UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

Date: January 10, 2007

MEMORANDUM

SUBJECT: **Orthosulfamuron**: Occupational Exposure/Risk Assessment for Proposed Section 3 Registration on Rice.

PC Code:	108209	Chemical Class:	Herbicide
DP Barcode:	D333763	Trade Name:	IR5878 GR IR5878 50 WG

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1.0 Executive Summary

The registrant, Isagro S.p.A., has submitted a request for a Section 3 Registration for the new active ingredient orthosulfamuron for control of various weeds in rice. The new active ingredient (ai) orthosulfamuron, is a systemic herbicide belonging to the sulfamoylurea class of chemicals. The mode of action for orthosulfamuron is through inhibition of the plant enzyme acetolactate synthase, which is also known as acetohydroxy acid synthase. Inhibition of this enzyme blocks branch-chain amino acid biosynthesis of valine, leucine, and isoleucine involved in plant growth processes leading to death of the plant. Formulations include: 1) a water dispersable granular formulation containing 51.5% active ingredient (IR5878 50 WG), and 2) a granular formulation containing 0.51% active ingredient (IR5878 GR). There are no proposed residential uses for orthosulfamuron.

Toxicology/Hazard

The target organs for orthosulfamuron are the liver, kidneys, and the thyroid gland. Subchronic exposure to orthosulfamuron leads to hepatotoxicity in dogs, but not in mice and rats. Chronic exposure results in hepatotoxicity in dogs, rats, and mice. Liver effects observed include increases in liver enzymes and weights, gross pathology and histopathology. Evidence of nephrotoxicity was seen only in rats, in the form of increased kidney weights, lesions, and nephropathy. Additionally in rats, long-term exposure led to thyroid histopathology and thyroid follicular cell adenomas. Based on the thyroid follicular adenomas, the Cancer Assessment Review Committee (CARC) concluded that orthosulfamuron demonstrated "Suggestive Evidence of Carcinogenicity" (J. Kidwell, CARC Report, TXR # 0054463).

There were no treatment-related effects observed in developmental toxicity studies in rats or rabbits. There were decreases in motor activity in offspring (F1 males) in a 2-generation reproduction study in rats. The decrease in motor activity is considered to be an isolated finding since similar decreases were not observed in females or F2 animals. In addition, there were no other treatment-related neurotoxic signs observed in the toxicology database. There is no concern for quantitative or qualitative susceptibility following *in utero* (rats and rabbits), and pre-and post-natal exposure (rats) to orthosulfamuron.

The endpoint applicable to this risk assessment is the occupational short-term inhalation endpoint. The inhalation endpoint is based on effects observed in a 2-generation study in rats, with a NOAEL of 88.6 mg/kg/day and LOAEL of 354.5 mg/kg/day. A 28-Day dermal toxicity study in rats was submitted for orthosulfamuron. There were no adverse treatment-related systemic or dermal effects observed at the limit dose of 1000 mg/kg/day. Therefore, no dermal endpoint was selected for this risk assessment.

Occupational Exposure/Risks

The following agricultural products have been assessed for occupational exposure: IR5878 50 WG and IR5878 0.5 GR. IR5878 50 WG contains 51.5% orthosulfamuron in a water-dispersible granular formulation for use as an agricultural herbicide on wet-seeded or dry-seeded rice. The proposed application rate is 0.055-0.069 lbs ai/A, applied by groundboom and aerial equipment.

IR5878 0.5 GR contains 0.51% orthosulfamuron in a granular formulation for use as an agricultural herbicide on permanently flooded rice. The proposed application rate is 0.066 lbs ai/A, applied by ground (tractor drawn spreader) and aerial equipment. Both proposed end-use products will be applied 1 time per year early in the growing season. Based on the number of seasonal applications indicated on the product labels, and information provided by the registrant, handler exposures are expected to be short-term in duration.

