs. The MOEs were then calculated using the acute dietary NOAEL of 58 mg/kg/day and they are > 100 . This means that the risks for toddler exposures from granular ingestion are below EPA's level of concern.

Risk Characterization

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

1.0 Background Information

The following active ingredients are included in this assessment:

<u>Common Chemical Name</u>	<u>PC Code</u>
Mefluidide	114001
Mefluidide, diethanolamine salt	114002
Mefluidide, potassium salt	114003

For the purposes of this assessment, all of the above active ingredients are collectively referred to as mefluidide.

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.

1.1 Purpose and Criteria for Conducting Exposure Assessments

Occupational and residential exposure and risk assessments are required for an active ingredient if: (1) certain toxicological criteria are triggered **and** (2) there is potential exposure to handlers during use, or to field workers entering treated areas after application is completed. Mefluidide meets both criteria. Some of the mefluidide products also contain other registered active ingredient herbicides such as paclobutrazol, imazapyr and imazethapyr. These ingredients are not addressed in this risk assessment.

1.2 Toxicological Endpoints

(HED memo of 3/31/07, A. Khasawinah, D322246)

A summary of the acute toxicity results is included in Table 1.2a, and a summary of endpoint selections is included in Table 1.2b.

Table 1.2 a. Acute Toxicity of Mefluidide and its salts (114001, 114002, 114003)				
Guideline No.	Study Type	MRID	Results (LD₅₀/LC₅₀)	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

Table 1.2b. Summary of Toxicological Dose and Endpoints for Mefluidide and its salt (114001, 114002, 114003) Used in Human Risk Assessment			
Exposure Scenario	Dose Used in Risk Assessment, UF	Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (general population)	NOAEL = 58 mg/kg/day UF = 100X Acute RfD = 0.58 mg/kg	aPAD = <u>Maternal NOAEL</u> Safety Factor = 0.58 mg/kg	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.
Short-Term Incidental Oral (1-30 days)	NOAEL = 58 mg/kg/day	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 signs. 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	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 dermal systemic toxicity at 1000 mg/kg/day (the highest dose tested), 2) The rabbit developmental study combined with the 14 day rabbit oral study indicated a developmental NOAEL of 60 mg/kg/day. Using the 10% dermal absorption factor of 10% (Section 4.3.4 above), the dermal equivalent NOAEL is 600 mg/kg/day and 3) The acute toxicity of mefluidide, where acute dermal LD50 is >4000 mg/kg, not a skin irritant and is not a dermal sensitizer.
Intermediate-Term Dermal (1 to 6 months)			
Long-Term Dermal (>6 months)			
Short-Term Inhalation (1 to 30 days)	Oral NOAEL = 58 mg/kg bw/day NOAEL = 58 mg/kg bw/day (inhalation-absorption rate = 100% oral)	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 signs. These data were also supported by the rabbit developmental study
Intermediate-Term Inhalation (1 to 6 months)		Occupational LOC for MOE = 100	

Exposure Scenario	Dose Used in Risk Assessment, UF	Level of Concern for Risk Assessment	Study and Toxicological Effects
	equivalent)		(NOAEL = 60 mg/kg bw/day) and rabbit 14 day oral study (LOAEL = 100 mg/kg bw/day based on mortality).
Long-Term Inhalation (>6 months)	NOAEL = 1.5 mg/kg/day (inhalation-absorption rate = 100% oral equivalent)	Residential LOC for MOE = 100; Occupational LOC for MOE = 100	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.
Cancer	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.		

UF = uncertainty factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure, LOC = level of concern, NA = Not Applicable. Safety factor = 100.

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

1.3 Incident Report

(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:

- 1) OPP Incident Data System (IDS) - No reports for mefluidide 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 descriptions of 1 case was submitted to the California Pesticide Illness Surveillance Program (1982-2003) were 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.

1.4 Summary of Use Patterns, Formulations and Application Methods

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). The total sales of mefluidide from year 2004 through 2006 are about 20,000 lbs.

HED has analyzed all existing mefluidide product labels. The label suggested use patterns, formulations, application methods and maximum application rates are summarized in Table 1.4 below.

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 1-L)	Groundboom, Backpack sprayer	Turf, commercial-industrial, public area	1.0 lbs ai/A	0.067 lbs ai/gallon
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

2.0 Occupational Handler/Applicator Exposures & Risks

2.1 Exposure Scenarios

Based upon the application methods listed in Table 1.4, the following exposure scenarios were 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

2.2 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. These values are listed in Table A-1 of the Appendix A.

- 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 are summarized in Tables A-2 and A-3 of Appendix A. A summary of PHED and ORETF is provided below.

PHED Data

PHED was designed by a task force of representatives from the US EPA, Health Canada, the California Department of Pesticide Regulation, and member companies of the American Crop Protection Association. PHED is a software system consisting of two parts – a database of measured exposure values for workers involved in the handling of pesticides under actual field conditions and a set of computer algorithms used to subset and statistically summarize the selected data. Currently, the database contains values for over 1,700 monitoring events. The distribution of exposure values for each body part (e.g., chest, upper arm) is categorized as normal, lognormal, or “other” (i.e., neither normal nor lognormal). A central tendency value is then selected from the distribution of the exposure values for each body part. These values are the arithmetic mean for normal distributions, the geometric mean for lognormal distributions, and the median for all “other” distributions. Once selected, the central tendency values for each body part are composited into a “best fit” exposure value representing the entire body.

