

Orthosulfamuron
PC Code: 108209

Dietary Exposure Assessment

DP Barcode: D332295
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM:

DATE: 2/14/2007

SUBJECT: Orthosulfamuron; Chronic Dietary Exposure Assessment for the Section 3
Registration Action on Rice. PP#: 5F6957

PC Code: 108209

DP Barcode: D332295

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Health Effects Division (7509P)

and

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Executive Summary

A chronic dietary risk assessment was conducted using the Dietary Exposure Evaluation Model (DEEM-FCID, Version 2.03), which uses food consumption data from the USDA's Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994-1996 and 1998. The analysis was performed to support a Section 3 request for a tolerance for residues of orthosulfamuron on rice.

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Acute Dietary Exposure Results and Characterization

An acute dietary exposure analysis was not performed because an acute dietary endpoint was not identified.

Chronic Dietary Exposure Results and Characterization

The chronic analysis is based on tolerance level residues and 100% crop treated assumptions. For drinking water, a conservative estimated drinking water concentration (EDWC) was used. This value was generated by EFED's Interim Rice Model for surface water. The general U.S. population and all population subgroups have risk estimates that are below HED's level of concern (i.e., 100% of the chronic population adjusted dose (cPAD)). The most highly exposed population subgroup is All Infants (<1 year old) which utilizes 57% of the cPAD. The general U.S. population utilizes 17% of the cPAD.

Cancer Dietary Exposure Results and Characterization

Orthosulfamuron was classified as demonstrating "suggestive evidence of carcinogenicity." The chronic dietary exposure analysis is considered to be protective of cancer effects.

I. Introduction

Dietary risk assessment incorporates both exposure and toxicity of a given pesticide. For acute and 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). This dose is referred to as the population adjusted dose (PAD). The PAD is equivalent to the no observable adverse effect level (NOAEL) divided by the assigned 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 (i.e., the risk exceeds 1×10^{-6}). 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," 6/21/2000, web link: <http://www.epa.gov/fcdrgst/EPA-PEST/2000/July/Day-12/6061.pdf>; or see SOP 99.6 (8/20/99).

As orthosulfamuron is a new active ingredient, this dietary exposure analysis is the first analysis to be performed by HED for this chemical.

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II. Residue Information

Residues in Food

Orthosulfamuron is a new active ingredient. As a result, no tolerances have as yet been established. HED is recommending in favor of the establishment of a tolerance of 0.05 ppm for rice. All issues and data regarding the tolerance request are discussed in the residue chemistry summary document prepared for the request (D332290, D. Dotson, 2/14/2007). In the processing studies, residues did not concentrate in the processed rice commodities (polished rice, bran, and hulls). As a result, no processing factors were used in the analyses.

Residues in Water

The Environmental Fate and Effects Division provided a drinking water assessment for orthosulfamuron (Memo, D330828, 10/31/2006, G. Orrick). The assessment provides EDWCs of orthosulfamuron in both surface water and in groundwater. They were generated with EFED's Interim Rice Model (for surface water) and SCI-GROW (for groundwater). Modeled application rates represent the maximum use pattern on the proposed labels for rice. Remaining model input parameters were chosen according to current guidance (EFED, 2002). EDWCs reflect exposure to orthosulfamuron and all potential degradates of concern. They are conservative because of the screening design of the exposure models and assumptions resulting from the limited number of available and acceptable environmental fate studies. The values are given in Table 1, below. As the surface water value is higher than the groundwater value, the surface water value was used in chronic assessment. A value of 40.5 ppb was used for the assessment even though EFED provided a value of <40.5 ppb.

Source	Annual Mean Concentration
Surface water	<40.5 ppb
Groundwater	<0.611 ppb

III. Percent Crop Treated

The assumption was made that 100% of the rice crop grown would be treated with orthosulfamuron.

IV. DEEM-FCID™ Program and Consumption Information

An orthosulfamuron chronic dietary exposure assessment was 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. The resulting residue consumption estimate for each food/food form is summed with the residue consumption 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.

