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Reregistration Eligibility Decision

Sulfometuron Methyl

List D

Case No. 3136

Reregistration Eligibility Decision (RED) Document for Sulfometuron Methyl

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Glossary of Terms and Abbreviations

ai	Active Ingredient
CFR	Code of Federal Regulations
CSF	Confidential Statement of Formula
DCI	Data Call-In
EC	Emulsifiable Concentrate Formulation
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
G	Granular Formulation
GLN	Guideline Number
LOC	Level of Concern
LOD	Limit of Detection
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	Milligrams Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MUP	Manufacturing-Use Product
NA	Not Applicable
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
NOAEL	No Observed Adverse Effect Level
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SAP	Science Advisory Panel
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TGAI	Technical Grade Active Ingredient
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UF	Uncertainty Factor
UV	Ultraviolet
WPS	Worker Protection Standard

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 U.S. Environmental Protection Agency, referred to as EPA or "the Agency." Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential 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" criterion of FIFRA.

This document summarizes EPA's human health and ecological risk assessments and reregistration eligibility decision (RED) for sulfometuron methyl. The document consists of six sections. Section I contains the regulatory framework for reregistration; Section II provides an overview of the chemical and a profile of its use and usage; Section III gives an overview of the human health and environmental risk assessments; Section IV gives an overview of information concerning the benefits associated with the use of this active ingredient and presents the Agency's decision on reregistration eligibility and risk management; and Section V summarizes the label changes necessary to implement the risk mitigation measures outlined in Section IV. Finally, the Appendices list related information, supporting documents, and studies evaluated for the reregistration decision. The risk assessments for sulfometuron and all other supporting documents are available in the Office of Pesticides Program (OPP) public docket at www.regulations.gov under docket number EPA-HQ-OPP-2008-0129.

I. Chemical Overview

A. Regulatory History

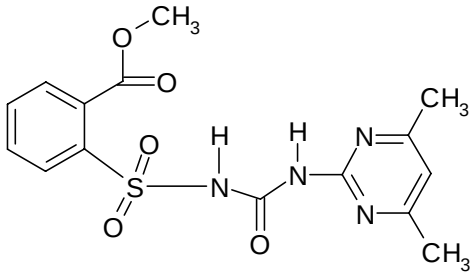
Sulfometuron methyl was originally registered as a pesticide active ingredient in the United States in February 1982. Commodity tolerances have never been established for sulfometuron since there are no food/feed uses. There are currently 24 products with sulfometuron as an active ingredient registered with the EPA. Currently, four companies hold active section 3 registrations to produce technical grade sulfometuron. Three data call-ins (DCIs) were issued for the active ingredient sulfometuron in 1992, 1993, and 1995. At this time, no outstanding DCIs exist.

B. Chemical Identification

Sulfometuron methyl is a sulfonylurea herbicide that provides broad spectrum pre- and post-emergence control of annual and perennial grasses and broad-leaf weeds in forestry and non-crop situations, including vegetative management and rights of way and railroad. Similar to other sulfonylurea herbicides, sulfometuron's mode of action involves inhibiting the activity of

the enzyme acetolactate synthase (ALS), which inhibits the production of amino acids required for cell growth in plants. Chemical information and the structure for sulfometuron are presented in Table 1.

Table 1. Physical-Chemical Properties of Sulfometuron Methyl

PC Code	122001
IUPAC Chemical Name	2-(4,6-Dimethylpyrimidin-2-ylcarbamoylsulfamoyl) benzoic acid, methyl ester ***OR*** 2-[3-(4,6-dimethylpyrimidin-2-yl)ureidosulfonyl] benzoic acid, methyl ester
CAS Chemical Name	2-[[[[(4,6-Dimethyl-2-pyrimidinyl) amino] carbonyl] amino] sulfonyl] benzoic acid, methyl ester
CAS number	74222-97-2
Structure	
Pesticide type	Herbicide
Chemical class	Sulfonylurea herbicide
Empirical formula	$C_{15}H_{16}N_4SO_5$
Molecular Mass (g/mol)	364.38
Vapor pressure at 20° C	5.4 x10^{-16} Torr
Henry's Law Constant at 20° C (atm m3/mol)	1.1 x 10^{-18}, calculated from vapor pressure
Solubility in water (mg/L)at 20°C	pH 5 buffer…. 6.42 ppm pH 7 buffer…. 244 ppm pH 8.6 buffer…. 12,500 ppm
Log K_{ow}	pH 5 = 1.03 pH 7 = -0.46 pH 9 = -1.87
pKa at 25°C	5.2

C. Use Profile

Type of Pesticide: Herbicide

Summary of Use: Applied to non-food/feed crops in agricultural and non-agricultural settings primarily forestry, non-cropland and rights of way uses

Formulation Type:	One registered sulfometuron methyl product is formulated as a granular; all other products are formulated as water dispersible granules (WDG)
Application Methods:	Applied aerially via helicopter and fixed wing aircraft, backpack sprayer, and ground application via broadcast, directed, open and closed cab
Use Rates:	From 0.0231 to 0.375 lb ai/A or 0.3696 to 6 oz ai/A
Common Trade Names:	Oust, Oust XP, SFM, Spyder
Basic Manufacturers:	E.I. DuPont de Nemours & Co. Inc., Arysta Life Science North America Corp., Vegetation Management LLC, Etigra LLC

D. Estimated Usage of Pesticide

Approximately 230,000 pounds of sulfometuron methyl are used per year according to the 2006 Screening Level Usage Analysis (SLUA). The heaviest use sites are forestry and rights of way use for roads and railroads.

II. Summary of Sulfometuron Methyl Risk Assessment

The following is a summary of EPA's human health and ecological risk findings and conclusions for sulfometuron methyl to help the reader better understand EPA's risk management decisions. The full risk assessments and related supporting documents are available in the public docket (http://www.regulations.gov) under docket number EPA-HQ-OPP-2008-0129.

A. Human Health Risk Assessment

The human health assessment addressed potential risks from all registered uses and sources. The Agency assessed exposures from both residential and occupational applications. Sulfometuron methyl is not used on any food commodity in the U.S. so dietary exposure via food was not assessed. However, dietary exposure via residues in drinking water was assessed because sulfometuron is used outdoors. For the complete human health risk assessment, refer to *Phase 3 Amendment of "Sulfometuron Methyl: HED Chapter of the RED Document"* (W. Britton D385620) and *Sulfometuron Methyl: Addendum to the HED Chapter of the RED* (W. Britton D346173), which are available in the public docket.

1. Toxicology

The available submitted toxicity data and published literature on sulfometuron methyl are adequate to assess the chemical's hazard potential. The toxicity database consists of acute toxicity studies, a chronic toxicity study in dogs, and mutagenicity tests. The Agency has reviewed 21-day dermal and pre-natal development toxicity studies in rats and rabbits, but they were not used for risk assessment purposes due to many deficiencies in the studies. Instead the toxicity end points were derived from the chronic feeding toxicity study in dogs (MRID No. 0129051)

Carcinogenicity studies on sulfometuron methyl were not required since it is a non-selective herbicide used on non-agricultural areas where human contact with previously treated areas is expected to be minimal. Long term handler exposure is not expected since sulfometuron is a non-food/non-feed pesticide making chronic exposure unlikely. Mutagenicity/genetic toxicity studies indicated sulfometuron does not produce mutagenic activity in bacteria or hamsters (MRID No. 00078792 & 00078793).

Neurotoxicity testing for sulfometuron methyl is not required as there are no food or feed tolerances and no indications of neurotoxicity in any available studies.

Sulfometuron methyl has a low acute toxicity profile (Toxicity Category III or IV) and it is neither a dermal irritant nor a dermal sensitizer. Sulfometuron methyl is not acutely toxic via dermal, inhalation, and oral routes of inhalation. Table 2 describes the acute toxicity profile of sulfometuron.

Table 2. Acute Toxicity Profile on Sulfometuron Methyl

Guideline No.	Study Type	MRID No.(s)	Results	Toxicity Category
870.1100	Acute oral rat	43089201	LD_{50} >5g/kg	IV
870.1200	Acute dermal rabbit	43089202	LD_{50} >2g/kg	III
870.1300	Acute inhalation rat	43089203	LC_{50} >5.0 mg/L	IV
870.2400	Acute eye irritation rabbit	00071412	Minimal irritant	III
870.2500	Acute dermal irritation rabbit	41672808	Not a dermal irritant*	IV
870.2600	Skin sensitization rabbit	43089204	Not a dermal sensitizer	N/A

All studies were conducted on technical grade sulfometuron methyl, of at least 98.8%, purity.
* Minimal skin irritation was noted in the acute dermal toxicity study (MRID No. 43089202) and an older dermal irritation study of a 75% formulation (MRID No. 00071411)

Subchronic, Chronic and other Toxicity Profile

The primary effect of this sulfonylurea herbicide is hemolytic anemia, which represents the most sensitive endpoint for risk assessment. Developmental rabbit studies resulted in abortions at much higher maternal doses of 750 mg/kg/day.

Table 3. Summary of Toxicological Doses and Endpoints for Sulfometuron Methyl for Use in Dietary and Non-Occupational Human Health Risk Assessments

Exposure/ Scenario	Point of Departure	Uncertainty Factors	RfD, LOC for Risk Assessment	Study and Toxicological Effects
Acute Dietary – Drinking Water Only (all population subgroups)	NOAEL= 27.5 mg/kg/day	UF_A= 10 x UF_H=10 x	Acute RfD = 0.275 mg/kg/day	Chronic 1-year dog study LOAEL = 148.5 mg/kg/day based on decreases in body weight in males (beginning on the fourth week of exposure and persisted throughout), hemolytic anemia and a slight increase in alkaline phosphatase in males and females.
Chronic Dietary – Drinking Water Only (All Populations)			Chronic RfD = 0.275 mg/kg/day	
Dermal Short- (1-30 days) and Intermediate-Term (1-6 months) (no residential uses)	NOAEL= 27.5 mg/kg/day	UF_A= 10x UF_H= 10x	LOC for MOE = 100	
Inhalation Short- (1-30 days) and Intermediate-Term (1-6 months) (no residential uses)				
Cancer (oral, dermal, inhalation)	No data available for assessment.			

NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). RfD = reference dose. MOE = margin of exposure. LOC = level of concern. N/A = not applicable.

2. Dietary Exposure and Risk (Drinking Water Only)

There are no registered food or feed uses for sulfometuron methyl, therefore a food related dietary risk assessment has not been conducted. However, since all of sulfometuron's registered uses are for outdoor uses, the potential for dietary exposure via drinking water exists.

Typically, the Agency uses the reference dose approach for estimating risk from acute and chronic dietary exposures. Therefore, the Margin of Exposure (MOE) approach was used to assess the risk from acute and chronic drinking water exposures. Both approaches incorporate the exposure and toxicity of the pesticide. For both assessments, the risk is expressed as a percentage of a maximum acceptable dose (i.e., the dose which the Agency has concluded will result in no unreasonable adverse health effects). This dose is referred to as the acute reference dose (aRfD) and the chronic reference dose (cRfD). The aRfD and cRfD are equivalent to a point of departure (POD); in this case a no observed adverse effect level (NOAEL), divided by the appropriate uncertainty factors.

The aRfD and cRfD values were both taken from the chronic dog feeding study (MRID 0129051). A NOAEL of 27.5 mg/kg/day was selected from this study. The lowest observed adverse effect level (LOAEL) of 148.5 mg/kg/day was based on decreases in body weight in males, hemolytic anemia in both sexes. The NOAEL value was combined with the uncertainty

factor of 100X (10 interspecies; 10 intraspecies) to produce an aRfD and cRfD of 0.275 mg/kg/day.

An acute and chronic screening-level drinking water only dietary assessment was conducted for sulfometuron methyl using the Dietary Exposure Evaluation Model Food Commodity Intake Database (DEEM-FCID™) (Version 2.03). Because sulfometuron is a non-food/non-feed use chemical, the dietary risk assessment was based on drinking water exposure of the parent compound sulfometuron methyl as well as the potential water degradates sulfometuron free acid, sulfometuron pyrimidine amine, sulfometuron sulfonamide, and saccharin, as the combined residues of parent and metabolites. It is conservative in its approach and is unlikely to underestimate the concentration of sulfometuron methyl in drinking water. The highest ground and surface water (acute) Estimated Drinking Water Concentrations (EDWC) relevant to the maximum supported use rate of sulfometuron methyl were 1.1 and 32.4 ppb, respectively. The highest ground and surface water (chronic) EDWCs relevant to the maximum supported use rate of sulfometuron methyl were 1.1 and 21.8 ppb, respectively. Accordingly, the larger surface water values of 32.4 (acute) and 21.8 (chronic) ppb were used in the acute and chronic screening-level drinking water dietary assessments.

An acute, water only dietary risk analysis for sulfometuron methyl yielded estimates well below 100% of the aRfD threshold exposure level of concern for the US population and each population subgroup. For the US Population, acute dietary risk was calculated at <1 % of the aRfD with an exposure level of 0.0017 mg/kg/day. For the subgroup with the highest estimated exposure, all infants less than 1 year old, acute dietary risk occupied 2.3 % of the aRfD with an exposure of 0.0064 mg/kg/day.

The chronic water only dietary analysis for sulfometuron methyl yielded risk estimates well below the 100% of the cRfD threshold level of concern for the US population and each population subgroup. For all populations including the subgroup with the highest estimated exposure, all infants less than 1 year old, chronic dietary risk occupied < 1 % of the cRfD.

Summary

The conservative acute and chronic screening-level drinking water dietary assessment made with DEEM-FCID™ indicates that exposures to sulfometuron methyl are below the Agency's level of concern for all population subgroups. Therefore, the Agency is not concerned that the non-food/ non-feed use of sulfometuron could result in unacceptable risk through potential exposure from drinking water sources.

3. Residential Exposure

Residential exposure/risk (handler and postapplication) was not assessed since label instructions do not allow applications of sulfometuron methyl to residential or recreational settings. While residential exposure is possible from drift from non-residential applications, it is not likely when applications are made according to the label. The occupational exposure scenarios for sulfometuron show direct exposure to sulfometuron to be well below the Agency's

level of concern (LOC) when workers are handling product, therefore it is unlikely that any indirect or accidental exposure that may occur in a residential setting will be of concern.

4. Aggregate Exposure and Risk

An aggregate exposure assessment is typically conducted for non-food chemicals when there is potential for human exposure through both water and residential pathways. However, sulfometuron methyl has no residential uses and no expected dietary contribution for food, therefore, the aggregate exposure assessment is equivalent to the drinking water assessment.

5. Occupational Exposure and Risk

a. Occupational Handler/Application Assessment

Based on current use patterns, sulfometuron methyl exposure to occupational handlers is expected. The representative scenarios selected by the Agency for assessment were evaluated using site specific maximum application product label rates (0.38, 0.19, and 0.09 lb ai/A for all occupational scenarios).

To assess the handler risks, the Agency used surrogate unit exposure data from the Pesticide Handlers Exposure Database (PHED). Short-term (1-30 days) and intermediate-term (31-90 days) exposures were evaluated that combined dermal and inhalation risks.

In the absence of acceptable dermal absorption data, a default 100% absorption factor has been assumed. For the short-term and long-term dermal and inhalation exposure scenarios for workers, the endpoint from a chronic oral toxicity study in dogs (MRID No. 00129051) was used in the absence of acceptable dermal and inhalation data.

Several scenarios both for ground and aerial applications were assessed, for a detailed listing see the human health risk assessments. Table 4 presents a summary of calculations for occupational sulfometuron methyl handlers with baseline personal protective equipment (PPE). All but two of the exposure scenarios have MOEs >100 (below the Agency's LOC). The two scenarios that resulted in MOEs ≤100 are for WDGs applied via aerial equipment on forestry and non-crop sites and dermal and combined exposure for liquids applied via low pressure hand wand.

Table 4. Sulfometuron Methyl MOEs Attributable to Short- and Intermediate-term Combined Dermal and Inhalation Occupational Exposure (Baseline PPE)

No.	Scenario	Target	App. Rate[b] (lb ai/acre)	Area Treated (acres)	Dermal[c] MOEs	Inhalation[d] MOEs	Combined[e] MOEs
Mixer/Loaders							
1	WDGs: Aerial Equipment (Fixed Wing and Helicopter)	Forestry (Hardwoods, Conifers), Non-Crop Areas (Public, Private, Military Lands)	0.38	1200	**65**	5600	**64**
		Turf (Unimproved)	0.19		130	11000	130
		Non-Crop Land Restoration	0.09		260	22000	260
Applicators							
2	Liquids: Aerial Applications (Fixed Wing and Helicopter)	Forestry (Hardwoods, Conifers), Non-Crop Areas	0.38	1200	900	63000	840
		Turf (Unimproved)	0.19		1700	130000	1700
		Non-Crop Land Restoration	0.09		3400	250000	3400
Flaggers							
3	Liquids: Aerial Sprays (Fixed Wing and Helicopter)	Forestry (Hardwoods, Conifers), Non-Crop Areas	0.38	350	1300	42000	1300
		Turf (Unimproved)	0.19		2700	84000	2600
		Non-Crop Land Restoration	0.09		5300	170000	5200
Mixer/Loader/Applicators							
4	Liquids: Low Pressure Handwand	Non-Crop Areas	0.38	1	**51**	170000	**51**
		Turf (Unimproved)	0.19		100	340000	100
		Non-Crop Land Restoration	0.09		210	680000	210

a Baseline = Long pants, long-sleeved shirt, no gloves
b Application rate based upon maximum labeled value.
c Dermal MOE = Dermal NOAEL (27.5 mg/kg/day)/ (Dermal Daily Dose [Reference W.Britton, 345025])
d Inhalation MOE = Inhalation NOAEL (27.5 mg/kg/day) / (Inhalation Daily Dose [Reference W.Britton, 345025])
e Combined MOE = 1/((1/Dermal MOE)+(1/Inhalation MOE))

Table 5 presents a summary of calculations for occupational sulfometuron methyl handlers with double layer PPE (coveralls, gloves, and shoes and socks in addition to the baseline PPE). The exposure scenario for mixing/loading of WDGs for aerial application to forestry and non-crop areas results in a combined MOE = 90 at the maximum level of personal protection (double layer with gloves) and, therefore, is of potential concern, however, as discussed in the risk characterization section below, no additional mitigation is necessary. The exposure scenario for low pressure hand wand application of liquid is not expected to be of concern with the use of additional PPE.

Table 5. Sulfometuron Methyl MOEs Attributable to Short- and Intermediate-term Combined Dermal and Inhalation Occupational Exposure with Required Additional PPE[a]

No.	Scenario	Target	App. Rate[a] (lb ai/acre)	Area Treated (acres)	Dermal[b] MOEs	Inhalation[c] MOEs	Combined[d] MOEs
Mixer/Loaders - Double Layer PPE[e]							
1	WDGs: Aerial Equipment (Fixed Wing and Helicopter)	Forestry (Hardwoods, Conifers), Non-Crop Areas (Public, Private, Military Lands)	0.38	1200	91	5600	90
Mixer/Loader/Applicators - Single Layer with Gloves Level of PPE							
8	Liquids: Low Pressure Handwand	Non-Crop Areas	0.38	1	12000	170000	12000

a Application rate based upon maximum labeled value.
b Dermal MOE = Dermal NOAEL (27.5 mg/kg/day)/ (Dermal Daily Dose [Reference W.Britton, 345025])
c Inhalation MOE = Inhalation NOAEL (27.5 mg/kg/day) / (Inhalation Daily Dose [Reference W.Britton, 345025])
d Combined MOE = 1/((1/Dermal MOE)+(1/Inhalation MOE))
e Double Layer PPE = Baseline PPE + Coveralls, Gloves, Shoes and Socks

An assessment of the occupational risks of mixing, loading, and applying fertilizer impregnated with sulfometuron methyl in forestry was conducted in *Sulfometuron Methyl: Addendum to "Sulfometuron Methyl: ORE Chapter of the RED* (W. Britton D346173). All of the sulfometuron impregnated fertilizer exposure scenarios have MOEs >100 and therefore risk estimates are below the Agency's LOC. For further detail, please see *Sulfometuron Methyl: Addendum to the HED Chapter of the RED*" (W. Britton D346173) which is available in the docket.

b. Occupational Post-Application Exposure

An assessment of occupational postapplication exposure to sulfometuron methyl was not performed. Since sulfometuron is a non-selective herbicide used in non-agricultural areas, the Agency has determined that contact with previously treated areas is likely to be insignificant.

c. Risk Characterization

The occupational handler dermal exposure scenario for forestry aerial applications is the only scenario for which risks above the Agency's LOC were estimated for some uses; risk estimates for other scenarios (e.g., chronic and acute drinking water) were not of concern. The exposure scenario mixing/loading of WDGs for aerial application to forestry and non-crop areas results in a combined MOE = 90 at the maximum level of personal protection (double layer with gloves). While this exposure scenario is of potential concern, this concern is significantly reduced because of the use of the conservative inputs as described below.

