

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

PESTICIDE FACT SHEET

Name of Chemical: Imazosulfuron

Reason for Issuance: Conditional Registration

Date Issued: December 14, 2010

I. DESCRIPTION OF CHEMICAL

Chemical Name: Imazosulfuron (2-chloro-*N*-[[4,6-dimethoxy-2-pyrimidinyl)-amino]carbonyl]imidazo[1,2-*a*]pyridine-3-sulfonamide)

Common Name: Imazosulfuron

EPA PC Code: 118602

Chemical Abstracts Service (CAS) Number: 122548-33-8

Year of Initial Registration: 2010

Pesticide Type: Herbicide

Chemical Class: Sulfonylurea

Mode of Action: Imazosulfuron is a systemic sulfonylurea (SU) herbicide that is absorbed both by roots and foliage and is translocated in the xylem and phloem. The mode of action is through the inhibition of the enzyme acetolactate synthase (ALS) leading to the blocking of the synthesis of the branch-chain amino acids such as valine, leucine, and isoleucine that are essential in the formation of new cells.

Registrant: Valent USA Corporation

II. USE PATTERNS AND FORMULATIONS

Application Sites: Imazosulfuron is a selective herbicide providing both pre- and post-emergence control of sedges and broadleaf weeds. Imazosulfuron is registered for application to residential and commercial turfgrass, rice, tomatoes, and peppers.

Types of Formulations: Imazosulfuron is registered as EPA Reg. 59639-RLU (154) Imazosulfuron Technical, EPA Reg. 59639-RAA (166) V-10142 Ag. Herbicide, and 59639-RLL (155) V-10142 Herbicide.

Application Methods and Rates: Imazosulfuron may be applied through a variety of application methods including aerial application and broadcast equipment. The maximum application rate for the food uses is 0.3 lb ai per acre with a single (ground only) application to tomato and pepper and two applications (ground or aerial), 21 days apart, in rice. The maximum application rate for turf grass is 0.67 lb ai per acre with a maximum of two applications (ground only), 21 days apart, per year.

Physical and Chemical Properties						
Parameter		Value			MRID #	
Molecular Weight	412.81				47305101	
Melting point/range	198.0 °C	198.0 °C				
рН	4.61 at 25 °C (1%	4.61 at 25 °C (1% suspension in water)				
Density	1.652 at 20 °C				47305105	
Water solubility (20°C)	429 mg/L at pH 7	3936 mg/l	L at pH 9		47305115	
Solvent solubility (20°C to 25°C)	174.6 mg/L in <i>n</i> -o 597.2 mg/L in tolu 4478.5 mg/L in ac 144.8 mg/L in met 12,744.7 mg/L in o	0.820 mg/L in hexane 174.6 mg/L in <i>n</i> -octanol 597.2 mg/L in toluene 4478.5 mg/L in acetone 144.8 mg/L in methanol 12,744.7 mg/L in dichloromethane 2,220.3 mg/L in ethyl acetate				
Vapor pressure (25°C)	below LOD (<3.5	x 10 ⁻⁶ Pa)			47305116	
Dissociation constant, pKa	3.94 in methanol/(0.30 in methanol/I			at 252 nm	47305113	
Octanol/water partition coefficient, log K _{OW} (25°C)	-0.07 at <i>n</i> -octanol/	2.43 at <i>n</i> -octanol/pH 4 buffer -0.07 at <i>n</i> -octanol/pH 7 buffer -1.56 at <i>n</i> -octanol/pH 9 buffer				
UV/visible absorption spectrum		.5 () .0 1 3.0 () 2.0 () 0.5 1 4.0 ()	<u>A</u>).8877 .1653).8293).8278 .1497).7607).8500	$ \underbrace{\frac{\varepsilon, x10^4}{3.55}}_{4.66} 3.32 \\ 3.31 \\ 4.60 \\ 3.04 \\ 3.40 $	47305111	

III. PHYSICAL AND CHEMICAL PROPERTIES

IV. HUMAN HEALTH RISK

A summary of the human health effects and risk of imazosulfuron as assessed in the Agency document entitled, "Human Health Risk Assessment for Proposed Uses on Rice, Peppers, and Tomatoes", is provided below.

A. Summary of Toxicological Effects

The toxicity data for imazosulfuron suggest that this herbicide possesses relatively low toxicity. Many of the effects of single or repeated dosing were observed near or beyond the respective limit doses.

Acute Toxicity Profile - Imazosulfuron						
Guideline No.	Study Type	MRID(s)	Results	Toxicity Category		
870.1100	Acute oral – rat	47305221	$LD_{50} > 5000 \text{ mg/kg}$	IV		
870.1200	Acute dermal – rat	47305227	$LD_{50} > 2000 \text{ mg/kg}$	III		
870.1300	Acute inhalation – rat	47305228	$LC_{50} > 2.12 \text{ mg/L}$	IV		
870.2400	Acute eye irritation - rabbit	47305229	Non-irritating	IV		
870.2500	Acute dermal irritation - rabbit	47305230	Non-irritating	IV		
870.2600	Skin sensitization – guinea pig	47305231	Negative	N/A		

Imazosulfuron is of low acute toxicity (Toxicity Category III/IV) by the oral, dermal and inhalation routes of exposure; it is not a skin or eye irritant or a dermal sensitizer.

The primary target organ of imazosulfuron in repeated-dose studies was the liver in all species tested. Mild to moderate thyroid effects were apparent only in the chronic toxicity study in dogs. Dramatic eye effects (retinal degeneration, lens vascularization, cataracts and corneal scarring) were observed in rats fed > 1000 mg/kg/day beginning at 3 months in the chronic toxicity/carcinogenicity study. Ocular effects (increased incidence of eye opacity, corneal edema, inflammation and neovascularization) were also observed in the high-dose males (4577 mg/kg/day) in the 90-day feeding toxicity study in rats. Decreased body weight and body weight gain compared to control were frequent findings throughout the toxicology database for imazosulfuron.

Clinical signs (decreased motor activity, abnormal gait, upward curvature of the spine and piloerection) were observed in males at the limit dose of the acute neurotoxicity study; however, these effects can be attributed to generalized toxicity and were resolved by Day 2 of the study. No neurotoxic effects were observed during the subchronic screening battery or noted as clinical signs in any other repeated-dose study.

No developmental effects were observed at the highest dose tested (125 mg/kg/day) in the rabbit developmental toxicity study. No developmental or reproductive toxicity was observed in the developmental (one-generation) rat study. Decreased pup viability was observed in the rat two-generation reproduction study at a dose approaching the limit dose (LOAEL = 892 mg/kg/day) in both the F1 and F2 offspring generations. Mortality was also observed in the parental generation at this dose. No increased qualitative or quantitative offspring susceptibility was apparent in any of the submitted studies for imazosulfuron.

There was no evidence of carcinogenicity in rats and mice up to the limit dose at 24 and 18 months, respectively. Imazosulfuron was determined to be non-mutagenic in bacteria and negative in an *in vivo* mammalian cytogenetics assay. Overall, there was no evidence that imazosulfuron was either mutagenic or clastogenic in either *in vivo* or *in vitro* assays. The cancer classification is "not likely to be carcinogenic to humans," based on the absence of significant tumor increases.

