



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

December 20, 2007

**MEMORANDUM**

**SUBJECT:** **Sulfometuron Methyl:** Acute and Chronic Screening-Level Drinking Water Only Dietary Risk Assessment for the Non-Food/Non-Feed Use Reregistration Eligibility Decision (RED). DP Barcode: D346139. PC Chemical Code: 122001.

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An unrefined acute and chronic screening-level drinking water only dietary assessment was conducted for the herbicide sulfometuron methyl using the Dietary Exposure Evaluation Model DEEM-FCID™, Version 2.03 which use food consumption data from the U.S. Department of Agriculture's Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994-1996 and 1998 to calculate dietary risk. The present assessment was undertaken to evaluate the potential for sulfometuron methyl exposure to humans through drinking water sources only. This was done to elucidate the risk levels associated with the proposed non-food/non-feed uses of this chemical, and to support the human health

risk assessment for the Reregistration Eligibility Decision (RED) for sulfometuron methyl.

### Characterization of Acute and Chronic Dietary Exposure Results

The present acute and chronic screening-level drinking water dietary assessment constitutes a conservative evaluation of exposure to sulfometuron methyl. It is based on the Environmental Fate and Effects Division (EFED) determination of Estimated Drinking Water Concentrations (EDWCs) for exposure (M. Barrett, D334287). Using the PRZM/EXAMS model, EFED calculated a peak day (acute) average of 32.4 ppb and a maximum 1 in 10 year annual average (chronic) surface water concentration of 21.8 ppb. The EDWCs include the parent compound, sulfometuron methyl, as well as the potential water degradates sulfometuron free acid, sulfometuron pyrimidine amine, sulfometuron sulfonamide, and saccharin. Ground water sources were not included, as the EDWCs for this water source are minimal in comparison to surface water. Food uses were not incorporated into this evaluation since only non-food/non-feed uses of sulfometuron methyl are being supported by the registrant.

Risk estimates were found to be below the 100% acute Reference Dose (aRfd) and chronic Reference Dose (cRfd) threshold levels of concern for all population subgroups. The acute and chronic drinking water exposure to sulfometuron methyl is estimated to be < 1 % of the RfDs for the general U.S. population. For the most highly exposed subgroup, all infants (< 1 year old), estimated acute dietary exposure is 2.3 % of the aRfd and chronic dietary exposure is < 1 % of the cRfd.

### Cancer Dietary Exposure Results and Characterization

A determination of cancer risk was not performed with DEEM-FCID™ as part of the screening-level drinking water sulfometuron methyl assessment, since there are no carcinogenicity studies. No studies were required because there are no food or feed tolerances for sulfometuron methyl.

#### **I. Introduction**

Dietary risk assessment incorporates both exposure and toxicity of a given pesticide. For acute or chronic assessments, the risk is expressed as a percentage of a maximum acceptable dose (i.e., the dose which HED has concluded will result in no unreasonable adverse health effects). For a drinking water assessment, this dosage is referred to as the Reference Dose (RfD). The RfD is equivalent to point of departure (PoD) (e.g., NOAEL or LOAEL) divided by the necessary uncertainty or safety factors.

For acute and non-cancer chronic exposures, HED is concerned when estimated dietary risk exceeds 100% of the PAD. HED is generally concerned when estimated cancer risk exceeds one in one million. References which discuss the acute and chronic risk assessments in more detail are available on the EPA/pesticides web site: "Available Information on Assessing Exposure from Pesticides, A User's Guide," 21-JUN-2000,

web link: <http://www.epa.gov/fedrgstr/EPA-PEST/2000/July/Day-12/6061.pdf> ; or see SOP 99.6 (20-AUG-1999).

## **II. Residue Information**

There are no proposed tolerances and percent crop treated information relevant to this action for consideration. Sulfometuron methyl is a non-food/non-feed use chemical with no current or proposed usages which could lead to dietary exposures from raw agricultural commodities and/or processed foods. It is registered for management of annual and perennial broadleaf weeds and grasses in non-agricultural sites (i.e., forestry, rights of way, industrial sites, and unimproved turf). As a result, FQPA requirements are not applicable to the current action pursuant to this RED. Because FQPA guidelines do not apply in this instance, screening-level drinking water only risk calculations are therefore expressed as RfDs rather than population adjusted doses (PADs). Consequently, there are no dietary risk assessments being made reflecting food consumption for sulfometuron methyl given the fact that it is a non-food/non-feed use active ingredient.