Due to a number of deficiencies identified in the conduct of the 21-day dermal study, it was deemed unsuitable for endpoint selection. In lieu of a route-specific study, the endpoint from the chronic oral toxicity study in dogs was used to estimate the potential for risk from dermal exposure to sulfometuron methyl. The Agency is confident that the use of the chronic oral study, combined with the required PPE, results in risk estimates that are not of concern for the following reasons:

- Although the 21-day dermal study had significant flaws, no toxicity was observed at 2000 mg/kg/day following 21 days of dosing;

- The results of the acute dermal toxicity study in rabbits shows an $LD_{50} \geq 2000$ mg/kg [Toxicity Category III]); and

- Dermal risks, which drive handler risks, were calculated assuming 100% dermal absorption due to lack of acceptable dermal absorption data. Assuming even a slightly lower dermal absorption of 90%, which is still likely to exceed the actual dermal absorption, would result in risk estimates which are not of concern for all scenarios, assuming some level of personal protective equipment is employed.

6. Human Incident Reports

The OPP Incident Data System (IDS) was consulted for poisoning incident data on the active ingredient sulfometuron methyl. There are 4 reported incidents in the IDS since 2000. The incidents are associated with a variety of symptoms including abdominal pain, diarrhea, tremors, joint pain, edema, hives, welts, hair loss, fingernail loss, jaundice, eye irritation, welts, respiratory irritation, weakness, and a fast pulse.

The American Association of Poison Control Center (AAPCC) data was also consulted (1993-2005) for poisoning incident data on sulfometuron methyl. A total of 40 incidents were reported for sulfometuron, with 37 of the 40 associated with EPA Registration Number 352-401 (3 of the 4 IDS cases were also associated with this product). Six of the incidents resulted in moderate effects as noted by AAPCC (3 occurring in a residential environment, 1 in a public area and 2 in the workplace) and 18 of the incidents resulted in minor effects (9 occurring in a residential environment, 6 in a public area and 3 in the workplace). There were no deaths and no major incidents related to sulfometuron exposure. The remaining 16 of the 40 AAPCC incidents were either not followed (15, with minimal to no effects expected from the exposure incident) or were determined to have resulted in no effects (1 incident). Based on the use sites authorized on the label (forestry, rights of way and railroads) and the toxicity profile of sulfometuron these incidents do not warrant regulatory concern.

7. Endocrine Disruption

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, sulfometuron methyl may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

B. Environmental Risk Assessment

The Agency conducted an environmental assessment for sulfometuron methyl for the purpose of making a reregistration decision. A summary of the environmental risk assessment findings and conclusions is provided below. For more detail on the sulfometuron environmental risk assessment, refer to *Environmental Fate and Ecological Risk Assessment for the Reregistration of Sulfometuron Methyl: Vegetative Management and Other Non-Crop Uses* (M. Barrett, K. Sappington D354292) which is available in the public docket.

1. Environmental Fate and Transport

Persistence

Sulfometuron methyl is expected to be relatively persistent in soil and water (half-life ranging from about 2 weeks to 6 months, depending on environmental conditions). Sulfometuron may degrade slowly under low pH conditions in soil and water.

Abiotic and microbially-mediated hydrolysis / degradation are both major routes of transformation of sulfometuron methyl in water, soil, and water-sediment systems. The degradation in soil and water appears to be enhanced in the presence of an active microbial population (aerobic and anaerobic degradation both proceed more slowly under sterile conditions).

Transport and Bioaccumulation

Sulfometuron methyl has a low potential to volatilize from soil or water or to bioaccumulate. Off-site transport of sulfometuron occurs via spray drift, and the wind erosion of soil particulates containing sulfometuron.

Sulfometuron methyl does not sorb strongly to soils and has the potential to leach to ground water and/or reach surface water during runoff events. Sulfometuron is a weak acid (pKa of 5.2). The mobility of sulfometuron is expected to increase with increasing pH based upon available data submitted to EPA for related sulfonylurea herbicides and published studies; however direct, definitive evidence of this for sulfometuron has not been produced.

2. Ecological Exposure and Risk

In ecological risk assessments, the ecological effects characterization describes the types of effects a pesticide can potentially produce in an animal or plant. This characterization is generally based on registrant-submitted studies that describe acute and chronic effects information for various aquatic and terrestrial animals and plants; however, these data may also be supplemented by data reported in the ECOTOXicology database (ECOTOX) (http://cfpub.epa.gov/ecotox/) or open/public literature sources that have met Agency criteria for acceptability.

Toxicity testing reported in this section does not include all species potentially affected by sulfometuron methyl usage. Only a few species for fish, aquatic invertebrates and birds are used to represent all species in the United States. For mammals, toxicity studies are limited to the laboratory rat. Also, neither reptiles nor amphibians are tested. The risk assessment assumes that estimates of risks to avian species are protective of reptilian and terrestrial-phase amphibians. The same assumption is used for fish and aquatic-phase amphibians. Terrestrial plant data are derived from the vegetative vigor and seedling emergence tests, typically on 10 agricultural crop species, and do not account for potential chronic or reproductive effects. Typically, five aquatic plant species are used to represent potential toxicity to all aquatic plant species.

Most of the studies with non-target organisms were conducted with sulfometuron methyl technical. An acute oral toxicity study in rats using the typical end use product (TEP) Oust® was submitted by the registrant. Other toxicity studies using the TEP Oust® were taken from ECOTOX.

a. Aquatic Organisms

Freshwater Fish, Invertebrates, Estuarine/Marine Fish

Available acute toxicity data for freshwater fish and invertebrates indicate that sulfometuron methyl is practically non-toxic on an acute exposure basis. All EC_{50}s/ LC_{50}s are >100 mg/L. For marine and estuarine fish and invertebrates, available acute toxicity data indicate that sulfometuron is at most slightly toxic on an acute exposure basis (EC_{50}/ LC_{50}s range from >38 to >45 mg ai/L).

No acceptable studies were available for evaluating the effects of chronic exposure to sulfometuron methyl on freshwater, estuarine or marine fish. Chronic no observable adverse effect concentrate (NOAEC) for freshwater fish was therefore estimated to be >21 mg ai/L using an acute-chronic ratio derived from flazasulfuron, another sulfonylurea herbicide with the same mode of action. The aquatic invertebrate NOAEC is 97 mg ai/L (highest concentration tested) at which survival and reproduction were not significantly different from controls. Estimated chronic effects for estuarine/marine fish and invertebrates are uncertain because no chronic data on saltwater species were submitted by the registrant. However, comparison of freshwater and

saltwater species acute toxicity values does not suggest considerable differences in sensitivity between freshwater and saltwater species.

Aquatic Plants

In a 14-day toxicity test, freshwater vascular duckweed (*Lemna gibba*; MRID 43538503) were exposed to sulfometuron methyl TGAI (95.7%) at five concentrations ranging from 0.13-1.045 µg ai/L. After 14 days, frond counts were reduced 4% at the NOAEC (0.21 µg/L) and 20% at the LOAEC (0.32 µg/L). The EC_{50} was observed at 0.48 µg/L. Following the 14-day exposure period, the study monitored the test plant's recovery for 14-days in an untreated medium. The study authors concluded that sulfometuron was phytotoxic to duckweed at concentrations of $\geq$ 0.590 ppb and phytostatic at 0.323 ppb. These data suggest that the effects of sulfometuron to aquatic vascular plants may be reversible following 14-d exposures at selected concentrations (0.323 ppb and below) provided a sufficient recovery period is available.

In a 120-hour tier 2 growth and reproduction study aquatic non-vascular plant green algae (*Selenastrum capricornutum*, MRID 41680102), was exposed to sulfometuron methyl (99.1%) six concentrations ranging from 0.63 to 20 µg/L. Using a reduction in cell density as the endpoint, an EC_{50} was observed at 4.6 µg ai/L and a NOAEC was observed at 0.63 ug ai/L. At the LOAEC of 1.3 µg/L, growth was reduced approximately 20%, while the cell growth at the NOAEC showed a slight increase relative to controls.

Since duckweed and green algae are the two most sensitive aquatic plant species tested they were used in the risk assessment. Additional non-vascular plant studies were cited in the ecological risk assessment for sulfometuron methyl. For further information on these studies please refer to *Environmental Fate and Ecological Risk Assessment in Support of the Reregistration Eligibility Decision for Sulfometuron Methyl* (M. Barrett, K. Sappington D354292).

b. Terrestrial Organisms

Avian Acute Oral, Dietary and Chronic

Sulfometuron methyl is practically non-toxic to birds (LD_{50} >4,650 mg/kg-bw; LC_{50} >4,600 mg/kg-diet) on an acute toxicity basis. No sublethal effects were observed from the acute toxicity studies of birds. Data on reproductive effects of sulfometuron to birds were not available.

The subacute dietary toxicity of sulfometuron methyl to the mallard duck (*Anas platyrhynchos*) and the Northern bobwhite quail (*Colinus virginiana*) was assessed over 8 days (MRIDs 71414 and 246409). The 8-day acute dietary LC_{50} values for bobwhite quail and mallard are > 5,620 mg ai/kg-diet and > 4,600 mg ai/kg-diet, respectively. There was no mortality, signs of clinical toxicity, or abnormal behavior in the studies.

No studies evaluating the chronic toxicity of sulfometuron methyl have been submitted. However, based on: (1) the mode of action of sulfometuron (inhibition of acetolactate synthase

in plants), (2) the lack of acute toxicity in birds, and (3) a comparison of sulfometuron terrestrial EECs to avian chronic toxicity endpoints for other sulfonylurea herbicides, it was concluded that the risk of chronic toxicity to avian fauna from direct exposure to sulfometuron was not likely.