A summary of the Toxicity profile for imazosulfuron is provided in the table at the start of the next page:

Toxicity P	rofile of Imazosulf	uron	
Guideline No.	Study Type	MRID No. (year)/ Classification /Doses	Results
870.3100	90-Day oral toxicity (rat)	47305232 (1991); 0, 2500, 10000, 45000 ppm; M: 0, 234.7, 956.3, 4577.2 mg/kg/day; F: 0, 265.7, 1081.4, 5135.7 mg/kg/day Acceptable/Guideline	NOAEL = 235/266 mg/kg/day in males/females; LOAEL = 956/1081 in males/females based on reduced mean body weights, body weight gains and food efficiency.
870.3100	90-Day oral toxicity (mouse)	47305233 (1991); 0, 2500, 10000, 45000 ppm; M: 0, 456, 1820, 9776 mg/kg/day; F: 0, 692, 2727, 12695 mg/kg/day Acceptable/Guideline	NOAEL = 1820/2727 mg/kg/day in males/females; LOAEL = 9776/12695 mg/kg/day in males/females based on central lobular hepatocyte hypertrophy and increased liver weights.
870.3150	90-Day oral toxicity (dog)	See 47305235; Justification to Bridge Data from a 1-year Chronic Study in Dogs	See 47305305
870.3200	21/28-Day dermal toxicity (rat)	47305236 (2006); 0, 100, 300, 1000 mg/kg/day Acceptable/Guideline	NOAEL = 1000 mg/kg/day in males and females.
870.3700a	Prenatal developmental (rat)	47305238 (1989); 0, 250, 500, 1000 mg/kg/day. Since no maternal toxicity was observed in the original treatment groups, an additional treatment group of 1500 mg/kg/day was added to the study.	Maternal NOAEL = 1000 mg/kg/day (limit); LOAEL = 1500 mg/kg/day based on decreased body weight gain and food consumption. Developmental NOAEL = 1500 mg/kg/day; > limit dose; LOAEL > 1500 mg/kg/day
870.3700b	Prenatal developmental (rabbit)	Acceptable/Guideline 47305301 (1990); 0, 25, 50, 125 mg/kg/day Acceptable/Non- Guideline*	Maternal NOAEL = 125 mg/kg/day; LOAEL > 125 mg/kg/day Developmental NOAEL = 125 mg/kg/day; LOAEL > 125 mg/kg/day
		*tested under FIFRA Subdivision F guidelines	

Guideline	Study Type	MRID No. (year)/	Results
No.	and the	Classification /Doses	
870.3800	Reproduction and fertility effects (rat)	47305304 (1990); 0, 100, 1,000, 10,000 ppm; M_{F0} : 0, 7.7, 77.8, 777.4 mg/kg/day; F_{F0} : 0, 8.93, 88.4, 868.5 mg/kg/day; M_{F1} : 0, 9.0, 89.4, 1006.5 mg/kg/day; F_{F1} : 0, 9.6, 96.9, 1097.0 mg/kg/day Acceptable/Guideline	Parental/Systemic NOAEL = (1000 ppm) 83.6/92.7 mg/kg/day in males/females (average of both generations); LOAEL = (10,000 ppm) 892/982.7 mg/kg/day in males/females (average of both generations) based on mortality, clinical signs, decreased body weights, body weight gains, and food consumption. Reproductive NOAEL = (10,000 ppm) 892/982.7 mg/kg/day in males/females (average of both generations); LOAEL > 892/982.7 mg/kg/day in males/females (not observed). Offspring NOAEL = (1000 ppm) 83.6/92.7 mg/kg/day in males/females (average of both generations); LOAEL = (10,000 ppm) 892/982.7 mg/kg/day in males/females (average of both generations)
			based on decreased pup viability and body weights.
870.4100b	Chronic toxicity (dog)	47305305 (1990); 0, 75, 150, 300 mg/kg/day Acceptable/Guideline	NOAEL = 75 mg/kg/day LOAEL = 150 mg/kg/day based on moderate thyroid hypertrophy (males at mid- and high- dose; mild hypertrophy in females at high- dose).
870.4200b	Carcinogenicity (mouse)	47305307 (1991); 0, 450, 4500, 45000 ppm; M: 0, 72.7, 741.3, 7848.1 mg/kg/day; F: 86.8, 870.0, 10303.5 mg/kg/day Acceptable/Guideline	NOAEL = 73/87 mg/kg/day in males/females. LOAEL = 741/870 mg/kg/day in males/females based on centrilobular swelling of hepatocytes. no evidence of carcinogenicity
870.4300	Chronic toxicity/Carcinogen icity (rat)	47305306 (1991); 0, 200, 2000, 20000 ppm; M: 0, 10.39, 106.10, 1123.99 mg/kg/day; F: 0, 12.94, 132.46, 1554.35 mg/kg/day. Acceptable/Guideline	NOAEL = 106/132 mg/kg/day in males/females; LOAEL = 1124/1554 mg/kg/day in males/females based on increased mortality, decreased body weight, decreased body weight gain, clinical ophthalmic observations (cataracts and retinal degeneration) and hepatotoxicity in females. no evidence of carcinogenicity
870.5100	Bacterial reverse mutation test	47305308 (1988) Acceptable/Guideline	TH-913 Technical: Test article has no reverse mutagenic potential under these experimental conditions
870.5100	Bacterial reverse mutation test	47305309 (1990) Acceptable/Guideline	UDPM: Test article has no reverse mutagenic potential under these experimental conditions

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Guideline No.	Study Type	MRID No. (year)/ Classification /Doses	Results
870.5100	Bacterial reverse mutation test	47305310 (1993) Acceptable/Guideline	IHOA: Test article has no reverse mutagenic potential under these experimental conditions
870.5100 870.5500	Bacterial reverse mutation test; DNA repair test	47305311 (1989) Acceptable/Guideline	M-1: Test article has no reverse mutagenic potential under these experimental conditions; negative with or without S9 metabolic activation
870.5100	Bacterial reverse mutation test	47305312 (1988) Acceptable/Guideline	IPSN: Test article has no reverse mutagenic potential under these experimental conditions
870.5100	Bacterial reverse mutation test	47305313 (1990) Acceptable/Guideline	ADPM: Test article has no reverse mutagenic potential under these experimental conditions
870.5300	<i>In vitro</i> mammalian cell gene mutation test	47305314 (1999) Acceptable/Guideline	Test article is not mutagenic in test system
870.5375	<i>In vitro</i> mammalian cell chromosome aberration test	47305315 (1988) Acceptable/Guideline	Test article "was considered to induce no chromosomal aberration because the test substance showed a suspect positive by the direct method but the same results were not reproduced." Test article did not induce chromosomal aberrations at any concentration in presence of S9.
870.5395	Mammalian erythrocyte micronucleus test	47305316 (2007) Acceptable/Guideline	Test article has no potential to induce micronuclei in mouse bone marrow cells under the conditions of this test
870.6200a	Acute neurotoxicity screening battery	47305319 (2007); 0, 80, 400, 2000 mg/kg Acceptable/Guideline	NOAEL = 400 mg/kg/day; LOAEL = 2000 mg/kg/day in males and females based on the following clinical signs: abnormal gait, decreased activity, piloerection and upward curvature of the spine and decreased motor activity in males.
870.6200b	Subchronic neurotoxicity screening battery	47305320 (2007); 0, 800, 2500, 8000 ppm; M: 0, 54.0, 169.2, 571.3 mg/kg/day; F: 0, 61.9, 200.8, 655.3 mg/kg/day Acceptable/Guideline	Systemic NOAEL = 169/201mg/kg/day in males/females; LOAEL = 571/655 mg/kg/day in males/females based on decreased body weight, body weight gain and food efficiency. Neurotoxicity NOAEL = 571/655 mg/kg/day in males/ females (HDT) LOAEL > 571.7 mg/kg/day for males and > 655.3 mg/kg/day for females

Toxicity Pr	Toxicity Profile of Imazosulfuron						
Guideline No.	Study Type	MRID No. (year)/ Classification /Doses	Results				
870.7485	Metabolism and pharmacokinetics (rat)	47305322 (2007) Acceptable/Guideline	Parent and 5 metabolites were identified and quantified. Parent was detected only in feces and amounted to 0.9% of the administered dose (AD). HMS, the predominant metabolite, was found in the urine at 6, 12 and 24 hours amounting to 31.1, 18.4 and 6.2 % of the dose, respectively, and in lesser amounts, in the feces (6.5). The lesser metabolites (< 5% AD), IHDU, HDS, IPSN and ACIS were identified in urine and feces.				
870.7485	Metabolism and pharmacokinetics (rat)	47305323 (2007) Acceptable/Guideline	The absorption rate was estimated to be ~100%. Near complete elimination (66.4% urine, 34.0% bile, 2.4% feces) within 24 hours after administration of radiolabeled compound was observed.				