Handlers

No chemical-specific data for assessing handler exposures were submitted to the Agency in support of the proposed uses. As a result, HED used surrogate data from the Pesticide Handlers Exposure Data Base (PHED) Version 1.1, and standard values established by the Health Effects Division (HED) Science Advisory Council for Exposure, for acres treated per day, body weight, and the level of personal protective equipment worn by handlers. The handler exposure estimates in this assessment are based on a central tendency estimate of unit exposure (from PHED) and an upper-percentile assumption for the application rate, and are considered to be representative of high-end exposures. The estimated exposures are believed to be reasonable high-end estimates based on observations from field studies and professional judgment.

A quantitative risk assessment for the dermal exposure route is not required. There were no adverse systemic or dermal effects seen up to the limit dose tested (LDT) of 1,000 mg/kg/day in the dermal toxicity study. The inhalation MOEs for short-term handler exposure range from 47,000 to 1,800,000 and the estimated risks do not exceed HED's level of concern (MOEs <100).

Postapplication

No postapplication chemical-specific data were submitted in support of this registration action. A dermal non-cancer agricultural short-term postapplication exposure assessment is not required due to the absence of systemic and dermal toxicity in the dermal toxicity study.

Orthosulfamuron has a medium vapor pressure of 1.1×10^{-4} mmHg at 20°C. Short-term postapplication inhalation exposures are expected to be minimal and less than the application exposures. Consequently, a quantitative postapplication inhalation exposure assessment was not performed.

Review of Human Research

This risk assessment relies in part on data from studies in which adult human subjects were intentionally exposed to a pesticide or other chemical. These studies, which comprise the Pesticide Handlers Exposure Database (PHED), have been determined to require a review of their ethical conduct, and have received that review.

2.0 Hazard Characterization/Assessment

2.1 Database Summary

Based on the proposed use pattern, the toxicology database for orthosulfamuron is adequate for risk assessment. There are acceptable studies available for endpoint selection that include: 1) subchronic oral toxicity studies in rats, mice, and dogs; 2) a chronic oral toxicity study in dogs and carcinogenicity studies in rats and mice; 3) developmental and reproduction studies in rats and a developmental study in rabbits; and 4) a subchronic dermal toxicity study in rats. There is also a complete mutagenicity battery, as well as an acceptable metabolism study in the rat. There are no available acute or subchronic neurotoxicity studies; however, the subchronic and carcinogenicity studies in rats included neurological evaluations. Acute and subchronic neurotoxicity studies are not required at this time.

2.2 Toxicological Effects

The critical toxicological effects observed after exposure to orthosulfamuron include: hepatotoxicity, nephrotoxicity, and adverse effects on the thyroid gland.

Hepatotoxicity was observed throughout the toxicology database in rats, dogs, and mice. In dogs, increases in absolute/relative liver weights and alkaline phosphatase (ALP) levels were observed after subchronic (90-day) exposure to orthosulfamuron. Chronic exposure (1-year) also resulted in increases in liver weights and ALP, as well as increases in alanine aminotransferase and liver histopathology. In rats and mice, chronic exposure led to increases in liver weights and liver histopathology. There were no adverse effects observed in rats and mice after subchronic exposure.

Evidence of nephrotoxicity was seen in rats in the 2-generation reproduction and carcinogenicity studies. Kidney effects observed were increases in relative weights, lesions, and nephropathy (carcinogenicity study). There were no signs of nephrotoxicity observed in any other species. Additionally, in rats, thyroid toxicity was observed after chronic exposure, in the form of thyroid histopathology and thyroid follicular cell adenomas. The CARC concluded that orthosulfamuron demonstrated "Suggestive Evidence of Carcinogenicity" (J. Kidwell, CARC Report, TXR 0054463).

There were no treatment-related effects observed in developmental toxicity studies in rats and rabbits.

The acute toxicity categories for orthosulfamuron technical material are summarized in Table 1.