## **III. Drinking Water Data**

The drinking water residues used in the dietary risk assessment were provided by the Environmental Fate and Effects Division (EFED) in the following memorandum: “Tier I Sulfometuron Methyl Drinking Water Assessment for Reregistration Eligibility Decision Document” (M. Barrett, D334287, 10/31/07) and incorporated directly into this dietary assessment. This assessment relied solely on modeling analyses to calculate both surface and ground water EDWCs for exposure. A number of degradates were identified and these have been added to the parent compound sulfometuron methyl. The drinking water assessment, therefore, models the parent compound sulfometuron methyl as well as degradates. 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) EDWCs 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 values of 32.4 (acute) and 21.8 (chronic) ppb were used in the present acute and chronic screening-level drinking water dietary assessments.

## **IV. DEEM-FCID™ Program and Consumption Information**

Sulfometuron methyl acute and chronic dietary exposure assessments (drinking water only) were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database DEEM-FCID™, Version 2.03 which incorporates consumption data from USDA’s Continuing Surveys of Food Intakes by Individuals (CSFII), 1994-1996 and 1998. The 1994-96, 98 data are based on the reported consumption of more than 20,000 individuals over two non-consecutive survey days. Foods “as consumed” (e.g., apple pie) are linked to EPA-defined food commodities (e.g.

apples, peeled fruit - cooked; fresh or N/S; baked; or wheat flour - cooked; fresh or N/S, baked) using publicly available recipe translation files developed jointly by USDA/ARS and EPA. For chronic exposure assessment, consumption data are averaged for the entire U.S. population and within population subgroups, but for acute exposure assessment are retained as individual consumption events. Based on analysis of the 1994-96, 98 CSFII consumption data, which took into account dietary patterns and survey respondents, HED concluded that it is most appropriate to report risk for the following population subgroups: the general U.S. population, all infants (<1 year old), children 1-2, children 3-5, children 6-12, youth 13-19, adults 20-49, females 13-49, and adults 50+ years old.

For chronic dietary exposure assessment, an estimate of the residue level in each food or food-form (e.g., orange or orange juice) on the food commodity residue list is multiplied by the average daily consumption estimate for that food/food form to produce a residue intake estimate. The resulting residue intake estimate for each food/food form is summed with the residue intake estimates for all other food/food forms on the commodity residue list to arrive at the total average estimated exposure. Exposure is expressed in mg/kg body weight/day and as a percent of the cPAD. This procedure is performed for each population subgroup.

For acute exposure assessments, individual one-day food consumption data are used on an individual-by-individual basis. The reported consumption amounts of each food item can be multiplied by a residue point estimate and summed to obtain a total daily pesticide exposure for a deterministic exposure assessment, or “matched” in multiple random pairings with residue values and then summed in a probabilistic assessment. The resulting distribution of exposures is expressed as a percentage of the aPAD on both a user (i.e., only those who reported eating relevant commodities/food forms) and a per-capita (i.e., those who reported eating the relevant commodities as well as those who did not) basis. In accordance with HED policy, per capita exposure and risk are reported for all tiers of analysis. However, for tiers 1 and 2, any significant differences in user vs. per capita exposure and risk are specifically identified and noted in the risk assessment.

However, it is important to note that sulfometuron methyl is a non-food/non-feed use chemical with no current or proposed usages which could lead to exposures from raw agricultural commodities and/or processed foods. Given this fact, there no proposed tolerances and/or percent crop treated information relevant to this action for consideration. For this assessment, no food items were included and only the drinking water “food form” was evaluated by the DEEM-FCID™ modeling software.

## **V. Toxicological Information**

To carry out the acute and chronic screening-level drinking water dietary assessments, a toxicological profile was assembled to identify the possible hazards for exposure. All information specific to the toxicity characteristics of sulfometuron methyl are presented in the risk assessment for the sulfometuron methyl RED (D346064, W. Britton, *et. al., in preparation*). The acute and chronic endpoint for drinking water exposure was selected from the toxicity study results. Using these data, a No Observed Adverse Effect Level

(NOAEL) of 27.5 mg/kg/day was selected and an aRfD and cRfD of 0.275 mg/kg/day were determined. The LOAEL is based on hemolytic anemia in both sexes and decreased body-weight gain in males (0-4 weeks).