B. Toxicological End Points and Doses Used in the Human Health Risk Assessment

<u>1. Acute Dietary:</u> For acute dietary exposure, an acute reference dose (aRfD)/acute population adjusted dose (aPAD) of 4 mg/kg/day was selected for assessment of all populations based on a NOAEL of 400 mg/kg/day in the rat acute neurotoxicity study. The LOAEL of 2000 mg/kg/day was based on decreased motor activity, piloerection and upward curvature of the spine observed in both sexes and decreased motor activity observed in males only. This is a conservative endpoint since effects were seen only at the limit dose and there is a substantial dose spread between the NOAEL and LOAEL.

<u>2. Chronic Dietary:</u> For chronic dietary exposure, a chronic reference dose (cRfD)/chronic population adjusted dose (cPAD) of 0.75 mg/kg/day was selected for assessment of all populations, based on a NOAEL of 75 mg/kg/day with moderate thyroid hypertrophy observed in the chronic dietary study in dogs. This study provides the most sensitive endpoints (NOAEL and LOAEL); the mouse carcinogenicity study yielded an equivalent NOAEL but with a larger dose spread. The selected NOAEL is protective of liver effects.

3. Short-term (1-30 days) and Intermediate-term (1-6 months) Incidental Oral and Inhalation: For short- and intermediate-term residential and occupational exposures involving incidental oral and inhalation exposure, the NOAEL of 235 mg/kg/day was selected from the rat subchronic toxicity study. This study was co-critical with the 2-generation reproductive toxicity study in rats and provided the best estimate of the NOAEL. Similar effects on body weight were seen at the LOAEL of 892 mg/kg/day in the 2-generation reproductive toxicity study. Combined, both studies are appropriate for the duration of exposure and populations exposed.

<u>4. Short-term (1-30 days) and Intermediate-term (1-6 months) Dermal:</u> No dermal hazard was identified in the 21-day dermal toxicity study in rats wherein hepatotoxicity and neurotoxicity were assessed. Therefore no dermal endpoint was selected for quantitative risk assessment for imazosulfuron.

<u>5. Long-term (>6 months) Dermal and Inhalation</u>: Neither dermal nor inhalation long-term exposure is expected; therefore, no endpoints were selected.

<u>6. Cancer:</u> Imazosulfuron is classified as "not likely to be carcinogenic to humans," based on the lack of evidence of carcinogenicity in acceptable carcinogenicity studies in the rat and mouse.

A summary of the toxicological endpoints are shown in the table below:

Summary of Toxico Assessments	Summary of Toxicological Doses and Endpoints for Imazosulfuron for Use in Dietary and Non-Occupational Human Health Risk Assessments				
Exposure/ Scenario	Point of Departure	Uncertainty/ Safety Factors	RfD, Level of Concern for Risk Assessment	Study and Toxicological Effects	
Acute Dietary (General Population, including Infants and Children)	NOAEL= 400 mg/kg/day	$UF_A = 10X$ $UF_H = 10X$ FQPA SF = 1X	Acute RfD = 4 mg/kg/day aPAD = 4 mg/kg/day	Acute neurotoxicity screening battery (rat; MRID 47305319). LOAEL = 2000 mg/kg/day based on the following clinical signs: abnormal gait, decreased activity, piloerection and upward curvature of the spine; and incidents of irregular breathing, reduced righting reflex, tremors, decreased visual placement response in males and increased response to sound in one female.	
Acute Dietary (Females 13-49 years of age)			eproductive animal s	3-49 because there was no prenatal or fetal tudies following a single oral dose.	
Chronic Dietary (All Populations)	NOAEL= 75 mg/kg/day	$UF_{A} = 10X$ $UF_{H} = 10X$ $FQPA SF = 1X$	Chronic RfD = 0.75 mg/kg/day cPAD =0.75 mg/kg/day	Chronic toxicity (dog; MRID 47305305) LOAEL = 150 mg/kg/day based on moderate thyroid hypertrophy (males at mid- and high- dose; mild hypertrophy in females at high-dose).	
Incidental Oral Short-Term (1-30 days) and Intermediate- Term (1-6 months)	NOAEL= 235 mg/kg/day (MRID 47305232)	$UF_A = 10X$ $UF_H = 10X$ FQPA SF = 1X	Residential LOC for MOE = 100	Reproduction, 2 generation (rat; MRID 47305304) and 90-day oral toxicity (rat; 47305232). LOAEL = 892 mg/kg/day based on mortality, clinical signs, decreased body weights, body weight gains and food consumption in parents (MRID 47305304). LOAEL = 956 mg/kg/day based on decreased body weight gains and food efficiency (MRID 47305232).	
Dermal Short- Term (1-30 days) and Intermediate- Term (1-6 months)	No systemic toxicity occurred at the limit dose and the primary toxic effects of concern (liver, eye) were adequately assessed in a 21 day dermal toxicity study (MPID 47305236). It is concluded that this compound				
Inhalation Short- Term (1-30 days) and Intermediate- Term (1-6 months)	NOAEL= 235 mg/kg/day (MRID 47305232; inhalation toxicity equivalent to oral toxicity)	$UF_{A} = 10X$ $UF_{H} = 10X$ $FQPA SF = 1X$	Residential LOC for MOE = 100	Reproduction, 2 generation (rat; MRID 47305304) and 90-day oral toxicity (rat; 47305232). LOAEL = 892 mg/kg/day based on mortality, clinical signs, decreased body weights, body weight gains and food consumption in parents (MRID 47305304). LOAEL = 956 mg/kg/day based on decreased body weight gains and food efficiency (MRID 47305232).	

Summary of Toxicological Doses and Endpoints for Imazosulfuron for Use in Dietary and Non-Occupational Human Health Risk Assessments

Exposure/ Scenario	Point of Departure	Uncertainty/ Safety Factors	RfD, Level of Concern for Risk Assessment	Study and Toxicological Effects	
Cancer (oral, dermal, inhalation)	Classification: "Not likely to be Carcinogenic to Humans" based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies (MRID 47305307, mouse; 47305306, rat).				

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. 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.

Summary of Toxicological Doses and Endpoints for Imazosulfuron 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 Short- Term (1-30 days) and Intermediate- Term (1-6 months)	No systemic toxicity occurred at the limit dose and the primary toxic effects of concern (liver, eye) were adequately assessed in a 21-day dermal toxicity study (MRID 47305236). It is concluded that this compound is not or poorly absorbed through the skin and, therefore, a quantitative risk assessment for this route and duration is not necessary.					
Inhalation Short- Term (1-30 days) and Intermediate- Term (1-6 months)	NOAEL= 235 mg/kg/day (MRID 47305232; inhalation toxicity equivalent to oral toxicity)	UF _A =10X UF _H =10X	Occupational LOC for MOE = 100	Reproduction, 2 generation (rat; MRID 47305304) and 90-day oral toxicity (rat; 47305232). LOAEL = 892 mg/kg/day based on mortality, clinical signs, decreased body weights, body weight gains and food consumption in parents (MRID 47305304). LOAEL = 956 mg/kg/day based on decreased body weight gains and food efficiency (MRID 47305232).		
Cancer (oral, dermal, inhalation)Classification: "Not likely to be Carcinogenic to Humans" based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies (MRID 47305307, mouse; 47305306, rat).						

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. 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.

C. FQPA Safety Factor

EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1x. That decision is based on the following findings:

1. The toxicology database for imazosulfuron is largely complete, lacking only an immunotoxicity study. EPA has evaluated the available toxicity data for imazosulfuron and determined that an additional database uncertainty factor is not needed to account for potential immunotoxicity. The most sensitive endpoint in the database is moderate thyroid hypertrophy. Liver toxicity accompanied by body weight and food consumption effects is seen throughout the toxicology database. No treatment-related changes indicative of potential immunotoxicity were seen in hematology parameters, organ weights (thymus, spleen), gross

necropsy (enlarged lymph nodes) or histopathology (spleen, thymus, lymph nodes) when tested up to the limit dose in mice and rats. Therefore, EPA does not believe that conducting a special series 870.7800 immunotoxicity study will result in a NOAEL less than 75 mg/kg/day, which is presently used as the point of departure for chronic risk assessment.

