



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

August 11, 2008

MEMORANDUM

SUBJECT: Sulfometuron Methyl: Addendum to “Sulfometuron Methyl:
Occupational and Residential Exposure Assessment for the Reregistration
Eligibility Decision (Non-Food).”

PC Code: 122001	DP Barcode: 346173
MRID No.: N/A	Registration No.: N/A
Petition No.: N/A	Regulatory Action: Phase 3
Risk Assessment Type: Response to Error Only Comments	Case No.: XX
TXR No.: N/A	CAS No.: 74222-97-2
MRID No.: N/A	40 CFR: N/A (Non-Food/ Non-Feed)

FROM: Wade Britton, MPH, Industrial Hygienist
Reregistration Branch 3
Health Effects Division (7509P)

THROUGH: Catherine Eiden, Branch Chief
Reregistration Branch 3
Health Effects Division (7509P)

TO: Russell Wasem, Chemical Review Manager
Reregistration Branch 1
Special Review and Reregistration Division (SRRD) (7508P)

This document serves an addendum to *Sulfometuron Methyl: Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision (Non-Food)*, W. Britton, D345025, dated December 20, 2007, with the purpose of assessing an additional use of sulfometuron methyl. The product LPI Sulfometuron Methyl, EPA Reg. No. 34704-1002 was conditionally registered on 5/13/2008. Labeling for this product describes a dry bulk fertilizer impregnation use for forestry (loblolly and slash pine) which has not been previously assessed. The LPI Sulfometuron Methyl is formulated as water dispersible granules (WDG) with a maximum application rate of 0.38 pound of active ingredient (ai) per acre.

Occupational Handler Exposure/Risk

Short- (up to 30 days) and intermediate-term (30 days to 6 months) dermal and inhalation exposures/risks were estimated for occupational handlers (mixing/loading and application) of sulfometuron methyl for the dry bulk fertilizer impregnation use. Two steps were assessed for the mixing of sulfometuron methyl active ingredient: 1) mixing the product with water to form a slurry and 2) mixing of the slurry in a closed rotary drum mixer with the dry bulk fertilizer (urea and blended). Aerial application (fixed wing aircraft and helicopter) of impregnated fertilizer for forestry was also assessed. Long-term handler exposures (greater than 6 months) are not expected to occur.

None of the exposure scenarios assessed for the impregnation of mixing/loading or application of dry bulk fertilizer, urea or blended, with sulfometuron methyl active ingredient is of concern to HED (i.e., an MOE \geq 100) at some level of personal protective equipment (PPE).

Occupational Postapplication Exposure/Risk

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

Residential Handler and Postapplication Exposure/Risk

Residential exposure/risk (handler or postapplication) was not assessed since label instructions do not allow applications of sulfometuron methyl to residential or recreational settings.

Spray Drift

Spray drift is always a potential source of exposure to residents near spraying operations. This is particularly the case with aerial application but, to a lesser extent, could also be a potential source of exposure from the ground application method. The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation and other parties to develop the best spray drift management

practices. On a chemical by chemical basis, the Agency is now requiring interim mitigation measures for aerial applications that must be placed on product labels/labeling. The Agency has completed its evaluation of the new database submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, and is developing a policy on how to appropriately apply the data and the AgDRIFT computer model to its risk assessments for pesticides applied by air, orchard airblast and ground hydraulic methods. After the policy is in place, the Agency may impose further refinements in spray drift management practices to reduce off-target drift with specific products with significant risks associated with drift.

Hazard Concerns

The toxicology database for sulfometuron methyl is limited, but sufficient to provide screening level endpoints for this non-food/non-feed pesticide. Sulfometuron methyl is not acutely toxic. It is classified as Toxicity Category III for acute dermal toxicity and Toxicity Category IV for acute inhalation and oral toxicity. Sulfometuron methyl shows minimal eye irritation and minimal skin irritation, but is not considered a dermal irritant or dermal sensitizer. Typically, acute toxicity Category III and IV pesticides require a 12 hour restricted entry interval (REI); however, due to *Pesticide Registration (PR) Notice 95-3: Reduction of Worker Protection Standard (WPS) Interim Restricted Entry Intervals (REIs) for Certain Low Risk Pesticides*, the REI for sulfometuron methyl was reduced from 12 to 4 hours. The acute toxicity for sulfometuron methyl is presented in Table 1.