Table 1: Acute Toxicity Profile – Orthosulfamuron (98%)

Guideline No.	Study Type	MRID(s)	Results	Toxicity Category
870.1100	Acute oral -Rat	46219019	LD_{50} = > 5000 mg/kg/bw (both sexes)	IV
870.1200	Acute dermal-Rat	46219020	LD_{50} = > 5000	IV

			mg/kg/bw (both sexes)	
870.1300	Acute inhalation-Rat	46219021	LC_{50} = > 2.19mg/L (both sexes)	IV
870.2400	Acute eye irritation-Rat	46219022	Conjunctivitis, moderate irritant	III
870.2500	Acute dermal irritation-Rabbit	46260101	Non-irritant	IV
870.2600	Skin sensitization-Guinea Pig	46219024	Not a sensitizer	N/A

2.3 FQPA Considerations

The toxicology database for orthosulfamuron is adequate to characterize potential pre- and/or post-natal risk for infants and children. Acceptable/guideline studies for developmental toxicity in rats and rabbits and a 2-generation reproduction study in rats were available for consideration during endpoint selection.

HED recommends the FQPA SF be reduced to 1X because there are no/low concerns and no residual uncertainties with regard to pre- and/or postnatal toxicity. After evaluating the toxicological and exposure data, the orthosulfamuron risk assessment team recommends that the FQPA SF be reduced to 1x based on the following:

- The toxicity data showed no increase in susceptibility in fetuses and pups with *in utero* and post-natal exposure.
- The dietary food exposure assessment is based on HED-recommended tolerance- level residues and assumes 100% crop treated for all commodities, which results in very high-end estimates of dietary exposure.
- The dietary drinking water assessment is based on values generated by model and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations.
- Levels of exposure to orthosulfamuron are expected to be low.

2.4 Hazard Identification and Toxicity Endpoint Selection

Incidental Oral Exposure

There are no residential uses proposed; therefore, a risk assessment is not required.

Dermal Absorption

A 28-Day dermal toxicity study in rats was submitted for orthosulfamuron. There were no adverse treatment-related systemic or dermal effects observed at the limit dose of 1000 mg/kg/day.

Occupational Dermal Exposure (Short- and intermediate-Term)

The risk assessment is not required.

Comments about Study/Endpoint/Uncertainty Factors:

Although there were decreases in motor activity observed in a 2-generation study, these effects are considered isolated findings and are attributed to the systemic (kidney alterations) toxicity observed, rather than frank neurotoxicity (see section 3.3.2). Therefore, the 2-generation study was not selected for a dermal endpoint.

Occupational Inhalation Exposure (Short-, and Intermediate- Term)

Study Selected: 2-Generation Reproduction-Rat
MRID No: 46219033
Dose and Endpoint for Risk Assessment: NOAEL= 88.6 mg/kg/day
Uncertainty Factor: 100x (10x interspecies extrapolation, 10x intraspecies variability)

Comments about Study/Endpoint/Uncertainty Factors:

A 2-generation reproduction study in rats was used to select the dose and endpoint for short-term inhalation exposure. The NOAEL of 88.6 mg/kg/day and the LOAEL of 354.5 mg/kg/day were based on kidney lesions in F0/F1 females. Uncertainty factors (100x) include: 10x interspecies extrapolation, and 10x intraspecies variability.

The doses and endpoints selected are summarized in Table 3.

Table 2: Summary of Levels of Concern for Risk Assessment.

Route	Short-Term (1 - 30 Days)	Intermediate-Term (1 - 6 Months)	Long-Term (> 6 Months)
Occupational (Worker) Exposure			
Dermal	N/A	N/A	N/A
Inhalation	100	N/A	N/A

Table 3: Summary of Toxicological Doses and Endpoints for Orthosulfamuron 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 (all exposures)	N/A	N/A	N/A	The risk assessment is not required.
Inhalation Short-(1-30 days)	NOAEL= 88.6 mg/kg/day	UF_A=10x UF_H=10x IAF=100%	Occupational LOC for MOE = 100	2-Generation Reproduction -Rat LOAEL (mg/kg/day): 354.5, based on kidney lesions in F_0 and F_1 females.
Cancer (oral, dermal, inhalation)	Classification: "Suggestive Evidence of Carcinogenicity" Quantification is not required and the cRfD is considered protective of the cancer effects.			

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). MOE = margin of exposure. LOC = level of concern. IAF= inhalation absorption factor.