2. No neurotoxic effects were observed during the subchronic screening battery or noted as clinical signs in any other repeated-dose study. Although untoward clinical signs were observed in the acute neurotoxicity study, these effects can be attributed to generalized toxicity and were resolved by Day 2 of the study. Based on these considerations, there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

3. There is no evidence that imazosulfuron results in increased susceptibility of offspring following pre- and postnatal exposure of rats or *in utero* exposure of rabbits. Neither the rat nor rabbit developmental studies identified developmental effects.

4. There are no significant residual uncertainties in the exposure databases. Data have been requested to confirm the stability of imazosulfuron during frozen storage and the metabolic profile of pyrimidine-labeled imazosulfuron in rice grain in the confined rotational crop trial. A field rotational crop study is also required for grain (wheat); however, as explained below, EPA does not expect these studies to have a measurable impact on exposure estimates for imazosulfuron.

a. Storage stability: The final reports of the storage stability studies must be submitted, reflecting frozen storage intervals of up to 11.8 months for peppers, up to 34.5 months for rice grain, and up to 17.3 months for tomatoes. Interim data suggest that imazosulfuron is stable in frozen storage, and similar sulfonylurea chemicals are known to be stable. Therefore, EPA expects imazosulfuron to be stable in frozen storage but is requiring the final study reports as confirmation.

b. Metabolic profile: The HPLC profile for the pyrimidinyl (Py)-label grain storage stability analysis must be submitted to confirm that the metabolite profile was stable in Py-label grain. Grain samples from the confined rotational crop study were stored for a relatively long interval (9 months) prior to completion of the analyses. Analysis of an imidozolyl (Im)-label sample after the 9 month period yielded a metabolic profile similar to that of a sample analyzed at the start of the period. A similar comparison must be made for the Py-label sample of grain. This is of no practical consequence for risk assessment because total residue levels on grain were small (<0.01 ppm at a 365-day plantback interval), imazosulfuron was not present, and no metabolites/degradates were considered toxicologically significant.

c. Field accumulation in rotational crops (grain): The grain (wheat) rotational crop study is needed to identify maximum levels of residues in grain and livestock feed items (forage, straw) as a function of the plantback interval. On an interim basis, a plantback interval of 12 months is being required for grains and soybeans. The results of the rotational crop study may allow a shorter plantback interval. The confined rotational crop study showed that imazosulfuron and metabolites will be negligible (<0.01 ppm) on forage, hay, straw, stover, and grain at a 365-day plantback interval and will, therefore, make no contribution to dietary exposure.

The dietary food exposure assessments were performed assuming tolerance-level residues and 100% crop treated for all commodities. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to imazosulfuron in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by imazosulfuron.

D. Cumulative Effects

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." EPA has not found imazosulfuron to share a common mechanism of toxicity with any other substances, and imazosulfuron does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that imazosulfuron does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <u>http://www.epa.gov/pesticides/cumulative</u>.

E. Aggregate Risk Assessment

1. Dietary (Food + Drinking Water) Risk:

Unrefined acute and chronic dietary risk analyses were conducted with 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.

Acute Dietary Risk: At the 95th percentile of exposure, all acute analyses yielded risk estimates well below the threshold level of concern (100% of the aPAD) for each population subgroup. The acute aggregate dietary exposure to imazosulfuron from food and drinking water will occupy <1% of the aPAD for the general U.S. population. For the subgroup with the highest estimated exposure (infants <1 year old), acute aggregate dietary risk will occupy 1.4% of the aPAD.

Chronic Dietary Risk: Estimated chronic dietary exposure to imazosulfuron from food and drinking water occupies 2.7% of the threshold level of concern (100% of the cPAD) for infants less than 1 year old, the population subgroup with the highest estimated chronic exposure.

Acute and Chronic Dietary Exposure and Risk Estimates for Imazosulfuron						
	DAD	DEEM-FCID TM	(food only)	DEEM-FCID [™] (food and water)		
Population Subgroup	PAD, mg/kg/day	Exposure, mg/kg/day	% PAD	Exposure, mg/kg/day	%PAD	
Acute Dietary Estimates (95 th Percentile of Exposure)						
U.S. Population		0.000333	<1	0.014919	<1	
All infants (< 1 yr)		0.000367	<1	0.056034	1.4	
Children 1-2 yrs		0.000896	<1	0.023470	<1	
Children 3-5 yrs		0.000739	<1	0.021335	<1	

Acute and Chronic Dietary Exposure and Risk Estimates for Imazosulfuron								
	DAD	DEEM-FCID TM	4 (food only)	DEEM-FCID [™] (food and water)				
Population Subgroup	PAD, mg/kg/day	Exposure, mg/kg/day	% PAD	Exposure, mg/kg/day	%PAD			
Children 6-12 yrs	4.0	0.000494	<1	0.014925	<1			
Youth 13-19 yrs		0.000313	<1	0.012125	<1			
Adults 20-49 yrs		0.000277	<1	0.013800	<1			
Adults 50+ yrs		0.000236	<1	0.012433	<1			
Females 13-49 yrs		0.000259	<1	0.013772	<1			
	Chronic Dietary Estimates							
U.S. Population		0.000084	<1	0.006043	<1			
All infants (< 1 yr)		0.000069	<1	0.019881	2.7			
Children 1-2 yrs		0.000200	<1	0.009043	1.2			
Children 3-5 yrs	0.75	0.000178	<1	0.008433	1.1			
Children 6-12 yrs	0.75	0.000121	<1	0.005811	<1			
Youth 13-19 yrs		0.000085	<1	0.004372	<1			
Adults 20-49 yrs]	0.000074	<1	0.005638	<1			
Adults 50+ yrs]	0.000056	<1	0.005918	<1			
Females 13-49 yrs		0.000069	<1	0.005605	<1			

2. Residential Risk:

There is a potential for exposure of homeowners applying products containing imazosulfuron on home lawns. There is also a potential for post-application exposure of adults and children entering turf areas that have been treated with imazosulfuron and for bystander exposure of adults and children in areas adjacent to pesticide applications.

For non-dietary exposures, the Agency uses the term Margin of Exposure (MOE) to refer to the risk associated with the exposure estimate. The MOE is defined as the ratio of the selected toxicological point of departure (POD), usually the No Observed Adverse Effects Level (NOAEL), to the estimated human exposure. An MOE of 100 means that the estimated level of human exposure is 100 times lower than the highest dose that produced no adverse effects in the relevant toxicology study. The greater the MOE, the lower the risk. For imazosulfuron, an MOE of 100 or greater indicates there are no risks of concern.

Residential handler exposure: Residential handlers may receive short-term dermal and inhalation exposure to imazosulfuron when mixing, loading and applying the pesticide on home lawns. Since a dermal endpoint of concern was not identified for imazosulfuron, only short-term inhalation exposures of residential handlers were assessed. MOEs for short-term inhalation exposure range from 2.6 million (broadcast applications) to 32 million (spot applications) and are, therefore, not of concern.

Handler Exposure and Risk Estimates for Residential Lawn Applicators						
Handler Scenario	Application Rate ¹ (lb a.i./A)	Area Treated ² (acres/day)	Inhalation Unit Exposure ³ (mg/lb ai)	Daily Dose ⁴ (mg/kg/day)	Short-Term MOE ⁵	
(1) Mix/load and spot application of liquid formulation (low-pressure hand sprayer)	0.75	0.023 (1,000 ft ²)	0.030	0.0000074	32,000,000	
(2) Mix/load and broadcast application of liquid formulation (garden hose-end sprayer)	0.75	0.50	0.017	0.000091	2,600,000	

¹Application rate is based on maximum values found in proposed label: V-10142 (EPA Reg. No. 59639-RLL).

 2 Area treated is based on the area that can be reasonably treated in a single day based on the application method (standard EPA/OPP/HED values).