The toxicological endpoints used to complete the occupational exposure assessment are summarized in Table 2. A full description of hazard characterization/assessment of sulfometuron methyl can be referenced in the memorandum, *Sulfometuron Methyl: Phase 3 Amendment of “Sulfometuron Methyl: HED Chapter of the Reregistration Eligibility Decision Document (RED)”*, (W. Britton, D385620).

Guideline No.	Study Type	MRID(s)	Results	Toxicity Category
870.1100	Acute oral - rat	43089201	LD ₅₀ = > 5000 mg/kg	IV
870.1200	Acute dermal [species]	43089202	LD ₅₀ = > 2000 mg/kg	III
870.1300	Acute inhalation – rat	43089203	LC ₅₀ = > 5 mg/L	IV
870.2400	Acute eye irritation [species]	00071412	Minimal Irritant	III
870.2500	Acute dermal irritation [species]	41672808	Not a Dermal Irritant	IV*
870.2600	Skin sensitization [species]	43089204	Not a Dermal Sensitizer	N/A

¹ 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 43089202) and an older dermal irritation study of a 75% formulation (MRID 00071411).

Table 2. Summary of Toxicological Doses and Endpoints for Sulfometuron Methyl for Use in Occupational Human Health Risk Assessments				
Exposure/ Scenario	Point of Departure	Uncertainty Factors	Level of Concern for Risk Assessment	Study and Toxicological Effects
Dermal and Inhalation Short- (1-30 days) and Intermediate-Term (1-6 months) (no residential uses)	NOAEL= 27.5 mg/kg/day (100% dermal and inhalation absorption assumed)	UF _A =10x UF _H =10x	MOE = 100	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
Cancer (oral, dermal, inhalation)	No data available for assessment			

UF = uncertainty factor. UF_A = extrapolation from animal to human (intraspecies). UF_H = potential variation in sensitivity among members of the human population (interspecies). MOE = margin of exposure.

Occupational Handler Exposure/Risk

Data and Assumptions

A series of assumptions and exposure factors served as the basis for completing the dry bulk fertilizer impregnation occupational handler risk assessment. The assumptions and factors used in the risk calculations include those described in the memorandum *Sulfometuron Methyl: Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision*, (W. Britton, D345025), as well as the following:

Unit Exposure

- Chemical-specific data for assessing exposure during pesticide handling activities were not submitted to the Agency in support of the sulfometuron methyl fertilizer impregnation use. It is HED policy to use data from the Pesticide Handlers Exposure Database (PHED) Version 1.1 to assess handler exposures for regulatory actions when chemical-specific data are not available (*HED Science Advisory Council for Exposure, SOP Number .007, January 1999*).
- Impregnated dry bulk fertilizer is typically prepared by local agricultural dealers, and is then transported to the areas to be treated and applied. According to the information provided in the alachlor RED, “there is a division of labor, in that most dealers, even small dealer operations, usually have different individuals running the mixing equipment and applying mix to fields. This is because of the different skill requirements and to achieve better productivity.” Thus, HED has performed separate assessments for mixer/loaders and applicators.
- Based upon several email exchanges between Mr. Russell Wasem of EPA and Mr. Ronnie Turner of Dupont Crop Protection (7/23-24/2008), information was provided about the mixing of the sulfometuron methyl product with a dry bulk

fertilizer and the methods employed to apply the treated fertilizer. A summary of the provided information is as follows: In order to prepare the WDG product for impregnation with a dry bulk fertilizer, a slurry must be prepared by applying water. The dry fertilizer and sulfometuron methyl/water slurry are then mixed in a closed rotary drum-type mixer (similar to a large cement mixer) allowing sufficient time to ensure uniform coverage. During mixing, the delivery nozzle should be positioned inside the rotary mixer to ensure uniform coverage. Treated fertilizer is applied aerially by fixed wing aircraft and helicopter.