2.5 Classification of Carcinogenic Potential

In accordance with *EPA's Final Guidelines for Carcinogen Risk Assessment* (March, 2005), the Cancer Assessment Review Committee (CARC) classified orthosulfamuron as demonstrating "Suggestive Evidence of Carcinogenicity," based on thyroid follicular cell adenomas observed in male rats. The Agency has determined that quantification of human cancer risk is not required, and that the NOAEL selected for the cRfD is protective of the cancer effects.

3.0 End-Use Products/Patterns

Orthosulfamuron(1-(4,6-dimethoxypyrimidin-3[2-dimethylcarbamoyl) phenylsulfamoyl] urea) is a systemic herbicide belonging to the sulfamoylurea class of chemicals. The proposed use is for control of broadleaf weeds and sedges in rice. The mode of action for orthosulfamuron is through inhibition of the plant enzyme acetolactate synthase, which is also known as acetohydroxy acid synthase. Inhibition of this enzyme blocks branch-chain amino acid biosynthesis of valine, leucine, and isoleucine involved in plant growth processes leading to death of the plant.

Table 4 summarizes the proposed use pattern and formulation specified in the two end-use products containing orthosulfamuron.

Table 4: Summary of Directions for Use of Orthosulfamuron

Applic. Timing, Type, and Equip.	Formulation	Applic. Rate (lb ai/A)	Max. No. Applic. per Season	Max. Seasonal Applic. Rate (lb ai/A)	REI	Use Directions and Limitations
Rice						
Ground and Aerial Spray	IR5878 50 WG Herbicide water-dispersible granule (51.5 % ai) EPA Reg. #80289	0.055 - 0.069 lbs ai/A	1 app/season	0.069 lbs ai/A	12 hrs	Apply to young emerging and actively growing weeds, between 2-4 leaves. Lowest application rate is intended for use with other compounds.
Ground and Aerial Spray	IR5878 0.5 GR Herbicide granular (0.51 % ai) EPA Reg. #80289	0.066 lbs ai/A	1 app/season	0.066 lbs ai/A	12 hrs	Do not apply more than one application per year. Apply to young emerging weeds, between 1-2 leaves. Apply to control weeds in permanently flooded rice only.

4.0 Residential (Non-Occupational) Exposure/Risk Characterization

As orthosulfamuron is a new active ingredient, there are no registered residential uses associated with it. Therefore, a quantitative non-occupational exposure assessment was not performed.

Spray drift is a potential source of exposure to residents living in close proximity to spraying operations. This situation is particularly the case with aerial application. However, to a lesser extent, spray drift resulting from the ground application of orthosulfamuron could also be a potential source of exposure. The Agency has been working with the Spray Drift Task Force (a membership of U.S. pesticide registrants), EPA Regional Offices, State Lead Agencies for pesticide regulation, and other parties to develop the best spray drift management practices. 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, and is developing a policy on how to apply appropriately 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 and risks associated with pesticide application.

5.0 Occupational Exposure/Risk Pathway

5.1 Short-Term Handler Risk

The following agricultural products have been assessed for occupational exposure: IR5878 50 WG and IR5878 0.5 GR.

IR5878 50 WG contains 51.5% orthosulfamuron in a water-dispersible granular formulation for use as an agricultural herbicide on wet-seeded or dry-seeded rice. The proposed application rate is 0.055 - 0.069 lbs ai/A applied by groundboom and aerial equipment. IR5878 50 WG Herbicide will be applied 1 time per year early in the growing season (2-4 leaves), at a maximum application rate of 0.069 lbs ai/A/season. Based on the number of seasonal applications indicated on these product labels, and information provided by the registrant, handler exposures are expected to be short-term in duration.

IR5878 0.5 GR contains 0.51% orthosulfamuron in a granular formulation for use as an agricultural herbicide on permanently flooded rice. The proposed application rate is 0.066 lbs ai/A applied by ground (tractor drawn spreader) and aerial equipment. IR5878 0.5 GR Herbicide will be applied 1 time per year early in the growing season (1-2 leaves), at a maximum application rate of 0.066 lbs ai/A/season. Based on the number of seasonal applications indicated on these product labels, and information provided by the registrant, handler exposures are expected to be short-term in duration.