³ Inhalation unit exposure values represent no respirator. Value for low-pressure handwand is reported in the PHED Surrogate Exposure Guide dated August 1998, and that for hose-end sprayer was obtained from the ORETF data.

⁴ Daily Dose (mg/kg/day) = (Unit Exposure * Application rate * Area treated) / 70 kg.

⁵ Short-Term MOE = NOAEL (235 mg/kg/day) / Daily Dose. The LOC is 100.

Post-application exposure: Adults and children may receive short-term inhalation and dermal exposures from entering turf areas treated with imazosulfuron. Volatilization of imazosulfuron may also be a source of short-term post-application inhalation exposure of bystanders nearby application sites. Finally, children may receive short-term incidental oral exposure (i.e., hand-to-mouth, object-to-mouth and soil ingestion exposure) during post-application activities on treated turf. EPA did not identify any dermal endpoints of concern for imazosulfuron; and a quantitative post-application inhalation exposure assessment was not performed for imazosulfuron due to its low acute inhalation toxicity, low vapor pressure (<3.5 x 10^{-6} Pa), low proposed use rate (0.3 lb ai/A), and the soil-directed application method (i.e., it is not applied using equipment, such as air blast sprayers, that would result in higher post-application inhalation exposures). Therefore, EPA assessed only short-term post-application incidental oral exposure of children (toddlers). The incidental oral MOE for children from combined hand-to-mouth, object-to-mouth and soil ingestion exposures is 17,000. This MOE is well above 100 and, therefore, not of concern.

Post-application Oral Hand-to-Mouth Exposure and Risk for Children from Treated Lawns									
Applicati on Rate (lb ai/A)	Post- applicati on day (t)	Fraction of ai Transferrable from the Foliage	Turf Transferr able Residue ¹ (μg/cm ²)	Hand Surface Area (cm ² /eve nt)	Saliva Extraction Factor	Freque ncy (events/ hr)	Body Weight (kg)	Daily Dose ² (mg/kg/ day)	Short- term Oral MOE ³
0.75	0	0.05	0.42	20	50%	20	15	0.011	21,00 0

¹ Turf Transferrable Residue _{Post-application day} (μ g/cm²) = Application rate (lb ai/A) x Fraction of a.i. Transferrable from the Foliage x (1- Fraction of Residue That Dissipates Daily, 0.1) ^{Post-application day} x 4.54E+8 μ g/lb x 2.47E-8 A/cm² ² Daily Dose = (Turf Transferrable Residue (μ g/cm²) x Hand Surface Area (cm²/event) x Saliva Extraction factor x Frequency (events/hr) x 0.001 mg/ μ g x Exposure time (2 hrs/day)] / [Body Weight (kg)] ³ Oral MOE = Oral NOAEL/Daily Dose; where Short-term NOAEL = 235 mg/kg/day.

Post-appli	Post-application Oral Object-to-Mouth (Turfgrass) Exposure and Risk for Children from Treated Lawns						
Applicati on Rate (lb ai/A)	Post- applicati on day (t)	Fraction of ai Transferra ble from the Foliage	Grass/Objec t Residue ¹ (µg/cm ²)	Ingestion Rate (cm ² /day)	Body Weight (kg)	Daily Dose ² (mg/kg/day)	Short-term Oral MOE ³
0.75	0	0.2	1.7	25	15	0.0028	84,000

¹Grass/Object residue _{Post-application day} (μ g/cm²) = Application rate (lb ai/A) x Fraction of a.i. Transferrable from the Foliage x (1- Fraction of Residue That Dissipates Daily)^{Post-application day} x 4.54E+8 μ g/lb x 2.47E-8 A/cm² ² Daily Dose = [Grass reside (μ g/cm²) x Ingestion rate (cm²/day) x 0.001 mg/ μ g] / [Body Weight (kg)]] 3 Oral MOE = Oral NOAEL / Daily Dose; where Short-term NOAEL = 235 mg/kg/day.

Post-applica	Post-application Incidental Soil Ingestion Exposure and Risk for Children from Treated Lawns					
Applicatio n Rate (lb ai/A)	Fraction of ai Retained in the Soil	Soil Residue ¹ (µg/g)	Ingestion Rate (mg/day)	Body Weight (kg)	Daily Dose ² (mg/kg/d ay)	Short-term Oral MOE ³
0.75	1	5.6	100	15	0.000038	6,300,000

¹ Soil residue Post-application day zero (μ g/cm²) = Application rate (lb ai/A) x Fraction of a.i. Retained on the Soil x (4.54E+8 μ g/lb x 2.47E-8 A/cm² x 0.67 cm³/g soil ² Daily Dose = [Soil reside (μ g/g) x Ingestion rate (mg/day) x 0.000001 g/ μ g] / [Body Weight (kg)]]

³ Oral MOE = Oral NOAEL/Daily Dose; where Short-term NOAEL = 235 mg/kg/day.

Children's Aggregate Exposure and Risk Estimates from Residential Lawns				
Children's Scenarios	$\frac{\text{TTR/GR/SR}_0}{(\text{ug/cm}^2 \text{ or g})^1}$	PDR _{0-norm} (mg/kg/day) ²	Short-Term MOE ³	Total Short-Term MOE ⁴
(1) Hand-to-Mouth	0.42	0.011	21,000	
(2) Mouthing Grass	1.7	0.0028	84,000	17,000
(3) Soil Ingestion	5.6	0.000038	6,300,000	

¹ TTR=turf transferable residue on day "0"; GR=grass residue on day "0"; SR₀=soil residue on day "0". ² PDR_{0norm}=potential dose rate on day "0".

 3 MOE = NOAEL/PDR; where Short-term NOAEL = 235 mg/kg/day.

⁴ Total MOE = $1/[(1/MOE_{Hand-to-Mouth}) + (1/MOE_{Grass}) + (1/MOE_{Soil})]$

3. Aggregate Risk:

Acute Risk: An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. As reported above in section E.1., estimated acute dietary exposure to imazosulfuron is low for all population subgroups ($\leq 1.4\%$ of the aPAD) and, therefore, not of concern.

Chronic Risk: EPA has concluded that chronic exposure to imazosulfuron from food and water will utilize <1 % of the cPAD for all population subgroups. Chronic residential exposure to residues of imazosulfuron is not expected.

Short-Term Risk: Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure from food and water (considered to be a background exposure level). For adults, EPA aggregated short-term residential handler inhalation exposure with chronic dietary exposure from food and water. The resulting MOE of 40,000 is not of concern. For children, EPA aggregated short-term incidental oral residential exposure plus chronic dietary exposure from food and water. The resulting MOE of 7,000 is not of concern.

Intermediate-Term Risk: Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure from food and water. An intermediate-term adverse effect was identified; however, imazosulfuron is not registered for any use patterns that would result in intermediate-term residential exposure. Therefore, EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for imazosulfuron.

Short-Term and/or Intermediate-Term Aggregate Risk Calculations								
	Short- or Intermediate-Term Scenario							
Population	LOC for Aggregate Risk ¹	MOE dietary (food + drinking water) ²	MOE incidental oral ³	MOE dermal ⁴	MOE inhalation ⁵	Aggregate MOE (food and residential) ⁶		
Adult Male	100	40,000	N/A	N/A	2,600,000	40,000		
Adult Female	100	40,000	N/A	N/A	2,600,000	40,000		
Child	100	12,000	17,000	N/A	N/A	7,000		

^T The LOC includes the standard inter- and intra- species uncertainty factors (UF_A and UF_H , respectively) totaling 100. ² MOE food = NOAEL/chronic dietary exposure: Where short- and intermediate-term NOAEL = 235 mg/kg/day and chronic dietary exposure = 0.006043 mg/kg/day (U.S. population), 0.019881 mg/kg/day (All infants < 1 yr). ³ MOE oral = From Table 6.2d..

⁴ $MOE \ dermal = N/A.$

⁵ MOE inhalation = From Table 6.1.