More information regarding the mixing/loading and application of an herbicide with dry bulk fertilizer was provided by the University of Illinois Extension Service, as referenced from the alachlor RED. “The herbicide is metered from a mini-bulk tank (several hundred gallons) to a mixing drum via a closed system. The herbicide is sprayed onto the fertilizer, which is stirred by an auger that lifts it to the top of the drum. After impregnation, the treated fertilizer is gravity-fed through a hopper onto a conveyor belt leading to an auger truck, which carries it to the field. At the field, the auger truck feeds the treated fertilizer onto the application vehicle. The transfer of the treated fertilizer is nearly dust free, as it has been moistened by the herbicide. Because all processes are mechanized, there is minimal contact of either the mixer at the treatment site or the loader at the transfer sites. Applicator exposure is minimized by the use of a closed cab.”

While a few differences exist, HED anticipates that the treatments of dry bulk fertilizer with alachlor and sulfometuron methyl are mostly similar. Alachlor is formulated as a liquid herbicide and applied by ground equipment. Since sulfometuron methyl is formulated as a WDG, it must be mixed with water in order to form the slurry that allows for transfer (metering), via delivery nozzle, into the closed mixing drum. As above in the alachlor description, slurry mixing/preparation is anticipated to occur in a mini-bulk tank. This initial step in the mixing/loading process is the only which HED would describe as open since all others are either closed or mechanized. Unlike alachlor, application of sulfometuron methyl treated dry bulk fertilizers are performed aerially (fixed wing aircraft and helicopter); though both methods of application involve the use of a closed cab.

- Based upon the information supplied by Dupont and referenced from the alachlor RED, HED has determined that two steps are required to assess the exposure/risk from the mixing of sulfometuron methyl product for dry bulk impregnation: 1) mixing the product with water to form a slurry and 2) mixing of the slurry in the closed rotary drum mixer with dry bulk fertilizer. The transfer of the slurry from the mini-bulk tank to the mixing drum a part of the closed system and, therefore, encompassed by the second step.

HED does not anticipate significant dermal or inhalation exposure to the occupational handler from the loading of the treated fertilizer from the mixing drum to the auger truck and, ultimately, the application equipment since these

processes are mechanized; however, HED has determined that the subsequent aerial application (fixed wing aircraft and helicopter) of the treated fertilizer requires quantitative risk assessment.

- In order to assess occupational handler exposure for the creation of slurry in the mini-bulk tank, HED used PHED data specific to dry flowable (DF) products since this formulation is similar to WDGs. The unit dermal exposure value for baseline (long sleeved shirt and pants or coveralls, no gloves and no respirator) mixing/loading of dry flowables is 0.066 mg/lb ai and the unit inhalation exposure value is 0.00077 mg/lb ai. The unit dermal exposure value for double layer clothing and gloves mixing/loading of dry flowables is 0.047 mg/lb ai. The mixing/loading of the slurry in the closed rotary drum mixer with dry bulk fertilizer was assessed using PHED data specific to liquids, closed mixing/loading. The unit dermal exposure value for this exposure scenario is 0.0086 mg/lb ai and the unit inhalation exposure value is 0.000083 mg/lb ai.
- HED has no data for aerial equipment (fixed wing aircraft, helicopter) applying impregnated fertilizer, and therefore data was selected from PHED "aerial fixed wing, enclosed cockpit, granular application" as the most appropriate surrogate data for estimating applicator exposure. PHED contains limited helicopter data, but the data are insufficient in number and quality to be used for risk assessments. Therefore, PHED data for aerial fixed wing, closed cockpit, granular application have been determined most appropriate for assessment of this exposure scenario. The dermal unit exposure value the assessed scenario is 0.0017 mg/lb ai and the inhalation unit exposure value is 0.0013 mg/lb ai.