V. Toxicological Information

The Health Effects Division (HED) has evaluated the toxicology database for orthosulfamuron. The risk assessment team reviewed the toxicology database with regard to the acute and chronic reference doses and the toxicological endpoint selection. Table 2 below provides a summary of the doses and endpoints used for the chronic dietary exposure assessment. The FQPA Safety Factor was retained at 10x for the general population and all population subgroups. Orthosulfamuron was classified as having suggestive evidence of carcinogenicity. The chronic dietary exposure analysis is considered to be protective of cancer effects, however.

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Table 2. Toxicological Doses and Endpoints for Use in Human Health Risk Assessments				
Exposure/ Scenario	Point of Departure	Uncertainty/ FQPA Safety Factors	RfD, PAD, Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (General population)	N/A	N/A	N/A	No appropriate endpoint attributable to a single dose identified for this population.
Acute Dietary (Females 13-49 years of age)	N/A	N/A	N/A	No appropriate endpoint attributable to a single dose was identified for this population
Chronic Dietary (All Populations):	NOAEL= 5 mg/kg/day	UF _A = 10x UF _H =10x FQPA SF=10x Total UF=1000x	Chronic RfD =0.005 mg/kg/day cPAD = 0.005mg/kg/day	<u>Combined Chronic/Carcinogenicity-Rat</u> LOAEL (mg/kg/day): 500, based on decreased body weight gains, slight hepatotoxicity, and slight nephrotoxicity in both sexes.
Cancer (oral, dermal, inhalation)	Classification: "Suggestive Evidence of Carcinogenicity"			

UF = uncertainty factor, FQPA SF = FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose.

VI. Results/Discussion

As stated above, for chronic dietary risk assessment, HED is concerned when dietary risk exceeds 100% of the cPAD. The DEEM-FCID™ analysis estimates the dietary exposure of the U.S. population and various population subgroups. The results reported in Table 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 of Chronic Dietary Exposure Analysis

The summary table below lists the results of the chronic dietary exposure analysis along with the results of the acute analysis at the regulated percentile of exposure (i.e., the 95th). The chronic dietary risk estimates for the general U.S. population and all population subgroups are below HED's level of concern. The chronic analysis is considered to be protective of cancer effects.

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Table 3. Summary of Dietary Exposure and Risk for Orthosulfamuron (Food and Drinking Water)				
Population Subgroup*	Chronic Dietary		Cancer	
	Dietary Exposure (mg/kg/day)	% cPAD	Dietary Exposure (mg/kg/day)	Risk
General U.S. Population	0.000868	17	Chronic analysis is protective of cancer effects.	
All Infants (< 1 year old)	0.002836	57		
Children 1-2 years old	0.001296	26		
Children 3-5 years old	0.001212	24		
Children 6-12 years old	0.000836	17		
Youth 13-19 years old	0.000630	13		
Adults 20-49 years old	0.000811	16		
Adults 50+ years old	0.000847	17		
Females 13-49 years old	0.000805	16		

VII. Characterization of Inputs/Outputs

This dietary exposure analysis is very conservative. Residues in foods were assumed to be equivalent to the tolerance levels. Tolerance level residues should always exceed the residue levels found on food commodities at the time of consumption. When field trials are performed, the maximum allowable application rate is used and crops are harvested at the minimum PHI. Samples are stored frozen until analysis to ensure minimal degradation of residues. In actual practice, however, growers will not usually use the maximum application rates for economic reasons. In addition, most crops are not harvested and immediately stored frozen. A conservative residue value was used for drinking water as well. The environmental fate modeler reported that the value is conservative because of the screening design of the exposure models and assumptions resulting from the limited number of available and acceptable environmental fate studies. For these reasons, HED is confident that this analysis does not underestimate risk to the general U.S. population or any population subgroup.

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VIII. Conclusions

Based on conservative assumptions, the orthosulfamuron chronic dietary risk estimates are below HED's level of concern for the general U.S. population and all population subgroups, including those comprised of infants and children. As the chronic analysis is protective of any risk of carcinogenicity, the cancer risk is also below HED's level of concern.