⁶ Aggregate MOE (food and residential) = 1/[(1/MOE food) + (1/MOE oral) + (1/MOE inhalation)]

F. Occupational Risk Assessment

<u>1. Handler Exposure and Risk:</u> The proposed uses of imazosulfuron may result in short- and intermediate-term occupational inhalation and dermal exposures of mixers, loaders, and applicators (both ground and aerial). Since a dermal endpoint of concern was not identified for imazosulfuron, only inhalation exposures were quantitatively assessed.

All handler inhalation MOEs are well above 100 (ranging from 59,000 to 930,000) and are, therefore, not of concern. The worst-case MOE of 59,000 is based on handlers mixing and loading dry flowable formulations for aerial applications to rice.

Short- and Intermediate	Short- and Intermediate-Term Occupational Handler Exposure and Risk for Imazosulfuron					
Exposure Scenario	Crop or Target	App Rate ^a (lb ai/A)	Acres Treated Daily ^b	Baseline Inhalation Unit Exposure ^c (mg/lb ai)	Short- and Intermediate-Term Dose (mg/kg/day) Inhalation ^d	Short- and Intermediate-Term MOE Inhalation ^e
	Mixer/Loader					
Mixing/Loading Dry Flowables for Groundboom Applications	Tomatoes, Peppers (Bell and Non-Bell), Rice	0.3	80	0.00077	0.000264	890,000
Mixing/Loading Dry Flowables for Aerial Applications	Rice	0.3	1200	0.00077	0.00396	59,000
		Ap	plicator			
Applying Sprays via Groundboom Equipment	Tomatoes, Peppers (Bell and Non-Bell), Rice	0.3	80	0.00074	0.000254	930,000
Applying Sprays via Aerial Equipment	Rice	0.3	1200	0.000068	0.000350	670,000
		F	agger			
Applying Sprays for Aerial Equipment	Rice	0.3	1200	0.00035	0.000180	130,000

a Application Rates based on proposed uses on label for V-10142 (EPA Reg. No. 59639-RLL).

b Exposure Science Advisory Council Policy No. 9.1.

c Unit Exposures based on PHED Version 1.1.

d Short- and Intermediate-Term Inhalation Dose (mg/kg/day) = daily unit exposure (mg/lb ai) x application rate (lb ai/acre) x acres treated / body weight (70 kg).

e Short- and Intermediate-Term Inhalation MOE = NOAEL (235 mg/kg/day) / inhalation daily dose (mg/kg/day). LOC = 100

2. Occupational Post-application Exposure and Risk: There are multiple potential sources of inhalation exposure of individuals performing post-application activities in previously treated fields. These potential sources include volatilization of the pesticide and resuspension of dusts and/or particulates that contain the pesticide. However, a quantitative occupational post-application inhalation exposure assessment was not performed for imazosulfuron, primarily because of imazosulfuron's low acute inhalation toxicity, low vapor pressure ($<3.5 \times 10^{-6}$ Pa), low proposed use rate (0.3 lb ai/A), and the soil-directed application method (i.e., it is not applied using equipment, such as air blast sprayers, that would result in higher post-application inhalation exposures).

V. ENVIRONMENTAL RISK

A summary of the environmental fate and ecological effects and risks of imazosulfuron as assessed in the Agency document entitled, "Ecological Risk Assessment for the First Food Use Registration of Imazosulfuron for Selective Sedge and Broadleaf Weed Control in Tomato, Pepper, and Rice and Revised Use rates in Turfgrass", is provided below.

A. Environmental Fate

<u>1. Degredation</u>: Major routes of imazosulfuron dissipation are aerobic and anaerobic biodegradation and aqueous photolysis. Imazosulfuron is expected to degrade with half-lives of several weeks in aerobic soil environment and anaerobic aquatic environments. Aquatic photolysis (half-life of 3.5 days) is expected to hasten degradation of imazosulfuron; however, it is stable to aquatic hydrolysis except at low pH.

<u>2. Mobility:</u> Because imazosulfuron is mobile to moderately mobile in soil, it is expected to move from the application site into groundwater and surface water. Additionally, off-site movement of imazosulfuron is expected through spray drift from aerial and ground spray; however, imazosulfuron is not volatile and, therefore, is not likely to be transported via atmospheric processes following application.

<u>3. Degradates of Concern</u>: The environmental degradates of imazosulfuron that are of possible exposure concern for surface water include the parent compound's major degradates, HMS, IPSN, ADPM, UPDM and SPDM. As the degradate HMS retains both major ring structures, its toxicity is likely comparable to the parent. IPSN, ADPM, UPDM and SPDM all retain at least one of the structural alerts as the parent, and therefore a total toxic residue (imazosulfuron + 5 degradates) was considered in the aquatic exposure assessment.

4. Expected Fate Scenario: Dissipation of imazosulfuron in the environment is expected to occur predominantly via runoff and leaching; however, imazosulfuron in leachate is not expected to persist under anaerobic soil conditions. Persistence of total toxic residue [imazosulfuron and degradates (HMS, IPSN, ADPM, IHOA and SPDM)] in soil is sufficient such that vulnerable aquifers may be impacted but exposure will be minimal compared to surface water concentrations. Imazosulfuron concentrations in surface waters may be relatively high when significant runoff events occur after application and / or spray drift to water bodies in close proximity to the treatment area occurs.

To address concerns with the potential leaching and runoff of imazosulfuron and its major degradates that may result from the persistence and mobility described above, labels are required to have language including surface and ground water advisories that stress the potential of runoff after treatment and descriptions of conditions that may promote leaching to groundwater. Required label language is described more fully under the "Regulatory Decision" section, below.

B. Ecological Risk

Ecological risk characterization integrates the results of the exposure and ecotoxicity data to evaluate the likelihood of adverse ecological effects. The means of integrating the results of exposure and ecotoxicity data is called the quotient method. For this method, risk quotients (RQs) are calculated by dividing exposure estimates by ecotoxicity values, both acute and chronic (RQ = Exposure/Toxicity). RQs are then compared to EPA's levels of concern (LOCs). The LOCs are criteria used by the Agency to indicate potential risk to non-target organisms. The criteria indicate whether a pesticide, when used as directed, has the potential to cause adverse effects to non-target organisms.

A screening-level risk assessment of the proposed uses suggests that imazosulfuron presents potential risk to terrestrial and aquatic vascular plants, and thus to the organisms that depend on the plants for habitat and

forage. There is also the potential for adverse effects on birds and mammals from chronic exposure to imazosulfuron; however, as discussed below, EPA believes the risk of such effects is low.

1. Risk to Birds:

Acute Risk: Imazosulfuron and the degradate, ISPN, are considered to be practically non-toxic to birds on an acute oral and sub-acute dietary basis. The acute and sub-acute endpoints for avian species are non-definitive, since no treatment-related mortality effects were seen at the highest limit dose and dietary concentration tested. The mallard acute oral study reported a significant reduction in female body weight gain at the highest treatment level; however, based on application rates and the results of these acute toxicity studies, acute risk concern levels are not exceeded for birds.

Chronic Risk: A mallard duck study reported definitive NOAEC/LOAEC (No Adverse Effects Concentration/Lowest Adverse Effects Concentration) values of 100/202 mg ai/kg diet based on reduced number of eggs laid. A bobwhite quail study reported a statistically significant number of cracked eggs (5%) and a significant reduction in the number of hatchlings/eggs laid (14%) in the 1230 mg ai/kg diet treatment group resulting in a NOAEC of 484 mg ai/kg diet. There was also a statistically significant reduction in female weight gain (28%) and reduction in shell thickness resulting in a NOAEC value of 194 mg ai/kg diet however these effects were not dose-responsive and there is some uncertainty whether these effects were treatment related.

In order to make the most conservative risk estimation, the mallard duck NOAEC/LOAEC value of 100/202 mg ai/kg diet were used to determine chronic dose-based and chronic dietary-based RQs. Dose-based RQs differ from dietary-based RQs in that they take into consideration the size, metabolic needs and feeding habits (granivore, insectivore, herbivore) of different birds as well as the nutritive content of different forages. Based on these NOAEC/LOAEC values, chronic dose-based levels of concern (LOCs) are exceeded for birds consuming shortgrass, tallgrass, and broadleaf plants/small insects for turf grass use only (RQs between 1.2 and 2.7). Chronic dose-based LOCs were not exceeded for or nonfood uses.