For the acute and chronic exposure scenarios, the standard 100 fold uncertainty factor (UF) was applied to account for inter-species extrapolation and intra-species variation. As previously noted, a cancer risk evaluation is not included in this screening-level drinking water assessment. In addition, FQPA guidelines do not apply given the fact that sulfometuron methyl is a non-food/non-feed use active ingredient. To provide an overview of this toxicological profile, a summary of the doses and endpoints selected for the drinking water exposure scenarios which were performed are provided in Table 1.

<b>Table 1. Summary of Toxicological Doses and Endpoints for the Screening-Level Drinking Water Risk Assessment of Sulfometuron Methyl</b>			
<b>Exposure Scenario</b>	<b>POD</b>	<b>Hazard and Exposure Based FQPA Safety Factor</b>	<b>Study and Toxicological Effects</b>
Acute Dietary <u>All populations</u>	NOAEL= 27.5 mg/kg/day UF = 100	The FQPA SF is not applicable to this risk determination since sulfometuron methyl is a non-food/non-feed use chemical.	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 <u>All populations</u>	<b>Chronic RfD = <math>\frac{NOAEL}{UF}</math></b> = 0.275 mg/kg/day		
Cancer (dermal, inhalation)	Not available for assessment.		

Point of Departure (PoD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. RfD = reference dose. FQPA = Food Quality Protection Act. SF = Safety Factor

## **VI. Results/Discussion**

For acute and chronic assessments, HED is concerned when dietary risk exceeds 100% of the RfD. The DEEM-FCID™ analysis estimates the exposure of the U.S. population and its various subgroups. The results reported in Tables 2 and 3 are for the general U.S. Population, all infants (<1 year old), children 1-2, children 3-5, children 6-12, youth 13-19, females 13-49, adults 20-49, and adults 50+ years.

### Results for Acute Dietary Exposure Analysis

An acute dietary risk analysis was conducted with the DEEM-FCID™ model to form a conservative evaluation of exposure for sulfometuron methyl. The acute analysis yielded estimates well below the 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. An overview summarizing the results of the acute dietary assessment with the population subgroup having the highest exposure being noted in bold is presented in Table 2.

<b>Table 2. Summary of Screening Level Drinking Water Exposure and Risk for Sulfometuron Methyl</b>		
<b>Population Subgroup</b>	<b>Acute Dietary<sup>1</sup></b>	
	<b>Dietary Exposure (95<sup>th</sup> percentile) (mg/kg/day)</b>	<b>%aRfD</b>
General U.S. Population	0.001690	< 1
<b>All Infants (&lt; 1 year old)</b>	<b>0.006372</b>	<b>2.3</b>
Children 1-2 years old	0.002652	< 1
Children 3-5 years old	0.002422	< 1
Children 6-12 years old	0.001686	< 1
Youth 13-19 years old	0.001371	< 1
Adults 20-49 years old	0.001566	< 1
Adults 50+ years old	0.001414	< 1
Females 13-49 years old	0.001575	< 1

<sup>1</sup> Acute dietary analysis based on a 0.275 mg/kg/day aRfD.

### Results of Chronic Dietary Exposure Analysis

A chronic dietary risk analysis was conducted with the DEEM-FCID™ model to form a conservative evaluation of exposure for sulfometuron methyl. The chronic analysis yielded risk estimates well below the 100% of the cRfD threshold level of concern for each population subgroup. For the US Population subgroup, chronic dietary risk was calculated at < 1 % of the cRfD with an exposure level of 0.00046 mg/kg/day. For the subgroup with the highest calculated exposure, all infants less than 1 year old, chronic dietary risk occupied < 1 % of the cRfD with an exposure of 0.0015 mg/kg/day. An overview summarizing the results of the chronic dietary assessment with the population subgroup having the highest exposure being noted in bold is presented in Table 3.