Area Treated

- Based upon the email exchanges between EPA and Dupont Crop Protection (7/23-24/2008), the rates of fertilizer applied per acre in forestry have been identified to range from 435 pounds per acre for urea fertilizer and 600 to 1000 pounds per acre for blended fertilizer. In addition, Dupont identified that a range of 160-220 tons (or a maximum of 440,000 pounds) fertilizer can be applied per day by fixed wing aircraft and 10-12 tons of fertilizer can be applied per hour for helicopter applications in a 5-6 hour work day, resulting in a maximum of 72 tons (144,000 pounds) of fertilizer applied per day via helicopter.

In order to determine the area treated per day by fixed wing aircraft and helicopter, HED took the ratio of the maximum poundage of fertilizer which can be applied per day for each application method and the fertilizer poundage per acre rate (urea and blended), as supplied by Dupont. The results are as follows:

- the area treated daily by fixed wing aircraft ranges from 1010 acres per day for sulfometuron methyl treated urea fertilizer to 733 acres per day for blended fertilizer; and

- the area treated daily for helicopter ranges from 331 acres per day for urea fertilizer to 240 acres per day for blended fertilizers.

Application Rate/ Amount of Active Ingredient Handled per Day

The maximum labeled application rate for the sulfometuron methyl dry bulk impregnation forestry use is 0.38 lbs ai/acre.

Dry Bulk Fertilizer Handler Exposure/Risk Estimates

Short- and intermediate-term dermal and inhalation exposures/risks were calculated for occupational handlers (mixing/loading and application) of sulfometuron methyl for the dry bulk fertilizer impregnation use. None of the exposure scenarios assessed are of concern to HED (i.e., an MOE \geq 100) at some level of PPE. A summary of risk estimates is presented in Table 3.

Table 3. Short- and Intermediate-term Exposure and Risk for Sulfometuron Methyl Impregnation with Dry Bulk Fertilizer for Forestry Applications

Scenario	Mitigation	Crop	Dermal Unit Exposure (mg/lb) ^b	Inhalation Unit Exposure (mg/lb) ^b	Application Rate ^c (lb ai/acre)	Acres Treated ^d (A/day)	Dermal Dose (mg/kg/day) ^e	Inhalation Dose ^f (mg/kg/day)	Dermal MOE ^g	Inhalation MOE ^h	Combined MOE ⁱ
Mixer/Loader											
WDG: Mixing to Prepare Slurry for Addition to Dry Bulk Fertilizer (Blended for Helicopter)	Baseline ^a (PHED)	Forestry (loblolly and slash pine)	0.066	0.00077	0.38	240	0.086	0.0010	320	27000	320
WDG: Mixing to Prepare Slurry for Addition to Dry Bulk Fertilizer (Urea for Helicopter)			0.066	0.00077		331	0.12	0.0014	230	20000	230
WDG: Mixing to Prepare Slurry for Addition to Dry Bulk Fertilizer (Blended for Fixed Wing Aircraft)			0.066	0.00077		733	0.26	0.0031	105	9000	104
WDG: Mixing to Prepare Slurry for Addition to Dry Bulk Fertilizer (Urea for Fixed Wing Aircraft)			Double Layer Clothing with Gloves	0.047		0.00077	1010	0.26	0.0042	107	6500

Table 3. Short- and Intermediate-term Exposure and Risk for Sulfometuron Methyl Impregnation with Dry Bulk Fertilizer for Forestry Applications

Scenario	Mitigation	Crop	Dermal Unit Exposure (mg/lb) ^b	Inhalation Unit Exposure (mg/lb) ^b	Application Rate ^c (lb ai/acre)	Acres Treated ^d (A/day)	Dermal Dose (mg/kg/day) ^e	Inhalation Dose ^f (mg/kg/day)	Dermal MOE ^g	Inhalation MOE ^h	Combined MOE ⁱ
Liquids: Mixing Slurry with Dry Bulk Fertilizer (Blended for Helicopter)	Engineering Control - Closed Transfer System (PHED)		0.0086	0.000083		240	0.011	0.00011	2500	250000	2400
Liquids: Mixing Slurry with Dry Bulk Fertilizer (Urea for Helicopter)			0.0086	0.000083		331	0.015	0.00015	1800	180000	1800
Liquids: Mixing Slurry with Dry Bulk Fertilizer (Blended for Fixed Wing Aircraft)			0.0086	0.000083		733	0.034	0.00033	800	83000	800
Liquids: Mixing Slurry with Dry Bulk Fertilizer (Urea for Fixed Wing Aircraft)			0.0086	0.000083		1010	0.047	0.00046	580	60000	580