The chronic "RQs" for birds reflect risk at the site of application following applications at the maximum use rate. RQs would be expected to drop rapidly as the distance from the treated area increases or when lower application rates are used. Further, the RQs assume that birds forage for food exclusively on the treated area and that they consume a single type of food. For instance, the RQ of 2.7 assumes that birds consume only short grass, the food source expected to result in the greatest imazosulfuron exposure. Since it's unlikely that birds would forage exclusively on the treated area or consume a single type of food, actual risk to most birds is likely substantially lower than estimated. EPA also notes that the models used to estimate concentrations of imazosulfuron in the environment are screening models, designed to provide high-end exposure estimates, further reducing the likelihood of actual risk to birds.

Although the risk of chronic effects on birds is low, it cannot be entirely discounted. To mitigate potential risk to birds, labels must include language intended to limit spray drift, thereby reducing the area of potential exposure to imazosulfuron residues.

2. Risk to Mammals:

Acute Risk: Imazosulfuron does not pose a potential risk to mammals on an acute oral exposure basis. The acute endpoints for mammals are non-definitive, since no treatment-related mortality effects were seen at the highest concentration tested; therefore, no acute risk quotients (RQs) were calculated.

The acute oral studies showed an increased acute sensitivity in mammals to the degradates IPSN, ADPM and UDPM as compared to imazosulfuron, with IPSN being the most toxic. In order to assess acute risk of these degradates to mammals, the application rate for turf grass (the highest proposed rate for imazosulfuron) was adjusted to reflect the percent of the metabolite that may result from degradation processes on the leaf surface of a grass blade. Based on the percent of each degradate detected at the highest proposed application rate, acute mammalian LOCs were not exceeded for these degradates. However, there is some uncertainty in this analysis as not all degradation processes may have been considered. To address this uncertainty and confirm that acute LOCs are not exceeded, additional studies on the effects of the most toxic degradate, IPSN, were required as a condition of registration.

Chronic Risk: No reproductive effects were found in a 2-generation laboratory rat reproduction study. Chronic mammalian dietary-based RQs did not exceed the chronic risk LOC of 1.0 for any of the proposed uses for imazosulfuron. Similarly, chronic mammalian dose-based risk LOCs were not exceeded for any sized mammals based on imazosulfuron uses in tomato, pepper and rice. However, dose-based chronic risk RQs ranging from 1.1 to 2.3 did exceed the LOC for all sized mammals based on imazosulfuron uses in turf grass.

Although dose-based RQs exceeded the chronic LOC for mammals in turf grass uses, EPA believes the risk of chronic effects is low for several reasons. As noted above in the discussion of chronic bird risk, the chronic RQs reflect risk at the site of application following applications at the maximum use rate. RQs would be expected to drop rapidly as the distance from the treated area increases or when lower application rates are used. Further, the RQs assume that mammals forage for food exclusively on the treated area and that they consume a single type of food. For most mammals, neither assumption is likely to be true. Also, the models used to estimate concentrations of imazosulfuron in the environment are screening models, designed to provide high-end exposure estimates, further reducing the likelihood of actual risk to mammals.

Although the risk of chronic effects on mammals is low, it cannot be entirely discounted. To mitigate potential risk to mammals, labels must include language intended to limit spray drift, thereby reducing the area of potential exposure to imazosulfuron residues.

3. Risk to Pollinators and other Terrestrial Invertebrates: Imazosulfuron is categorized as practically non-toxic to honey-bees. In addition to the honey-bee study, two non-guideline 14-day acute earthworm toxicity studies resulted in LC50 values of >1000 mg/kg-dw soil for imazosulfuron TGAI and >996 mg/kg dw soil for IPSN. The effects of IPSN on non-target insects were also documented through 2 non-guideline studies, using ground beetles and rove beetles. Both the 14-day study on ground beetle and 28-day study on rove beetle reported LD50 values of >1000 mg ai/kg dw soil and no effects due to IPSN on the beetles. Based on these studies, minimal risk to honey-bees and other terrestrial invertebrates is assumed from all the proposed imazosulfuron uses.

4. Risk to Fish (Freshwater and Estuarine/Marine):

Acute Risk: For acute risk to freshwater and marine fish, there was no toxicity observed at the highest concentration of the technical grade imazosulfuron tested, at 100 mg ai/L nominal concentration. Therefore, acute risk quotients were not calculated and there is not a potential acute risk to freshwater fish.

Chronic Risk: As the calculated RQ was less than the chronic risk LOC of 1.0 for all the proposed new uses including turfgrass, imazosulfuron is not expected to pose risk to freshwater fish from chronic exposure. Chronic toxicity data are not available for estuarine/marine fish. As the NOAEC value based on acute exposure studies on fathead minnow (for which chronic data are available) and sheepshead minnow were similar, it is reasonable to use the fathead minnow NOAEC value from chronic exposure study for sheepshead minnow. The low RQ of 0.09 calculated using the fathead minnow NOAEC value suggests that imazosulfuron does not pose risk to estuarine/marine fish.

5. Risk to Aquatic Invertebrates (Freshwater and Estuarine/Marine):

Acute Risk: Peak EECs (Estimated Environmental Concentrations) were compared to acute toxicity endpoints to derive acute risk quotients. For acute risk to freshwater and marine invertebrates, there was no toxicity observed at the highest concentration of the technical grade imazosulfuron tested, at 100 mg ai/L nominal concentration. Therefore, acute risk quotients were not calculated and acute risk to freshwater or marine invertebrates is not expected.

Chronic Risk: The 21-day EECs were compared to chronic toxicity endpoints (NOAEC values) to derive chronic risk quotients for invertebrates. Chronic RQs were calculated for sediment-dwelling midge larvae by comparing the highest pore water concentration of imazosulfuron that resulted from the rice scenario (279 μ g /L) to the pore water-based NOAEC (11,000 μ g ai/L). The resulting RQ of 0.02 suggests that imazosulfuron is not expected to pose risk to freshwater benthic organisms from chronic exposure. There were no LOC exceedances for estuarine/marine mollusks based on data for the Eastern Oyster. The EC50 and NOAEC values were 63 and 13 mg ai/L, respectively, based on reduced shell deposition. The RQ, calculated using the highest peak EEC (279 μ g ai/L for rice) and the EC50 (63,000 μ g ai/L), is <0.01, below the LOC for chronic effects to estuarine/marine invertebrates.

6. Risk to Plants:

Terrestrial Plants: As is expected with herbicides, terrestrial plants are sensitive to imazosulfuron. For a single ground application on tomato, pepper, and rice at the maximum rate, the LOC was exceeded for listed and non-listed non-target terrestrial plants in semi-aquatic environments only. For a single aerial application on rice, the LOC was exceeded for listed and non-listed non-target terrestrial plants in semi-aquatic environments only. For a single aerial application on rice, the LOC was exceeded for listed and non-listed non-target terrestrial plants in semi-aquatic environments and listed plants in dry upland areas. For a single ground application to turfgrass, the LOC was exceeded for listed and non-listed non-target terrestrial plants in dry upland and semi-aquatic environments. In addition to the growth effects observed for several plant species, unusually high mortality was observed for some plants in the seedling emergence and vegetative vigor tests. There were significant reductions in survival at 21 days for soybean at 2 lb ai/A (32%), flax at 0.67 lb ai/A (37%), and radish at 0.67 lb ai/A (60%). Minimal effects were observed in the Poaceae family (wheat, corn, and ryegrass). This is supported by the fact that imazosulfuron is not a grass herbicide. Imazosulfuron exposure may result in non-target plant mortality, especially when applied aerially.

Aquatic Plants: LOCs for listed and non-listed aquatic vascular plants were exceeded for all the proposed uses. Non-vascular plant RQs only exceeded concern levels for uses in rice, which may be attributed to the extremely conservative nature of the modeling used specifically for rice scenarios. An aquatic vascular plant (Lemna gibba) study using the degradate, IPSN demonstrated no toxicity to the plant.