<b>Table 3. Summary of Screening Level Drinking Water Exposure and Risk for Sulfometuron Methyl.</b>		
<b>Population Subgroup</b>	<b>Chronic Dietary<sup>1</sup></b>	
	<b>Dietary Exposure (99<sup>th</sup> percentile) (mg/kg/day)</b>	<b>%cRfD</b>
General U.S. Population	0.000460	< 1
<b>All Infants (&lt; 1 year old)</b>	<b>0.001508</b>	<b>&lt; 1</b>
Children 1-2 years old	0.000683	< 1
Children 3-5 years old	0.000639	< 1
Children 6-12 years old	0.000441	< 1
Youth 13-19 years old	0.000332	< 1
Adults 20-49 years old	0.000429	< 1
Adults 50+ years old	0.000452	< 1
Females 13-49 years old	0.000428	< 1

<sup>1</sup> Chronic dietary analysis based on a 0.275 mg/kg/day cRfD.

## **VII. Characterization of Inputs/Outputs**

The acute and chronic screening-level dietary assessments (drinking water only) made with DEEM-FCID™ for sulfometuron methyl is an unrefined analysis. It utilized conservative EDWCs derived through EFED modeling which are unlikely to underestimate the concentration of sulfometuron methyl in drinking water for its intended use as an herbicide. The present DEEM-FCID™ analysis assumes that all drinking water will contain sulfometuron methyl at the highest EDWC levels modeled by EFED for ground water or surface water relevant to the highest supported use rate. In addition, the EDWC levels modeled include the parent compound as well as all anticipated degradates (sulfometuron free acid, sulfometuron pyrimidine amine, sulfometuron sulfonamide, and saccharin). For these reasons, it can be concluded that the DEEM-FCID™ analysis does not underestimate risk from exposure to sulfometuron methyl for the general U.S. population and all its subgroups.

## **VIII. Conclusions**

The conservative acute and chronic screening-level drinking water dietary assessments made with DEEM-FCID™ indicates that exposures to sulfometuron methyl are below HED's level of concern. The analysis utilizes a survey-based consumption distribution together with an upper-bound residue value for drinking water. The acute and chronic dietary exposure to sulfometuron methyl is estimated to be < 1 % for the general U.S. population. For the most highly exposed subgroup, all infants (< 1 year old), the acute and chronic risk estimates are also below HED's level of concern. For this subgroup, the resulting acute dietary exposure is 2.3 % of the aRfD and chronic dietary exposures is < 1

% of the cRfD. Therefore, HED does not believe that the non-food/non-feed use of sulfometuron methyl could result in unacceptable risk through the potential exposure from drinking water sources.

**IX. List of Attachments**

1. Attachment 1: Acute Drinking Water Assessment Input File
2. Attachment 2: Acute Drinking Water Assessment Results File
3. Attachment 3: Chronic Drinking Water Assessment Input File
4. Attachment 4: Chronic Drinking Water Assessment Results File

# Attachment 1

U.S. Environmental Protection Agency Ver. 2.02  
DEEM-FCID Acute analysis for SULFOMETURON METHYL  
Analysis Date 12-14-2007 Residue file dated: 12-14-2007/13:36:56/8  
Reference dose: aRfD = 0.275 mg/kg bw/day NOEL = 27.5 mg/kg bw/day  
Comment: Acute drinking water only (PRZM-EXAMS parent + metabolites)

EPA Code	Crop Grp	Food Name	Def Res (ppm)	Adj. Factors #1	Adj. Factors #2	Comment
86010000	0	Water, direct, all sources	0.032350	1.000	1.000	
86020000	0	Water, indirect, all sources	0.032350	1.000	1.000	

## Attachment 2

U.S. Environmental Protection Agency Ver. 2.02  
 DEEM-FCID ACUTE Analysis for SULFOMETURON METHYL (1994-98 data)

Adjustment factor #2 NOT used.

Analysis Date: 12-14-2007/13:39:53 Residue file dated: 12-14-2007/13:36:56/8

NOEL (Acute) = 27.500000 mg/kg body-wt/day

Daily totals for food and foodform consumption used.