Mammalian Acute and Chronic

Wild mammal testing is required on a case-by case basis depending on toxicity testing done for the human health risk assessments, intended use pattern and pertinent environmental characteristics. Wild mammal testing is not required for sulfometuron methyl. In an acute oral toxicity study on rats (Sprague-Dawley, MRID 43089201, no mortalities occurred at the limit dose of 5,000 mg/kg-bw. Therefore the acute oral LD_{50} value is >5000 mg/kg-bw, indicating that sulfometuron is practically non-toxic to small mammals on an acute oral basis.

From chronic assessment purposes, a developmental toxicity study with rabbits (Accession No. 78798) showed no treatment related effects on fetal or maternal endpoints at the highest dose tested. Based on this study the developmental NOAEL of sulfometuron methyl is 300 mg/kg/day.

Non-Target Terrestrial Plants

Tier 2 terrestrial plant toxicity studies were conducted to establish the toxicity of sulfometuron methyl to non-target terrestrial plants. For sulfometuron, six dicots and four monocots were tested using the Tier 2 protocols for effects on seedling emergence and vegetative vigor.

The most sensitive endpoints for all plant species indicate that seedling emergence and vegetative vigor are impacted at exposures well below the maximum application rate of 0.375 lb ai/acre for sulfometuron methyl.

For seedling emergence the EC_{25} for the most sensitive monocot (sorghum) was 1.9×10^{-4} lb ai/acre and the EC_{25} for the most sensitive dicot (sugar beets) was 3.2×10^{-5} lb ai/acre. The EC_{05} and NOAEC for the sorghum and sugar beet are 4.3×10^{-5} and 2.9×10^{-5} lb ai/acre, respectively.

Results from the vegetative vigor study indicate the most sensitive monocot (corn) and dicot (soybean) are impacted at somewhat lower levels compared to the seedling emergence study. The EC_{25} values for corn and soybean (shoot dry weight) are 3.7×10^{-5} and 1.8×10^{-5} lb ai/acre, respectively. The maximum application rate for sulfometuron methyl is approximately 10,000 and 20,000 times these EC_{25} values. Because the no effect concentration (NOEC) exceeded the EC_{25} values for both species, the EC_{05} is used for risk assessment with threatened and endangered species. The EC_{05} values for corn and soybean are 8.4×10^{-6} and 9.9×10^{-7} lb ai/acre, respectively.

Insects

In a 48-hour acute contact toxicity study (MRID 416728-10) honey bees were exposed to five sulfometuron methyl treatments ranging from 13 to 100 µg ai/bee and a solvent and a negative control. The contact 48-hour LD_{50} for sulfometuron is >100 µg ai/bee
Based on the 48-hour LD_{50} of >100 µg ai/bee, sulfometuron is classified as practically non-toxic to honey bees on an acute contact basis.

c. Risk Characterization

A deterministic risk assessment was conducted for sulfometuron methyl. The risk quotient (RQ) is used to characterize potential for adverse effects associated with the proposed use of sulfometuron. The basis of the RQ approach is a comparison of the ratio of exposure concentrations to effects endpoints with predetermined LOCs. Specifically, estimated environmental concentrations (EECs) are divided by acute and chronic toxicity values to calculate RQs. If the RQs exceed the LOC, the Agency presumes there is a potential to affect species in that taxa. Laboratory environmental fate, laboratory ecological effects, and use data provide the basis for these RQs and were discussed previously. Although risk is often defined as the likelihood and magnitude of adverse ecological effects, a deterministic risk characterization does not provide a quantitative estimate of likelihood and/or magnitude of an adverse effect. These LOCs are indicators of whether a pesticide, used as directed on the label, has the potential to cause adverse effects on non-target organisms.

A summary of RQs is presented in Table 6. RQs for direct exposure of sulfometuron methyl to aquatic and terrestrial animals are below 0.04. Therefore direct exposure of sulfometuron is not of concern for non-plant species. RQs for direct exposure of sulfometuron to non-target aquatic and terrestrial plants range from 6.7 to >18000. These RQs exceed the LOC and show sulfometuron exposure to non-target aquatic and terrestrial plants to be of concern. Although use of 'typical' application rates would result in RQs of up to one order of magnitude lower than the maximum application rate these RQs would still exceed Agency LOC for terrestrial and aquatic plants. The conclusion of potential risks to aquatic and terrestrial plants from sulfometuron application in non-crop uses is consistent with findings from other sulfonylurea herbicide risk assessments and ecological incident reports associated with sulfometuron usage. The Agency does not have tools to assess risks from wind erosion, but wind-driven erosion of soil containing sulfometuron residues has been alleged in a large ecological incident (EIIS Incident Report 1011666-001). This mode of exposure remains an uncertainty in the Agency's risk assessments.

The Agency is also interested in indirect effects to non-target species. While no direct adverse effects for terrestrial or aquatic animals are of concern, any animal that depends on specific plants for survival or reproduction may be potentially at risk from indirect effects of sulfometuron methyl exposure to aquatic or terrestrial plants.

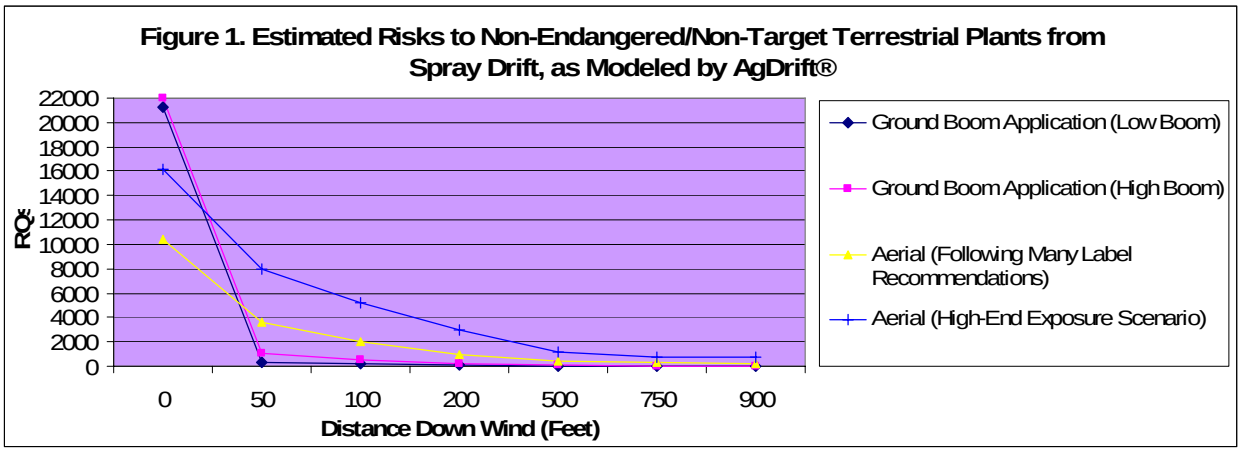
Table 6. The Highest RQs for Listed Taxa in the Sulfometuron Methyl Risk Assessment

Environment	Taxa	Type of Risk	Type of Endpoint	Endpoint	Units	RQ
Aquatic	Freshwater Fish	Acute	LC_{50}	>148	mg ai/L	<0.001
		Chronic	ACR	17[(a)]	mg ai/L	<0.001
	Freshwater Invertebrates	Acute	EC_{50}	>150	mg ai/L	<0.001
		Chronic	NOAEC	97	mg ai/L	<0.001
	Estuarine/Marine Fish	Acute	LC_{50}	>45	mg ai/L	<0.01
	Estuarine/Marine Invertebrates	Acute	EC_{50}	>38	mg ai/L	<0.01
	Non-Vascular Plants	Acute	EC_{50}	4.6	µg ai/L	6.7
		Listed	NOAEC	0.63	µg ai/L	49
	Vascular Plants	Acute	EC_{50}	0.48	µg ai/L	65
		Listed	NOAEC	0.21	µg ai/L	148
Terrestrial	Avian	Acute	LD_{50}	>4,650	mg ai/kg-bw	<0.04
		Sub-Acute	NOAEC	>4,600	mg ai/kg-diet	<0.02
	Mammalian	Acute	LD_{50}	>5,000	mg ai/kg-bw	<0.01
		Chronic	NOAEL	>300[(b)]	mg ai/kg-diet	<0.01
	Plants	Acute	EC_{25}	1.8×10^{-5}	lb ai/A	>6000
		Listed	NOAEC	9.9×10^{-7}	lb ai/A	>18000

[(a)]Using the data for another sulfonylurea herbicide with a similar toxicity profile and the same mode of action (flazasulfuron, PC code: 119011), an acute to chronic (ACR) of 7 was used for rainbow trout.
[(b)]Highest dose tested

Plant Risks

Potential risks to aquatic and terrestrial plants are indicated by this risk assessment, as LOCs are widely exceeded for terrestrial and aquatic plants at the maximum application rate. For terrestrial plants an exposure assessment was conducted using Tier I and II AgDRIFT® (version 2.01). Calculated RQs at the edge of a treated field resulting from spray drift alone were as high as 22,000 for non-endangered plants and 400,000 for endangered plants. Terrestrial plant RQs dropped substantially 50 ft from the edge of a field treated with an aerial application but still exceeded Agency LOC at 900 ft (700 to 12,000 for non-endangered and endangered plants, respectively). Terrestrial plant RQs also dropped substantially 50 ft from the edge of a field treated with a ground high boom application but still exceeded Agency LOCs at 900 ft (33 to 606 for non-endangered and endangered plants, respectively). [Note: AgDRIFT® provides reliable exposure estimates up to 900 ft.; estimates beyond 900 ft. are beyond the model's applicability domain]. The impact of spray drift practices recommended by the label did not reduce RQ values below LOCs for terrestrial plants (RQs were reduced only by a factor of three compared to 'high end' exposure assumptions). Potential risks to terrestrial plants from irrigation with sulfometuron methyl contaminated surface water were also evident (RQ = 3.9 and 71 for non-endangered and endangered species, respectively). Figure 1 illustrates AgDRIFT® results.