Table 3. Short- and Intermediate-term Exposure and Risk for Sulfometuron Methyl Impregnation with Dry Bulk Fertilizer for Forestry Applications

Scenario	Mitigation	Crop	Dermal Unit Exposure (mg/lb) ^b	Inhalation Unit Exposure (mg/lb) ^b	Application Rate ^c (lb ai/acre)	Acres Treated ^d (A/day)	Dermal Dose (mg/kg/day) ^e	Inhalation Dose ^f (mg/kg/day)	Dermal MOE ^g	Inhalation MOE ^h	Combined MOE ⁱ
Applicator											
Granular: Aerial Application (Helicopter) of Treated Blended Fertilizer	Engineering Control - Closed Cab (PHED)	forestry (loblolly and slash pine)	0.0017	0.0013	0.38	240 A/day	0.0022	0.0017	12000	16000	7000
Granular: Aerial Application (Helicopter) of Treated Urea Fertilizer			0.0017	0.0013		331 A/day	0.0031	0.0023	9000	12000	5100
Granular: Aerial Application (Fixed Wing Aircraft) of Treated Blended Fertilizer			0.0017	0.0013		733 A/day	0.0068	0.0052	4100	5300	2300
Granular: Aerial Application (Fixed Wing Aircraft) of Treated Urea Fertilizer			0.0017	0.0013		1010 A/day	0.0093	0.0071	3000	4000	1700

- a. Baseline = Single layer clothing (long sleeved shirt and pants or coveralls), no gloves and no respirator
- b. PHED Version 1.1
- c. Maximum application rate based on conditionally registered label for sulfometuron methyl (EPA Reg. No. 34704-1002)
- d. The area (acres) treated per day is based upon email communication between Mr. Russell Wasem of EPA and Mr. Ronnie Turner of Dupont Crop Protection (7/23-24/2008)
- e. Dermal Dose (mg/kg/day) = [Rate (lb ai/A) x UE (mg /lb ai) x Acres Treated (A/day)] / BW (70 kg)
- f. Inhalation Dose (mg/kg/day) = [Rate (lb ai/A) x UE (mg /lb ai) x Acres Treated (A/day)] / BW (70 kg)
- g. Dermal MOE = [Dermal NOAEL (27.5 mg/kg/day)]/ Dermal Dose (mg/kg/day)
- h. Inhalation MOE = [Inhalation NOAEL (27.5 mg/kg/day)] / Inhalation Dose (mg/kg/day)
- i. Combined MOE = 1/((1/Dermal MOE)+(1/Inhalation MOE))

Occupational Postapplication Exposure/Risk

An occupational postapplication assessment of exposure to sulfometuron methyl was not performed. Since sulfometuron methyl is a non-selective herbicide used in non-agricultural areas, HED has determined that contact with previously treated areas is likely to be insignificant. As addressed previously, the required 12 hour REI for an acute toxicity Category III and IV pesticide was reduced for sulfometuron methyl to 4 hours due to *Pesticide Registration (PR) Notice 95-3: Reduction of Worker Protection Standard (WPS) Interim Restricted Entry Intervals (REIs) for Certain Low Risk Pesticides*. Considering that contact from previously treated areas is likely insignificant, HED concurs with the 4 hour REI.

Residential Handler and Postapplication Exposure/Risk

Residential exposure/risk (handler or postapplication) was not assessed since label instructions do not allow applications of sulfometuron methyl to residential or recreational settings.