Run Comment: "Acute drinking water only (PRZM-EXAMS parent + metabolites)"

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 Summary calculations (per capita):

	95th Percentile			99th Percentile			99.9th Percentile		
	Exposure	% aRfD	MOE	Exposure	% aRfD	MOE	Exposure	% aRfD	MOE
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U.S. Population:	0.001690	0.61	16272	0.003174	1.15	8663	0.006351	2.31	4330
All infants:	0.006372	2.32	4316	0.009134	3.32	3010	0.016362	5.95	1680
Children 1-2 yrs:	0.002652	0.96	10370	0.004428	1.61	6210	0.006440	2.34	4270
Children 3-5 yrs:	0.002422	0.88	11352	0.003797	1.38	7243	0.006197	2.25	4437
Children 6-12 yrs:	0.001686	0.61	16307	0.002804	1.02	9807	0.003829	1.39	7181
Youth 13-19 yrs:	0.001371	0.50	20058	0.002307	0.84	11922	0.004149	1.51	6628
Adults 20-49 yrs:	0.001566	0.57	17563	0.002622	0.95	10488	0.004743	1.72	5798
Adults 50+ yrs:	0.001414	0.51	19449	0.002022	0.74	13600	0.003279	1.19	8386
Females 13-49 yrs:	0.001575	0.57	17464	0.002534	0.92	10851	0.004494	1.63	6119

### Attachment 3

U.S. Environmental Protection Agency  
DEEM-FCID Chronic analysis for SULFOMETURON METHYL

Ver. 2.00  
1994-98 data  
Adjust. #2 NOT used

Analysis Date 10-29-2007      Residue file dated: 10-29-2007/10:53:27/8  
Reference dose (RfD) = 0.275 mg/kg bw/day  
Comment:Chronic drinking water only (PRZM-EXAMS parent + metabolites)

Food Crop			Residue (ppm)	Adj.Factors		Comment
EPA Code	Grp	Food Name		#1	#2	
86010000	O	Water, direct, all sources	0.021820	1.000	1.000	
86020000	O	Water, indirect, all sources	0.021820	1.000	1.000	

## Attachment 4

U.S. Environmental Protection Agency Ver. 2.00  
 DEEM-FCID Chronic analysis for SULFOMETURON METHYL (1994-98 data)  
Adjustment factor #2 NOT used.  
 Analysis Date 10-29-2007/10:58:39 Residue file dated: 10-29-2007/10:53:27/8  
 Reference dose (RfD, Chronic) = .275 mg/kg bw/day  
 COMMENT 1: Chronic drinking water only (PRZM-EXAMS parent + metabolites)

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Total exposure by population subgroup

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Population Subgroup	Total Exposure	
	mg/kg body wt/day	Percent of Rfd
U.S. Population (total)	0.000460	0.2%
U.S. Population (spring season)	0.000456	0.2%
U.S. Population (summer season)	0.000494	0.2%
U.S. Population (autumn season)	0.000445	0.2%
U.S. Population (winter season)	0.000445	0.2%
Northeast region	0.000420	0.2%
Midwest region	0.000465	0.2%
Southern region	0.000437	0.2%
Western region	0.000527	0.2%
Hispanics	0.000522	0.2%
Non-hispanic whites	0.000449	0.2%
Non-hispanic blacks	0.000437	0.2%
Non-hisp/non-white/non-black	0.000564	0.2%
All infants (< 1 year)	0.001508	0.5%
Nursing infants	0.000559	0.2%
Non-nursing infants	0.001868	0.7%
Children 1-6 yrs	0.000643	0.2%
Children 7-12 yrs	0.000418	0.2%
Females 13-19 (not preg or nursing)	0.000324	0.1%
Females 20+ (not preg or nursing)	0.000459	0.2%
Females 13-50 yrs	0.000445	0.2%
Females 13+ (preg/not nursing)	0.000447	0.2%
Females 13+ (nursing)	0.000637	0.2%
Males 13-19 yrs	0.000338	0.1%
Males 20+ yrs	0.000412	0.1%
Seniors 55+	0.000452	0.2%
Children 1-2 yrs	0.000683	0.2%
Children 3-5 yrs	0.000639	0.2%
Children 6-12 yrs	0.000441	0.2%
Youth 13-19 yrs	0.000332	0.1%
Adults 20-49 yrs	0.000429	0.2%
Adults 50+ yrs	0.000452	0.2%
Females 13-49 yrs	0.000428	0.2%

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