VIII. List of Attachments

Attachment 1: Residue Input File for Chronic Analysis

Attachment 2: Results of Chronic Dietary Exposure Analysis

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Attachment 1: Residue Input File for Chronic Dietary Exposure Analysis

Chemical: Orthosulfamuron
DEEM-FCID Version 2.03
CSFII 1994-1996 data with a supplemental children's survey (1998)

NOAEL (Chronic): 5 mg/kg bw/day
PAD (Chronic): 0.005 mg/kg bw/day

Filename: C:\Documents and Settings\ddotson\My
Documents\DEEMFCID\Orthosulfamuron\Ortho.R98
Date created/last modified: 11-1-2006/16:50:09/8

EPA Comment Code	Crop Grp	Commodity Name	Def Res (ppm)	Adj. Factors	
				#1	#2
15003230	15	Rice, white	0.050000	1.000	1.000
15003231	15	Rice, white-babyfood	0.050000	1.000	1.000
15003240	15	Rice, brown	0.050000	1.000	1.000
15003241	15	Rice, brown-babyfood	0.050000	1.000	1.000
15003250	15	Rice, flour	0.050000	1.000	1.000
15003251	15	Rice, flour-babyfood	0.050000	1.000	1.000
15003260	15	Rice, bran	0.050000	1.000	1.000
15003261	15	Rice, bran-babyfood	0.050000	1.000	1.000
86010000	0	Water, direct, all sources	0.040500	1.000	1.000
86020000	0	Water, indirect, all sources	0.040500	1.000	1.000

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Attachment 2: Results of Chronic Dietary Exposure Analysis

DEEM-FCID Version 2.03 Chronic Analysis for orthosulfamuron
CSFII 1994-1996 data with a supplemental children's survey (1998)
Adjustment factor #2 NOT used.

NOAEL (Chronic) = 5.0 mg/kg body-wt/day. cPAD = 0.005 mg/kg body-wt/day

Residue file: Ortho.R98

Analysis Date: 11-2-2006/10:28:31.

Residue file dated: 11-1-2006/16:50:09/8

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Total exposure by population subgroup

Population Subgroup	Total Exposure	
	mg/kg body wt/day	Percent of PAD
U.S. Population (total)	0.000868	17.4%
U.S. Population (spring season)	0.000861	17.2%
U.S. Population (summer season)	0.000932	18.6%
U.S. Population (autumn season)	0.000839	16.8%
U.S. Population (winter season)	0.000839	16.8%
Northeast region	0.000796	15.9%
Midwest region	0.000873	17.5%
Southern region	0.000823	16.5%
Western region	0.000998	20.0%
Hispanics	0.000995	19.9%
Non-hispanic whites	0.000842	16.8%
Non-hispanic blacks	0.000825	16.5%
Non-hisp/non-white/non-black	0.001112	22.2%
All infants (< 1 year)	0.002836	56.7%
Nursing infants	0.001062	21.2%
Non-nursing infants	0.003509	70.2%
Children 1-6 yrs	0.001219	24.4%
Children 7-12 yrs	0.000792	15.8%
Females 13-19 (not preg or nursing)	0.000611	12.2%
Females 20+ (not preg or nursing)	0.000862	17.2%
Females 13-19 yrs	0.000839	16.8%
Females 13+ (preg/not nursing)	0.000848	17.0%
Females 13+ (nursing)	0.001197	23.9%
Males 13-19 yrs	0.000644	12.9%
Males 20+ yrs	0.000779	15.6%
Seniors 55+	0.000846	16.9%
Children 1-2 yrs	0.001296	25.9%
Children 3-5 yrs	0.001212	24.2%
Children 6-12 yrs	0.000836	16.7%
Youth 13-19 yrs	0.000630	12.6%
Adults 20-49 yrs	0.000811	16.2%
Adults 50+ yrs	0.000847	16.9%
Females 13-19 yrs	0.000805	16.1%



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