RQs for aquatic plants exceeded LOCs and ranged from 49 to 148 for endangered nonvascular and vascular plants, respectively and from 6.7 to 65 for non-endangered nonvascular and vascular plants, respectively. Based on comparisons of adverse effect levels with longer-term average EECs predicted from the PRZM/EXAMS model (e.g., 90-d EEC of 16 µg/L), the ability of duckweed and other vascular aquatic plants to recover from predicted long-term exposure concentrations of sulfometuron methyl in adjacent, static aquatic systems appears unlikely under the exposure conditions modeled.

Use of 'typical' application rates would result in RQs of up to one order of magnitude lower than the maximum application rate, which would still result in RQs above Agency LOCs for terrestrial and aquatic plants. The conclusion of potential risks to aquatic and terrestrial plants from sulfometuron methyl application in non-crop uses is consistent with findings from other sulfonylurea herbicide risk assessments and ecological incident reports associated with sulfometuron usage.

Terrestrial and aquatic plants appear most sensitive to sulfometuron methyl exposure. While toxicity data were available for endpoints related to systemic growth, seedling emergence and visual injury, these guideline studies are not designed to capture reproductive endpoints. There is some evidence to suggest plant reproduction may be affected by sulfonylurea herbicides at levels below effects on vegetative growth or visual injury (Fletcher et al., 1993). Therefore, the Agency, in a DCI, will request a special study to evaluate reproductive risk to non-target plants exposed to small droplets of sulfometuron.

d. Endangered Species

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation measures that address these impacts. The Endangered Species Act (ESA) requires federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. To analyze the potential of registered pesticide uses that may affect any particular species, EPA uses basic toxicity and exposure data and 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, these analyses take into consideration any regulatory changes recommended in this RED being implemented at that time.

The ecological assessment that EPA conducted for this RED does not, in itself, constitute a determination as to whether specific species or critical habitat may be harmed by the pesticide. Rather, this assessment serves as a screen to determine the need for any species-specific assessment that will evaluate whether exposure may be at levels that could cause harm to specific listed species and their critical habitat. The species-specific assessment refines the screening-level assessment to take into account information such as the geographic area of pesticide use in relation to the listed species and the habits and habitat requirements of the listed species. If the Agency's specific assessments for sulfometuron methyl result in the need to modify use of the pesticide, any geographically specific changes to the pesticide's registration will be implemented through the process described in the Agency's *Federal Register* Notice (54 FR 27984) regarding implementation of the Endangered Species Protection Program.

Based on EPA's screening level assessment for sulfometuron methyl, RQs exceed the LOC for terrestrial and aquatic plants. However, these findings are based solely on EPA's screening-level assessment and do not constitute "may affect" findings under the ESA. A determination that there is a likelihood of potential effects to a listed species may result in limitations on the use of the pesticide, other measures to mitigate any potential effects, and/or consultations with the Fish and Wildlife Service or National Marine Fisheries Service, as necessary. If the Agency determines that the use of sulfometuron "may affect" listed species or their designated critical habitat, EPA will employ the provisions in the Services regulations (50 CFR Part 402). To reduce potential effects to non-target endangered species, EPA is requiring various mitigation measures, including rate reductions and additional labeling language to reduce the movement of pesticide away from target application areas.

3. Ecological Incident Reports

An analysis of the Agency's Ecological Incident Information System (EIIS) was conducted in September, 2007. EIIS is an Agency database that manages information on incidents of adverse field effects to non-target plants and animals that have been linked to pesticide exposure. This analysis revealed 35 incidents of varying degrees of confidence involving application or misapplication of sulfometuron methyl. Confidence classification of sulfometuron application's (or misapplication) involvement in these incidents was determined by analysis of the available evidence and the best professional judgment of the Agency scientists. Of these 35 incidents, one was classified as highly probable, 20 were classified as probable and 14 were classified as possible. The highly probable classification was applied because significant details are known about applications of a sulfometuron near the incident area and sulfometuron residues were found in soil samples from the incident areas following the incident. Probable classifications were applied to incidents reported relatively close in distance and time to an application of sulfometuron, though fewer details reported, which reduced the Agency's confidence that the incident occurred as a direct result of sulfometuron application (or misapplication). Incidents classified as possible contain even less information than those classified as probable, warranting lower confidence of sulfometuron's involvement in the

incident. Possible classifications may be applied to incidents where there is either a general lack of confirmatory evidence, or where there is more than one explanation of the cause is plausible, for instance when more than one pesticide was applied in the area just prior to the incident.

The highly probably incident (EIIS Incident Report 1011666-001) allegedly resulted from an application of Oust™ herbicide (containing sulfometuron methyl) made by the Bureau of Land Management (BLM) in the fall of 2000 to approximately 22,000 acres of Idaho forest and grassland that had been severely damaged by wildfires. Investigations by the Idaho Department of Agriculture reported that following the aerial application of Oust™ at a rate of 0.0625 lb ai/A, drought and windy conditions (up to 20-40 mph) caused wind erosion of dry treated soil containing sulfometuron. Thousands of acres were alleged to have been affected and crop damage was estimated to be in excess of $78 million.

For further information on the incidents classified as highly probable and probable, please see "Appendix E: Adverse Ecological Incidents Associated with Sulfometuron Methyl Use" in *Environmental Fate and Ecological Risk Assessment for the Reregistration of Sulfometuron Methyl: Vegetative Management and Other Non-Crop Uses* (M. Barrett, K. Sappington D354292), which is available in the public docket. For further information on the EIIS database, please visit the Agency's website (http://www.epa.gov/oppefed1/general/databasesdescription.htm - eiis)

IV. Risk Management and Reregistration Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient-specific) data required to support reregistration of products containing sulfometuron methyl as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing sulfometuron.

The Agency has completed its assessment of the human health and ecological risks associated with the use of pesticide products containing sulfometuron methyl. The Agency has determined that sulfometuron products are eligible for reregistration provided the risk mitigation measures outlined in this document are adopted and label amendments are made to implement these mitigation measures, as outlined in Chapter V. Appendix A summarizes the uses of sulfometuron that are eligible for reregistration. Appendix B identifies the generic data that the Agency reviewed as part of its determination of reregistration eligibility of sulfometuron, and lists the submitted studies that the Agency found acceptable. Data gaps are identified as generic data requirements that have not been satisfied with acceptable data. Should a registrant fail to implement any of the reregistration requirements identified in this document, the Agency may take regulatory action to address these concerns.

B. Public Comments and Responses

When making its reregistration decision, the Agency considered all comments received in the docket during the public participation phase. EPA also worked with stakeholders and the public to reach the regulatory decisions for sulfometuron methyl. During the public comment period, which closed on April 28, 2008, the Agency received a comment from an interested stakeholder. This comment did not compel the Agency to amend the risk assessments for sulfometuron. This comment in its entirety is available in the public docket (EPA-HQ-OPP-2008-0129) at www.regulations.gov. The RED document, supporting documents for sulfometuron and the Agency's response to the received comment are also available in the docket. In addition, the sulfometuron RED document may be downloaded or viewed through the Agency's website at http://www.epa.gov/pesticides/reregistration/status.htm. A 60 day post-signature public comment will be conducted.

C. Benefits of Vegetation Management for Rights of Way and Non-Crop Sites

Sulfometuron methyl is a broad spectrum herbicide, belonging to the sulfonylurea chemical group and it is used for vegetation management on: non-crop sites, rights of way, forest site preparation, forest release treatments, and turfgrass release treatments. Sulfometuron is taken-up by leaves, roots, and shoots of plants. Its efficacy at very low use rates (1 to 2 oz ai/acre) and residual activity are the unique characteristics of this herbicide. It inhibits amino acid synthesis and has preemergence and postemergence activity. It is used to selectively control unwanted vegetation, remove trees and brush under power lines, improve visibility along highways, and reduce competition from other plants for forest and warm season turfgrass establishment. The most recent usage data available to the Agency dates from the late 1990's and indicates that sulfometuron was one of the top 10 products based on acres treated for: forestry, roadside, railroad, electric utilities, and pipeline and industrial usage. At the time, sulfometuron was applied to over 1.5 million acres. Little recent data are available for these sites because, compared to agricultural uses, they represent a small proportion of total pesticide use and demand for usage information is low. Public and private entities rarely survey the sector. California pesticide usage reports for forestry/timberland (2001-2006) indicate that sulfometuron remains one of the top 10 herbicides for that site, but listings for other sites can be vague and are difficult to aggregate.

Because there is a large diversity in weedy plant species in the use sites for sulfometuron methyl, a large number of herbicides have been developed for their control. A brief list of herbicides commonly used on non-crop sites includes: atrazine, bromacil, chlorsulfuron, clopyralid, 2,4-D, dicamba, diuron, fosamine, glyphosate, hexazinone, imazapyr, imazapic, mefluidide, metsulfuron methyl, picloram, simazine, sulfometuron methyl, tebuthiuron, and triclopyr. The available alternatives all have a wide range of species that are controlled but no one herbicide can control all weedy species. In many cases users will mix different herbicides to expand the number of species controlled. Non-chemical alternatives consist of cultivating or plowing, hand removal, burning, pruning, or mowing when weeds are small; these methods are more time consuming, require more labor and the associated high costs of labor and are not

possible in all terrains. Based on currently available data, the Agency cannot identify a unique niche for this chemical, but neither can it determine if adequate alternatives are available. Sulfometuron provides another form of chemical control for the management of weedy species in the registered use sites and, as such, provides benefits to its users.

D. Requirements for Reregistration

Sulfometuron methyl products are eligible for reregistration provided that registrants comply with the requirements outlined in this document including the following: (1) submit required data and (2) implement risk mitigation measures.

1. Required Data

Sulfometuron methyl products are eligible for reregistration provided that registrants submit data as required by the generic data call-ins and product-specific data call-ins the Agency intends to issue as a result of this RED (see Section V).

a. Human Health Risk

The Agency determined that all potential dietary (water only) risks from sulfometuron methyl are not of concern. Sulfometuron has no residential uses, therefore, residential risks are not of concern.