A quantitative risk assessment for the dermal exposure route is not required. There were no adverse systemic or dermal effects seen up to the limit dose tested (1,000 mg/kg/day) in the dermal toxicity study. Based on the information provided by the registrant, handler inhalation exposures are expected to be short-term in duration. The following exposure scenarios have been assessed:

- Loading Granular Formulation for Tractor Drawn Spreader
- Loading Granular Formulation for Aerial Fixed Wing
- Mixing/Loading Dry Flowable (Water-Dispersible Granule) Formulation for Groundboom
- Mixing/Loading Dry Flowable (Water-Dispersible Granule) Formulation for Aerial Fixed Wing
- Applying Sprays using Groundboom
- Applying Sprays using Aerial Fixed Wing
- Applying Granules using Aerial Fixed Wing
- Applying Granules with Tractor Drawn Spreader
- Flagging Sprays
- Flagging Granules

5.1.1 Data and Assumptions for Handler Exposure Scenarios

The following assumptions, parameters and factors were used in this exposure and risk assessment:

Non-cancer application rates were based on the maximum rates on the proposed labels.

Unit Exposures:

- Chemical-specific data for assessing exposure during pesticide handling activities were not submitted to the Agency in support of this Section 3 application. 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 7, January 1999).

- Occupational handler exposure assessments were completed by HED using baseline level of Personal Protective Equipment (PPE). The baseline clothing level for occupational exposure scenarios is generally an individual wearing long pants, a long-sleeved shirt, no chemical-resistant gloves, and no respirator.

- An inhalation absorption factor of 100% was used to calculate non-cancer risks.

- Based on the proposed label, no mixing methods are necessary for the proposed end-use product IR5878 0.5 GR. This herbicide product is to be applied as a direct application without dilution in water. Therefore, a mixing exposure assessment was not performed for this particular end-use product.

Area Treated:

Based on the Science Advisory Council for Exposure Policy 9.1: Standard Values for Daily Acres Treated in Agriculture, the following ***acres per day treated*** were assumed:

- 1200 acres/day for mixing/loading and applying dry flowable (water-dispersible granule) to rice using aerial equipment
- 200 acres/day for mixing/loading and applying dry flowable (water-dispersible granule) to rice using groundboom
- 1200 acres/day for loading and applying granular to rice using aerial equipment
- 200 acres/day for loading and applying granular to rice using tractor drawn spreader
- 350 acres/day for flagging liquids to rice using aerial equipment
- 350 acres/day for flagging granules to rice using aerial equipment

Body Weight:

- An average adult body weight of 70 kg was used for short-term exposure assessments, since the inhalation endpoint was based on effects that were not sex-specific.

Equations/Calculations:

The following equations were used to calculate handler exposure and risk:

$$\textit{Inhalation Dose (mg/kg/day)} = \frac{\textit{Rate (lb ai/A) x UE (mg /lb ai) x Acres Treated (A/day)}}{\textit{BW (kg)}}$$

Where:

Rate (Application Rate)	= Maximum application rate on product label (lb ai/A)
UE (Unit Exposure)	= Exposure value derived from August 1998 PHED Surrogate Exposure Table
Acres Treated	= Maximum number of acres treated per day (A/day) derived from information provided by the registrant
BW	= Body weight (70 kg)

MOE = Short-term NOAEL (88.6 mg/kg/day)/Inhalation Dose (mg/kg/day)

5.1.2 Exposure and Risk

A dermal exposure assessment is not required since there were no systemic or dermal effects seen in the dermal toxicity study. Summaries of the non-cancer (MOEs) short-term risks for handlers at the baseline are included in Table 5. The inhalation MOEs for short-term handler exposure range from 47,000 to 1,800,000 and the estimated risks do not exceed HED's level of concern (MOEs <100)

The handler exposure estimates in this assessment are based on a central tendency estimate of unit exposure and an upper-percentile assumption for the application rate, and are assumed to be representative of high-end exposures. The uncertainties associated with this assessment stem from the use of surrogate exposure data (e.g., differences in use scenario and data confidence) and assumptions regarding the amount of chemical handled. The estimated exposures are believed to be reasonable high-end estimates based on observations from field studies and professional judgment.