The unit exposure values calculated by PHED generally range from the geometric mean to the median of the selected data set. To add consistency and quality control to the values produced from this system, the PHED Task Force has evaluated all data within the system and has developed a set of grading criteria to characterize the quality of the original study data. The assessment of data quality is based upon the number of observations and the available quality control data. These evaluation criteria and the caveats specific to each exposure scenario are summarized in Tables A-2 and A-3 of Appendix A. While data from PHED provide the best available information on handler exposures, it should be noted that some aspects of the included studies (e.g., duration, acres treated, pounds of active ingredient handled) may not accurately represent labeled uses in all cases. HED has developed a series of tables of standard unit exposures for many occupational scenarios that can be used to ensure consistency in exposure

assessments.

ORETF Data

Handler exposure data generated by the Outdoor Residential Exposure Task Force (ORETF) were used for assessing the lawn care operator scenarios. These studies are summarized in the HED Memorandum "Summary of HED's Reviews of ORETF Chemical Handler Exposure Studies; MRID 449722-01", DP Barcode D261948 of April 30, 2001. These studies used Dacthal as a surrogate compound with a target application rate of 2.0 lbs/ai acre. These studies were conducted in accordance with current Agency guidelines and the data generated were of high quality. These studies have been reviewed by HED and Health Canada.

2.3 Occupational Handler Exposure and Risk Estimates

Calculation Methodology and Equations

Daily inhalation doses and Margins of Exposure (MOEs) were calculated using standard HED methodology as described in Appendix A-1. The target MOE is 100 for short/intermediate/long term exposure. Scenarios with an MOE less than the target MOE indicates a risk of concern for the occupational population.

Results and Comparison to HED's levels of concern (MOE)

The MOEs for occupational handlers are summarized in Table 2.3 and a detailed listing is included in Appendix B (Excel spreadsheet). 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 2.3 – Mefluidide Inhalation MOEs for Occupational Handlers					
Exposure Scenario	Use Site	Application Rate	Daily Amount Treated or Applied	Inhalation Unit Exposure at Baseline	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	0.011b 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.					

2.4 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.

3.0 Occupational Post Application Exposure and Risks

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).

4.0 Residential Handler Exposures and Risks

No product labels specified for professional use only. The residential products are typically formulated as granules, or as liquid concentrates, or ready- to- use sprinkler can sprays. Several

of these formulations include other active herbicides. Spot and broadcast treatments are both included on the labels. Exposures are expected to be short term in duration.

4.1 Residential Handler Scenarios, Data Sources and Assumptions

Scenarios

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 scenarios #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 (this study was discussed in Section 2.2). Exposure data for scenario #4 was taken from MRID 444598-01, 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, which now belongs to the ORETF. Below is the title of the cited study:

Carbaryl: MRID 44459801 Mixer/Loader/Applicator Exposure Study during Application of RP-2 Liquid (21%) Sevin® Ready to Use Insect Spray or Sevin® 10 Dust to Home Garden Vegetables. Agrisearch Study No. 1519. EPA MRID 444598-01. Report dated August 22, 1998, Author; Thomas C. Mester, Ph.D., Sponsor: Rhone Poulenc Ag Company.

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.

4.2 Residential Handler Exposure and Risk Estimates

The MOE calculations are included in Appendix C and a summary is included in Table 4.2. The MOEs exceed the target MOE of 100 and the risks are below EPA's level of concern.

Table 4.2- 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 (MRID444598-01)	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 (MRID444598-01)	6.0E-06	9,000,000

4.3 Residential Handler Risk Characterization

The MOEs greatly exceed 100, therefore, risk characterization is not needed.

5.0 Residential Turf Post Application Exposure and Risks

5.1 Residential Turf 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 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 Appendix A. The MOEs were calculated using the short/intermediate term incidental oral endpoint which has a NOAEL of 58 mg/kg/day.

5.2 Residential Turf Post- Application Exposure and Risk Estimates

The MOEs are summarized in Table 5.2 and the detailed calculations are included in Appendix D. All of the MOEs exceed 100. This means that the risks are below EPA’s level of concern.

Table 5.2 - 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

5.3 Residential Turf Post Application Risk Characterization

The risk assessment for toddler turf exposures is 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.

6.0 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 6.0. 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 6.0 - 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 References

See Appendix A.

8.0 Glossary of Terms Used in Occupational/Residential Exposure Assessment

TERM	DEFINITION
SOP	Standard operating procedures
AI	Active ingredient
Baseline PPE	Includes long pants, long sleeved shirt, shoes, socks and no gloves or respirator
DAT	Day after treatment
Dose	The amount of pesticide that is absorbed into the body.
Double Layer PPE	Includes coveralls over single layer PPE
ExpoSac - Scientific Advisory Committee for Exposure	A committee within the EPA Health Effects Division that reviews pesticide exposure assessments and develops policy.
Exposure	The amount of pesticide that impinges upon the skin or is inhaled.
Handler/Applicator	A worker who mixes, loads and/or applies pesticides
MOE - Margin of Exposure	The ratio of the “safe” dose (usually the NOAIL) divided by the estimated exposure. Formerly called the Margin of Safety.
LOAEL	Lowest Observed Adverse Effect Level
NOAEL	No Observed Adverse Effect Level
ORETF	Outdoor Residential Exposure Task Force
PF5 Respirator	A filtering facepiece respirator (i.e. dustmask) that has a protection factor of 5 when properly fitted.
PF10 Respirator	A half face respirator with cartridges that has a protection factor of 10 when properly fitted.
PHED	Pesticide Handlers Exposure Database
ROW - Right of Way	Areas such as roadsides, powerlines, railway right-of-way and pipelines.
Single Layer PPE	Includes baseline PPE with chemical resistant gloves