Occupational dermal risks, which drive handler risks are of concern at the current level of required PPE. When adding an additional level of PPE (double layer with gloves) to the baseline PPE, occupational exposure scenarios for mixing/loading WDGs for aerial application to forestry and non-crop areas result in a combined MOE = 90 and, therefore, is of potential concern. Because conservative inputs in the risk estimates (e.g., 100% dermal absorption) were used in the assessment, EPA believes there are no significant risk concerns to workers. Additionally, through required label changes, aprons and chemical resistant gloves will become mandatory baseline PPE for mixers and loaders of sulfometuron methyl WDGs to further mitigate occupational dermal risks.

b. Ecological Risk

At the maximum registered application rate for sulfometuron methyl (0.375 lb ai/A), LOCs for direct effects on aquatic and terrestrial animals are not exceeded. Lack of risk from direct effects on animals is consistent with the mode of action of sulfometuron and findings from other sulfonylurea herbicide risk assessments. Although LOCs were not exceeded for terrestrial or aquatic animals, animals that depend on plants for survival or reproduction (presumably all taxa at the screening level) may be at risk from indirect effects resulting from potential direct effects to aquatic or terrestrial plants. Direct risks to aquatic and terrestrial plants are expected from use of sulfometuron. Data gaps exist on the reproductive effects of small amounts of sulfometuron. Please see the ecological risk characterization section and *Environmental Fate and Ecological Risk Assessment for the Reregistration of Sulfometuron Methyl: Vegetative*

Management and Other Non-Crop Uses (M. Barrett, K. Sappington D354292) for further discussion.

To address data gaps on the reproductive effects of small amounts of sulfometuron methyl, the Agency will issue a DCI requesting a special study to evaluate reproductive risk to non-target plants exposed to small droplets of sulfometuron.

2. Risk Mitigation and Regulatory Position

Products containing sulfometuron methyl are eligible for reregistration provided the specific labeling requirements listed below are reflected on the sulfometuron labels:

Dermal exposure risks from occupational applications of WDGs.

- For mixers and loaders for aerial applications, aprons and chemical resistant gloves are required in addition to the baseline PPE.
- For mixers, loaders, and applicators applying using low pressure hand wand, gloves are required in addition to baseline PPE.

Non-target plant exposure through soil particle drift.

- All product labels will include language requiring weather conditions meet label specifications when applications are made to powdery dry soil or light sandy soil.
- Prohibit applications in counties where the average annual rainfall is 10 inches or less.

Non-target exposure to plants through spray drift.

- Product labels will include language requiring weather conditions meet label specifications.
- Applications must be made using medium- to coarse-sized droplets.
- Aerial applications must be made with a boom whose length does not exceed 75% of the wing span or 80% rotor blade diameter.
- Aerial applications more than 10 feet above the canopy will be prohibited. Label language will be added to require 500 foot, no-spray vegetative buffer zones around surface water bodies such as rivers, lakes, streams, ponds, irrigation sources, and crops.
- Prohibit ground applications within 100 feet of surface water bodies such as rivers, lakes, streams, ponds, irrigation sources, and crops.

Registration Review

Under Pesticide Registration Improvement Act II (PRIA II), the Agency is required to evaluate the risks from each registered pesticide every 15 years. The Agency has committed to address endangered species issues at that time. The sulfonylurea herbicides are scheduled to be assessed in Registration Review as a group beginning with docket openings in 2011.

3. Endangered Species

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation measures that address these impacts. The ESA requires federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. To analyze the potential of registered pesticide uses that may affect any particular species, EPA uses basic toxicity and exposure data and 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, these analyses take into consideration any regulatory changes recommended in this RED being implemented at that time.

The ecological assessment that EPA conducted for this RED does not, in itself, constitute a determination as to whether specific species or critical habitat may be harmed by the pesticide. Rather, this assessment serves as a screen to determine the need for any species-specific assessment that will evaluate whether exposure may be at levels that could cause harm to specific listed species and their critical habitat. The species-specific assessment refines the screening-level assessment to take into account information such as the geographic area of pesticide use in relation to the listed species and the habits and habitat requirements of the listed species. If the Agency's specific assessments for sulfometuron methyl result in the need to modify use of the pesticide, any geographically specific changes to the pesticide's registration will be implemented through the process described in the Agency's *Federal Register* Notice (54 FR 27984) regarding implementation of the Endangered Species Protection Program.

Based on EPA's screening level assessment for sulfometuron methyl, RQs exceed the LOCs for terrestrial and aquatic plants. However, these findings are based solely on EPA's screening-level assessment and do not constitute "may affect" findings under the ESA. A determination that there is a likelihood of potential effects to a listed species may result in limitations on the use of the pesticide, other measures to mitigate any potential effects, and/or consultations with the Fish and Wildlife Service or National Marine Fisheries Service, as necessary. If the Agency determines that the use of sulfometuron "may affect" listed species or their designated critical habitat, EPA will employ the provisions in the Services regulations (50 CFR Part 402).

V. What Registrants Need to Do

The Agency has determined that products containing sulfometuron methyl (PC 122001) are 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. 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.

For sulfometuron methyl technical grade active ingredient products, the registrant needs to submit the following items:

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

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

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

Within the time limit specified in the generic DCI:

(1) citations of any existing generic data that address data requirements or submit new generic data responding to the DCI.

Please contact Rusty Wasem at (703) 305-6979 with questions regarding generic reregistration.

By U.S. Mail:
Document Processing Desk (DCI/SRRD)
Rusty Wasem
Office of Pesticide Programs (7508P)
1200 Pennsylvania Ave., NW
Washington, DC 200460

By Express or Courier Service:
Document Processing Desk (DCI/SRRD)
Rusty Wasem
Office of Pesticide Programs (7508P)
Room S-4900
One Potomac Yard
Arlington, VA 22202

For end-use products containing the active ingredient sulfometuron methyl, registrants need to submit the following items for each product.

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

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

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

Within eight months from receipt of the PDCI:

(1) submit two copies of the confidential statement of formula, EPA form 8570-4;

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

(3) five copies of the draft label incorporating all label amendments outlined in Table 7 of this document;

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

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

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

Within the time limit specified in the generic PDCI:

(1) Citations of any existing generic data that address data requirements or submit new generic data responding to the DCI.

Please contact Karen Jones at 703-308-8047 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed:

By U.S. Mail:
Document Processing Desk (DCI/SRRD)
Karen Jones
Office of Pesticide Programs (7508P)
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A. Manufacturing Use Products

1. Additional Generic Data Requirements

Within the scope of the uses and currently registered products subject to reregistration, the generic database supporting the reregistration of sulfometuron methyl has been reviewed and determined to be substantially complete. However, the data listed below are necessary to confirm the reregistration eligibility decision documented in this RED.

Special Study Plant Toxicity – Effects of Small Droplets on Non-target Plants

2. Labeling for Manufacturing-Use Products

To ensure compliance with FIFRA, manufacturing-use product (MUP) labeling should be revised to comply with all current EPA regulations, address applicable PR Notices, and applicable policies. The MUP labeling should bear the labeling contained in Table 7.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The Registrant must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product. The Agency intends to issue a separate product-specific data call-in (PDCI), outlining specific data requirements. For any questions regarding the PDCI, please contact Karen Jones at 703-308-8047.

2. Labeling for End-Use Products

To be eligible for reregistration, labeling changes are necessary to implement measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 7. Generally, conditions for the distribution and sale of products bearing old labels/labeling will be established when the label changes are approved. However, specific existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors.

C. Labeling Changes Summary Table

In order to be eligible for reregistration, amend all product labels to comply with the required language show in the following table. Table 7 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 Sulfometuron Methyl

Description	Amended Labeling Language	Placement on Label
For all Manufacturing Use Products	"Only for formulation into a herbicide for the following use(s) [fill blank only with those uses that are being supported by MP registrant]."	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	Precautionary Statements
End Use Products Intended for Occupational Use		
PPE Requirements Established by the RED[1] for WDG Formulations	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are" (*registrant inserts correct chemical-resistant material*). "If you want more options, follow the instructions for category" *[registrant inserts A,B,C,D,E,F,G,or H]* "on an EPA chemical-resistance category selection chart." "All mixers, loaders, applicators and other handlers must wear: Long-sleeved shirt and long pants and Shoes plus socks. Chemical-resistant gloves when mixing and loading to support aerial applications and when using handheld nozzles or equipment, and Chemical-resistant apron when mixing and loading to support aerial applications." See engineering controls for more requirements	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

PPE Requirements Established by the RED[1] For Liquid Formulations	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are" (*registrant inserts correct chemical-resistant material*). "If you want more options, follow the instructions for category" *[registrant inserts A,B,C,D,E,F,G,or H]* "on an EPA chemical-resistance category selection chart." "All liquid mixers, loaders, applicators, and other handlers must wear: Long-sleeved shirt and long pants, and Shoes plus socks. Chemical-resistant gloves when mixing, loading, and applying for low pressure hand wand."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry." "Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements
Engineering Controls for WDG and Granular formulations that permit aerial application	"Pilots must use an enclosed cockpit in a manner that is consistent with the WPS for Agricultural Pesticides [40 CFR170.240(d)(6)].	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)
User Safety Recommendations	"User Safety Recommendations Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing*. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)
Environmental Hazards	"For terrestrial uses, except for under the forest canopy: 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 washwater or rinsate." "Exposure to (Brand Name) can injure or kill plants. Damage to susceptible plants can occur when soil particles are blown or washed off target onto cropland. Wind can blow treated powdery dry soil or light sandy soil off target when rainfall does not occur within 48 hours of application. Irrigated crops will suffer the greatest injury if contacted by the pesticide or treated soil particles."	Precautionary Statements immediately following the User Safety Recommendations

Restricted-Entry Interval for products with directions for use within scope of the Worker Protection Standard for Agricultural Pesticides (WPS)	Basic REI Statement for all crops: "Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours."	Directions for Use, Under Agricultural Use Requirements Box
Early Entry Personal Protective Equipment for products with directions for use within the scope of the WPS	"PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is: * coveralls, * shoes plus socks, and * chemical-resistant gloves made of any waterproof material"	Direction for Use Agricultural Use Requirements box
Entry Restrictions for products having occupational uses on the label not subject to the WPS	***Entry Restriction for non-WPS uses applied as a spray:*** "Do not enter or allow others to enter until sprays have dried." ***Entry Restriction for non-WPS uses applied dry:*** "Do not enter or allow others to enter until dusts have settled."	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.
General Application Restrictions	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."	Place in the Direction for Use directly above the Agricultural Use Box.
Other Application Restrictions (Risk Mitigation)	"Do not apply (Brand Name) to powdery dry soil or light sandy soil when less than a 60% chance of rainfall is predicted to occur in the treatment area within 48 hours of application." "Do not apply (Brand Name) in counties where the average annual rainfall is 10 inches or less."	Directions for Use