Table 5: Short-term Handler Exposure and Risk for Orthosulfamuron

Exposure Scenario	Mitigation Level	Inhalation Unit Exposure (mg/lb ai)	Application Rate (lb ai/A)	Amount Treated	Inhalation Dose [a] (mg/kg/day)	Total MOE [b]
Mixer/Loader & Loader						
Granular for Aerial Application (1) **(Loading only)**	Baseline	0.0017	0.066	1200 A/day	0.0019	47,000
Granular for Solid Broadcast Spreader		0.0017	0.066	200 A/day	0.00032	280,000

Table 5: Short-term Handler Exposure and Risk for Orthosulfamuron						
Exposure Scenario	**Mitigation Level**	**Inhalation Unit Exposure (mg/lb ai)**	**Application Rate (lb ai/A)**	**Amount Treated**	**Inhalation Dose [a] (mg/kg/day)**	**Total MOE [b]**
Application (2) **(Loading only)**						
Dry Flowable (WG) for Aerial Application (3)		0.00077	0.055	1200 A/day	0.000726	120,000
			0.069		0.000911	97,000
Dry Flowable for Groundboom Application (4)		0.00077	0.055	200 A/day	0.000121	730,000
			0.069		0.000152	580,000
Applicator						
Sprays for Aerial Application (5)	Baseline	0.000068	0.055	1200 A/day	0.000064	1,400,000
			0.069		0.000080	1,100,000
Aerial Application (granular formulation) (6)		0.0013	0.066	1200 A/day	0.001471	60,000
Sprays for Groundboom Application (7)		0.00074	0.055	200 A/day	0.000116	760,000
			0.069		0.000146	610,000
Solid Broadcast Spreader Application (8)		0.0012	0.066	200 A/day	0.000226	390,000
Flagger						
Liquid for Aerial Application (Liquid Formulation) (9)	Baseline	0.00035	0.055	350 A/day	0.000096	920,000
			0.069		0.00012	740,000
Aerial Application (Granular Formulation) (10)		0.00015	0.066	350 A/day	0.000050	1,800,000

a. Short-term Inhalation Dose (mg/kg/day) = [Rate (lb ai/A) x UE (mg /lb ai) x Acres Treated (A/day)]/BW (70 kg)
b. MOE = Short-term NOAEL (88.6 mg/kg/day)/ Inhalation Dose (mg/kg/day)

5.2 Short-Term Postapplication Risk

No postapplication chemical-specific data were submitted in support of this registration action.

A dermal non-cancer agricultural short-term postapplication exposure assessment is not required due to the absence of systemic and dermal toxicity in the dermal toxicity study.

Orthosulfamuron has a medium vapor pressure of 1.1×10^{-4} mmHg at 20°C. Short-term postapplication inhalation exposures are expected to be minimal and less than the application exposures. Therefore, a quantitative postapplication inhalation exposure assessment was not performed.

Restricted Entry Interval

The restricted entry interval (REI) is based on the acute toxicity of orthosulfamuron technical material which is classified as Category III for eye irritation and Category IV for acute oral, acute dermal, and acute inhalation. Acute toxicity Category III and IV chemicals for these potential hazards require a 12 hour REI. The interim12-hour REI which appears on the IR5878 50 WG and IR5878 GR herbicides labels is appropriate under the requirements of the Worker Protection Standard (WPS).

6.0 References

Orthosulfamuron. Petition for the Establishment of Tolerances on the Raw Agricultural Commodities of Rice. Summary of Analytical Chemistry and Residue Data. PP#5F6957. D. Dotson, D332290.

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Orthosulfamuron. Evaluation of the Carcinogenic Potential of Orthosulfamuron. J. Kidwell. TXR 0054463. 9/20/06

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R142114

Chemical: Orthosulfamuron

PC Code:
108209

HED File Code: 11000 Chemistry Reviews
Memo Date: 1/10/2007
File ID: DPD333763
Accession #: 000-00-0119

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