Spray Drift	**Droplet Size** "Applications must be made using Medium or coarser droplet size spectrum according to ASAE (S572) definition." **Wind Direction and Speed** "Do not apply when wind speed is greater than 10 mph." **Temperature Inversion** "Do not make aerial or ground 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 smoke and observing a smoke layer near the ground surface." **Additional Requirements for Ground Applications** "For ground boom applications, apply using a nozzle height of no more than 4 feet above the ground or crop canopy." **Additional Requirements for Aerial Applications** "Spray must be released at the lowest height consistent with pest control and flight safety. Do not release spray at a height greater than 10 feet above the crop canopy unless a greater height is required for aircraft safety." "The spray boom should be mounted on the aircraft as to minimize drift caused by wingtip or rotor vortices. The minimum practical boom length should be used and must not exceed 75% of the wing span or 80% rotor blade diameter." "Flight speed and nozzle orientation must be considered in determining compliance with the allowable droplet size spectrum." "When applications are made with a cross-wind, the swath will be displaced downwind. The applicator must compensate for this displacement at the downwind edge of the application area by adjusting the path of the aircraft upwind."	Directions for Use

Buffer Zone Requirements	**For Ground Applications:** "For ground applications, do not apply within 100 feet of aquatic vegetation (such as, but not limited to, lakes, reservoirs, rivers, streams, marshes, ponds, estuaries, and commercial fish ponds, or water used as an irrigation source) and crops." **For Aerial Applications:** "Do not apply within 500 feet of aquatic vegetation, water used as an irrigation source, and crops."	Directions for Use under General Precautions and Restrictions and/or Application Instructions

Appendix A. Non-Food and Non-Feed Use Patterns Subject to Reregistration of Sulfometuron Methyl

Product Type	Product Use Site	Max % A.I.	Max AR
Occupational Uses			
WDG, L	Forestry (Hardwoods, Conifers)	1	0.38 lb ai/A
WDG, L	Non-Crop Areas (Public, Private, Military Lands)	1	0.38 lb ai/A
WDG, L	Turf (Unimproved)	1	0.38 lb ai/A
WDG, L	Non-Crop Land Restoration	1	0.38 lb ai/A

Formulation Codes
WDG: Water Dispersible Granules
L: Liquid

Appendix B. Data Supporting Guideline Requirements for Sulfometuron Methyl

Data Supporting Guideline Requirements for the Reregistration of Sulfometuron Methyl		
Guideline Number	**Study Description**	**Citation(s)**
PRODUCT CHEMISTRY		
830.1550	Product Identity and Composition	41672801
830.1600	Description of Materials Used	41672801
830.1620	Description of Production Process	41672801
830.1670	Discussion of Formation of Impurities	41672801
830.1700	Preliminary Analysis	41672801
830.1750	Certified Limits	41672801
830.1800	Enforcement Analytical Method	41672801
830.6302	Color	41672802
830.6303	Physical State	41672802
830.6304	Odor	41672802
830.6313	Stability	41672802
830.6314	Oxidizing or Reducing Action	46439401
830.7000	pH	41672802
830.7050	UV/Visible Absorption	46546103
830.7200	Melting Point	41672802
830.7300	Density	41672802
830.7370	Dissociation Constant	41672802

830.7550 830.7570	Octanol / Water Partition Coefficient	41273601
830.7840 830.7860	Solubility	41680101
830.7950	Vapor Pressure	41672802
ECOLOGICAL EFFECTS		
850.1010	Aquatic Invertebrate Acute	43501803
850.1025	Oyster Acute Toxicity Test	41672805
850.1035	Mysid Acute Toxicity Test	41672804
850.1055	Bivalve Acute Toxicity Test	41672805
850.1075	Fish Acute Toxicity	
	Freshwater	43501801, 43501802
	Estuarine / Marine	41672803
850.1300	Aquatic Invertebrate Life Cycle (Freshwater)	41672806
850.1730	Fish BCF	41418623
850.1850	Aquatic Food Chain Transfer	Data Gap
850.2100	Avian Acute Oral Toxicity	78700
850.2200	Avian Subacute Dietary Toxicity	71414, 246409 (1)
850.3020	Honey Bee Acute Contact Toxicity	41672810
850.4100	Seedling Emergence and Growth	43538501
850.4150	Vegetative Vigor	43538501
850.4400	Aquatic Plant Growth	43538503, 43538502, 41680102, 41680102
ENVIRONMENTAL FATE		
835.1230	Leaching and Adsorption / Desorption	42789301
835.2120	Hydrolysis	42715201
835.2240	Photodegradation in Water	42182401, 43174101
835.2410	Photodegradation in Soil	41420601
835.4100	Aerobic Soil Metabolism	42091401, 43174102, 245375
835.4200	Anaerobic Soil Metabolism	Reference 835.4100
835.4300	Aerobic Aquatic Metabolism	42091403, 43174103
835.4400	Anaerobic Aquatic Metabolism	42091403, 43174103, 143540
835.6100	Terrestrial Field Dissipation	43212101, 43637101
835.6300	Forestry Field Dissipation	42091404, 43174104
Special Study	Plant Toxicity – Effects of Small Droplets on Non-target Plants	Data Gap
HUMAN HEALTH EFFECTS/TOXICOLOGY		
870.1100	Acute Oral Toxicity	43089201
870.1200	Acute Dermal Toxicity	43089202
870.1300	Acute Inhalation Toxicity	43089203
870.2400	Acute Eye Irritation	71412
870.2500	Acute Dermal Irritation	41672808, 71411
870.2600	Skin Sensitization	43089204
870.3100	90-Day Oral Toxicity in Rodents	43154101
870.3150	90-Day Oral Toxicity in Non-rodents	129051
870.3200	21/28 —Day Dermal Toxicity	126714

870.3700	Prenatal Developmental Toxicity	78798, 78797, 78796
870.4100	Chronic Toxicity	129051
870.5265	Gene Mutation (Ames assay)	78792, 78793
870.5385	Bone Marrow Chromosomal Aberration Test	146846
870.5550	Unscheduled DNA Synthesis in mammalian cells in culture	146847

[(1)]Accession Number

Appendix C. Technical Support Documents

Additional documentation in support of the sulfometuron methyl RED is maintained in the OPP Regulatory Public Docket, located in Room S-4400 One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. It is open Monday through Friday, excluding legal holidays, from 8:30 a.m. to 4:00 p.m. All documents may be viewed in the OPP Docket room or viewed and/or downloaded via the Internet at www.regulations.gov under docket number EPA-HQ-OPP-2008-0129. The Agency's documents in support of this RED include the following:

HED Documents:

Sulfometuron Methyl: Phase 3 Amendment of "Sulfometuron Methyl: HED Chapter of the Reregistration Eligibility Decision (RED) Document." Britton, W., D385620.

Sulfometuron Methyl: Addendum to the HED Chapter of the Reregistration Eligibility Decision (RED). Britton, W., D346173.

EFED Documents:

Environmental Fate and Ecological Risk Assessment for the Reregistration of Sulfometuron Methyl: Vegetative Management and Other Non-Crop Uses. Barrett, M., Sappington, K., D354292.

Tier I Sulfometuron Methyl Drinking Water Assessment for Reregistration Eligibility Decision Document (slightly revised). Barrett, M., D334277.

Appendix D. Bibliography

In addition to the studies listed in Appendix B, this bibliography contains additional citations considered to be part of the database supporting the reregistration decision for sulfometuron methyl.

In addition to the MRID study references listed in Appendix B, this bibliography contains the expanded study citations as well as additional literature considered to be part of the database supporting the reregistration decision for sulfometuron methyl.

MRID	Citation
71411	Dashiell, O.L.; Henry, J.E. (1980) Skin Irritation Test on Rabbits for EPA Pesticide Registration: Haskell Laboratory Report No. 964-80. (Unpublished study received Jan 23, 1981 under 352-EX-107; submitted by E.I. du Pont de Nemours & Co., Wil- mington, Del.; CDL:244195-M)
71412	Dashiell, O.L.; Henry, J.E. (1980) Eye Irritation in Rabbits, Haskell Laboratory Report No. 963-80. E.I du Pont de Nemours, Wilmington, Del.;CDL:244195-N. Unpublished.
71414	Dudeck, S.H.; Twigg, C.J. (1980) Final Report: Avian Dietary Toxic- ity (LC50) Study in Mallard Ducks: Project No. 201-548; HLO-788- 80. (Unpublished study received Jan 23, 1981 under 352-EX-107; prepared by Hazleton Laboratories America, Inc., submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:244195-P)
78700	Dudeck, S.H.; Bristol, K.L. (1981) Final Report: Single-dose Oral Toxicity in Mallard Ducks: Project No. 201-552. (Unpublished study received Jun 17, 1981 under 352-EX-108; prepared by Hazle- ton Laboratories America, Inc., submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:245375-A)
78792	Taylor, J.D. (1979) Mutagenic Activity in the Salmonella Microsome Assay: Haskell Laboratory Report No. 271-79. E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:245515-K. Unpublished.
78793	Krahn, D.F.; Fitzpatrick, K. (1981) Chinese Hamster Ovary Cell Assay for Mutagenicity; Haskell Laboratory Report No. 1074-80. E. I. du Pont de Nemours & Co., Wilmington, Del.; CDL:245515-L. Unpublished.
78796	Lu, M.H. (1981) Teratogenicity Study by Diet in the Rat with Benzoic acid, 2-(((((4,6-dimethyl-2-pyrimidinyl) amino) carbonyl)-amino)sulfonyl)-methyl ester: Haskell Laboratory Report No. 316-81. E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:245515-O. Unpublished.
78797	Hoberman, A.M.; Bristol, K.L.; Wolfe, G.W. (1981) Pilot Oral Tera- tology Study in Rabbits H-13647-02: Benzoic Acid,2????(4,6-di- methyl-2-pyrimidinyl)amino|carbonyl|amino|sulfonyl|-,methyl Ester: Project No. 201-554; HLO-234-81. Final rept. (Unpub- lished study received Jul 1, 1981 under 352-401; prepared by Hazleton Laboratories America, Inc., submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:245515-P)
78798	Serota, D. G.; Fieser, S.; Durloo, R.S.; et al (1981) Teratology Study in Rabbits: H-13647-02: Benzoic Acid, 2-(((((4,6-dimethyl ester: Project No. 201-555; HLO-331-81. Hazleton Laboratories America, Inc., E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:245515-Q. Unpublished.
126714	Dashiell, O.; Hinckle, L. (1983) Subacute Dermal Toxicity (21-days) in Rabbits: Haskell Laboratory Report No. 792-82. E.I du Pont de Nemours & Co., Wilmington, DE; CDL:249865-A. Unpublished.
129051	Wood, C.; O'Neal, F. (1983) One-year Feeding Study in Dogs with Benzoic Acid, 2-(((((4,6-dimethyl-2-pyrimidinyl)-amin0)carbonyl) amino)sulfonyl)-Methyl Ester INT-5648: Haskell Laboratory Report No. 482-82. E.I du Pont de Nemours & Co., Inc., Wilmington, DE; CDL:250590-A, Unpublished.
143540	Dulka, J.; Anderson, J. (1982) The Fate of [Carbon radiolabeled]- DPX-T5648 in an Anaerobic Environment. Unpublished study pre- pared by E. I. du Pont de Nemours and Co., Inc. 28 p.
146846	Galloway, S. (1981) Mutagenicity Evaluation of H#13,647-03 in an *in vitro* Cytogenetic Assay Measuring Chromosome Aberration Frequencies in Chinese Hamster Ovary (CHO) Cells: (Benzoic Acid, 2-((((4,6-dimethyl-2-pyrimidinyl) amino) carbonyl)amino)sulfonyl-methyl ester): Project No. 20990. Litton Bionetics, Inc. Unpublished.

146847	Ford, L. (1982) Unscheduled DNA Synthesis/Rat Hepatocytes in vitro☹Benzoic Acid, 2-((((4,6-dimethyl-2-pyrimidinyl)amino)carbonyl)amino)-sulfonyl)-Methyl Ester): Haskell Laboratory Report No. 769-82. E.I du Pont de Nemours and Co., Unpublished.
41418623	Harvey, J.; Dulka, J.; Anderson, J. (1985) Properties of Sulfome- turon methyl affecting its environmental fate: aquous hydrolysis and photolysis, mobility and adsorption on soils and bioaccumu- lation potential. Journal of Agricultural Food Chemistry. 33: 590-596.
41420601	Ryan, D.; Atkins, B. (1986) Photodegradation of ?Phenyl(U)-Carbon 14|Sulfometruron Methyl and ?Pyrimidine-2-Carbon 14|Sulfometuron Methyl on Soil: Lab Project Number: AMR-573-86. Unpublished study prepared by E. I. du Pont de Nemours and Co. 35 p.
41672801	Brennan, D. (1990) Sulfometuron Methyl: Product Identity and Composition, Analysis and Certification of Product Ingredients: Lab Project Number: AMR-1674-90. Unpublished study prepared by E.I. du Pont de Nemours and Co. 129 p.
41672802	Brennan, D. (1990) Sulfometuron Methyl: Physical and Chemical Characteristics: Lab Project Number: AMR-1746-90. Unpublished study prepared by E.I. du Pont de Nemours & Co. 111 p.
41672803	Ward, T.; Boeri, R. (1990) Static Acute Toxicity of IN T5648-40 to the Sheepshead Minnow, Cyprinodon □ariegates: Lab Project Num- ber: 4581-804: 90108-DU. Unpublished study prepared by Resource Analysts, Inc. 32 p.
41672804	Ward, T.; Boeri, R. (1990) Static Acute Toxicity of IN 75648-40 to the Mysid, Mysidopsis bahia: Lab Project Number: 615-90: 90109- DU. Unpublished study prepared by Resource Analysts, Inc. 32 p.
41672805	Ward, T.; Boeri, R. (1990) Static Acute Toxicity of IN T5648-40 to Bivalve Mollusc Embryos and Larvae: Lab Project Number: 633-90: 90110-DU. Unpublished study prepared by Resource Analysts, Inc. 31 p.
41672806	Baer, K. (1990) Chronic Toxicity of IN T5648-40 to Daphnia magna: Lab Project Number: 614-90: MR-4581-804. Unpublished study pre- pared by Haskell Laboratory. 260 p.
41672808	Sarver, J. (1990) Primary Dermal Irritation Study with INT 5648-40 in Rabbits: Lab Project Number: 137-90: 4581-804. Haskell Laboratory. Unpublished.
41672810	Hoxter, K. ; Smith, G. (1990) An Acute Contact Toxicity Study with the Honey Bee: Lab Project Number: 112-243: 583-90. Unpublished study prepared by Wildlife International Ltd. 14 p.
41680102	Hoberg, J. (1990) Sulfometuron methyl-Toxicity to the Freshwater Green Alga Selenastrum capricornutum: Lab Project Number: AMR- 1893-90. Unpublished study prepared by Springborn Laboratories, Inc. 24 p.
42091401	Monson, K.; Hoffman, D. (1990) Aerobic Soil Metabolism of ?Pyrimid- ine-2-Carbon 14|Sulfometuron: Methyl in Keyport Silt Loam: Lab Project Number: AMR-1113-88. Unpublished study prepared by E.I. du Pont de Nemours and Co. 42 p.
42091403	Rhodes, B. (1991) Aerobic Aquatic Metabolism of Carbon 14-Sulfometuron Methyl: Lab Project Number: AMR-1896-90. Unpublished study prepared by E.I. du Pont de Nemours and Co. 40 p.
42091404	Michael, J.; Neary, D. (1991) Movement of Sulfometuron Methyl in Forest Watersheds After Aerial Application of Oust for Herba- ceous Weed Control (75% Dispersible Granule): Lab Project Number : AMR-1641-90. Unpublished study prepared by Auburn University Southern Forest Experiment Station. 172 p.
42182401	Schneiders, G.; Bachmura, S. (1992) Photodegradation of Phenyl-Carbon 14(U) and ?Pyrimidine-2-carbon 14| Sulfometuron Methyl in Water—Conducted in Simulated Sunlight: Lab Project Number: AMR 2179-91. Unpublished study prepared by E.I. du Pont de Nemours and Co. 48 p.

42715201	Schneiders, G. (1993) Hydrolysis of (Phenyl-carbon 14 (U)) and (Pyrimidine-2-carbon 14))Sulfometuron Methyl in Buffer Solutions of pH 5, 7, and 9: Lab Project Number: AMR 2426-92. Unpublished study prepared by E.I. du Pont de Nemours & Co. 48 p.
42789301	Kraut, G. (1993) Batch Equilibrium (Adsorption/Desorption) Study of (Phenyl(U)—(carbon 14))Sulfometuron Methyl, IN-X993, IN-D5803, and Saccharin: Lab Project Number: AMR 2607-93. Unpublished study prepared by E.I. □arieg de Nemours and Co. 84 p.
43089201	Sarver, J. (1990) Oral LD50 Test with INT-5648-11 in Male and Female Rats: Lab Project Number: 0581-886: HLR 870-80. E.I. du Pont de Nemours and Co. Unpublished.
43089202	Sarver,J. (1990) Acute Skin Absorption LD50 with INT-5648-13 in Male and Female Rabbits: Lab Project Number 0581-907:HLR-1078-80. E.I du Pont de Nemours and Co. Unpublished.
43089203	O'Neill, A. (1990) Acute Inhalation Toxicity Study with INT-5648-18 in Rats: Lab Project Number: 0581-944: HLR-657-82. E.I. du Pont de Nemours and Co. Unpublished.
43089204	Sarver, J. (1990) Primary skin Irritation and Sensitization Test with INT-5548-03 on Guinea Pigs: Lab Project Number : 0581-790: HLR 232-79. E.I du Pont de Nemours and Co. Unpublished.
43154101	Malek, D. (1994) Combined Chronic Toxicity/Oncogenicity Study with INT-5648, Long-Term Feeding and Two-Generation, Four-litter Reproduction Study in Rats: Supplement No. 2: Lab Project Number: 4052-001: 367-84. Unpublished study prepared by E.I. du Pont de Nemours and Co. 145 p.
43174101	Schneiders, G. (1994) Photodegradation of (Phenyl-(carbon 14)(U)) and (Pyrimidine-2-(carbon 14)) Sulfometuron Methyl in Water Conducted in Simulated Sunlight: Supplement: Lab Project Number: AMR 2179-91. Unpublished study prepared by DuPont Agricultural Products. 18 p.
43174103	Rhodes, B. (1994) Aerobic Aquatic Metabolism of (Carbon 14)-Sulfometuron Methyl: Supplement: Lab Project Number: AMR 1896-90. Unpublished study prepared by DuPont Agricultural Products. 7 p.
43174104	Trubey, R. (1994) Movement of Sulfometuron Methyl in Forest Watersheds After Aerial Application of Oust for Herbaceous Weed Control (75% Dispersible Granule): Lab Project Number: AMR 1641-90. Unpublished study prepared by Southern Forest Experiment Station, Auburn University and DuPont Agric. Products. 38 p.
43212101	Trubey, R. (1994) Field Soil Dissipation on Oust Herbicide: Sulfometuron Methyl: Lab Project Number: AMR/1922/91: DUPDE01B- 2. Unpublished study prepared by E.I. du Pont de Nemours and Co. and Alta Analytical Lab., Inc. 1151 p.
43174102 and 245375	Anderson, J. (1994) Microbial Metabolism of (carbon 14)-Phenyl-Labeled DPX-T5648 in a Viable Soil Ecosystem: Supplement: Lab Project Number: AMR 34-81. Unpublished study prepared by DuPont Agricultural Products. 7 p.
43501801	Brown, M. (1994) Static, Acute, 96-Hour LC50 of DPX-T5648-42 (Sulfometuron Methyl) to Bluegill Sunfish, Lepomis macrochirus: (Limit Test): Lab Project Numbers: 9868-001: 590-94: HLR 590-94. Unpublished study prepared by E.I. du Pont de Nemours and Co. 27 p.
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