To address and mitigate risks to non-target terrestrial, aquatic and semi-aquatic plants, spray drift language intended to keep the pesticide on the treatment area, thereby reducing the potential for non-target plant exposure has been required for the labeling of imazosulfuron products.

VI. REGULATORY DECISION

The Agency registered a technical and 2 end-use products for use on residential and commercial turfgrass, rice, peppers, and tomatoes. As required by FIFRA, the Agency published a notice of receipt of applications (dated January 27, 2010; no comments were received) to register pesticide products containing the new active ingredient, imazosulfuron.

A. Data Requirements

The human health risk assessment concluded that the database is largely complete and adequate for a dietary, residential, and occupational risk assessment. The following studies were required as a condition of registration:

- <u>870.7800 Immunotoxicity</u>. EPA began requiring functional immunotoxicity testing of all food and non-food use pesticides on December 26, 2007. Since this requirement is relatively new, this study was not available for imazosulfuron. As explained in section IV.C., this study is not expected to alter the Agency's risk conclusions for imazosulfuron.
- <u>860.1360 Multiresidue Methods</u>. The following additional information will be provided concerning the multiresidue methods testing for imazosulfuron: the petitioner must explain why testing for imazosulfuron under Protocol D through the complete method without cleanup was not conducted or provide the results of testing without cleanup. This information is not used in human health risk assessment. Nor is it critical for enforcement of the proposed tolerances, since an acceptable single-analyte enforcement analytical method is available to enforce the tolerances.
- <u>860.1380 Storage Stability</u>. The final report(s) of the storage stability studies will be submitted, reflecting frozen storage intervals of up to 11.8 months for peppers, up to 34.5 months for rice grain, and up to 17.3 months for tomatoes. Interim data indicate that imazosulfuron is stable in frozen storage; however, the final reports are needed to confirm its stability.
- <u>860.1850 Confined Accumulation in Rotational Crops</u>. The HPLC profile for the pyrimidinyl (Py)label grain storage stability analysis will be submitted to confirm that the metabolite profile was stable in Py-label grain. This information is not expected to alter the Agency's risk conclusions for imazosulfuron.
- <u>860.1900 Field Accumulation in Rotational Crops</u>. The grain (wheat) rotational crop study is needed to identify maximum levels of residues in grain and livestock feed items (forage, straw) as a function

of the plantback interval. On an interim basis, a plantback interval of 12 months is being imposed for grains and soybeans. The confined rotational crop study showed that residues will be negligible (<0.01 ppm) on forage, hay, straw, stover, and grain at a 365 day plantback interval. The results of the field rotational crop study may allow a shorter plantback interval.

The environmental fate and effects review concluded that the database is adequate for a screening level assessment of the proposed uses. The following ecological studies were required as a condition of registration:

- <u>850.1075, 850.1300, 850.1300 Acute Toxicity (for a degradate of imazosulfuron)</u>. Mammals showed increased sensitivity to exposure of the degradate IPSN as compared to the parent, imazosulfuron. Although the calculated RQs did not exceed the LOCs for mammals, there is still uncertainty regarding the acute toxicity of ISPN to fish, aquatic invertebrates (water column-dwelling), and aquatic non-vascular plants exposed to the degradate. Studies (Guideline numbers: 850.1075 for fish, 850.1300 for invertebrates, and 850.5400 for non-vascular plants) addressing the effects of ISPN on aquatic organisms were therefore required as a condition of registration to address this uncertainty and confirm that LOCs for aquatic species are not exceeded.
- <u>850.2100 Avian Acute Oral Toxicity</u>. The recently revised FIFRA data requirements (CFR 40 Part 158) require an avian acute oral toxicity study be conducted using a passerine species (Passeriformes). Since the available studies in mallards and quail indicate that imazosulfuron and the degradate, ISPN, are practically non-toxic to birds on an acute oral and sub-acute dietary basis, this study is considered to be confirmatory and was required as a condition of registration.
- Imazosulfuron is a sulfonylurea (SU) herbicide. Research involving chlorsulfuron, the first SU herbicide registered in the US (1981), has indicated that chlorsulfuron may have effects on plant seed/fruit production at extremely low concentrations. Based on this research, the Agency may require additional plant studies to better characterize the potential for SU herbicides to cause reproductive effects in plants. These studies are not guideline requirements for the registration of a new chemical and are not being required for imazosulfuron at this time, but may be required in the future as part of the Agency's effort to address this generic issue for the SU class of herbicides.

B. Labeling Requirements

In order to mitigate risks to non-target plants and animals, label language is required that is intended to keep the pesticide on the treatment area, thereby reducing the potential for exposure of non-target plants and animals. For example, spray drift management language is required on the occupational/commercial labeling that advises users of applicator responsibilities and requires specific techniques to reduce the possibility of spray drift. In addition, surface and ground water advisories are required on all labeling, which may further reduce residues in drinking water and exposure of non-target organisms.

Label Language Required for all End-use products to Reduce Residues of Imazosulfuron in Drinking Water:

• Surface Water Advisory:

"Imazosulfuron and its degradates may impact surface water quality through spray and runoff of rain water. This is especially true for poorly draining soils and soils with shallow ground water. Imazosulfuron and degradates are classified as having high potential for reaching surface water via runoff for several months or more after application. A level, well maintained vegetative buffer strip between areas to which this product is applied and surface water features such as ponds, streams, and springs will reduce the potential loading of imazosulfuron and degradates from runoff water and sediment. Runoff of this product will be reduced by avoiding applications when rainfall is forecast to occur within 48 hours."

• Ground Water Advisory:

"Imazosulfuron and several of its degradates have properties and characteristics associated with chemicals detected in ground water. These chemicals may leach into ground water if used in areas where soils are permeable, particularly where the water table is shallow."

Language Required for Labels that include Residential Uses:

• Buffer Language:

"Maintain a 10 ft. vegetative buffer strip between treated areas and natural bodies of water (rivers, streams, lakes, wetlands, etc)."

• Rate Restriction:

"Do not broadcast apply more than 0.66 lb imazosulfuron per acre (0.015 lb ai per 1000 sq. ft.) per application."

"Do not broadcast apply more than 1.34 lb imazosulfuron per acre per year."

• Spray Drift/Run-off Management Language for Residential Uses:

"Do not irrigate within 4 hrs before or after application."

"Do not apply if rain is expected within 24 hours after application."

"Make broadcast applications with equipment at a height no greater than 2 feet above the ground. Making applications at the lowest height that is safe reduces exposure of droplets to evaporation and wind."

"All ground application equipment must be properly maintained and calibrated using appropriate carriers."

"Do not apply under circumstances where possible drift can occur to unprotected persons or to food, forage or other plantings that might be damaged or crops thereof rendered unfit for sale, use or consumption."

Language Required for Labels That Include Agricultural Uses:

• Use Rate Restriction:

"Do not apply more than 0.3 lb imazosulfuron per acre per year."

• Plant-Back Interval (PBI) Restriction:

Pending submission of field rotational crop data, a 12-month plant-back interval must be included for rotation to soybean and cereal grain crops.

• Labels that include use on rice must include the following restriction:

"Do not apply to rice fields if fields are used for the aquaculture of edible fish and/or crustaceans."

• Buffer Language:

"Do not apply imazosulfuron within 100 feet of emerged non- target crops."

"Maintain a 10 ft. vegetative buffer strip between treated areas and natural bodies of water (rivers, streams, lakes, wetlands)."

• Spray Drift Management Language:

"SPRAY DRIFT MANAGEMENT:

The interaction of many equipment and weather related factors determines the potential for spray drift. The applicator and the grower are responsible for considering all factors involved in minimizing drift potential."

"Importance of Droplet Size

The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. Use nozzle types and nozzle arrangements that will provide maximum coverage and minimize the potential for off target movement of spray particles. Droplet size for both ground and air applications must be in the "medium" size category as defined in the August 1999 ASAE S572 publication entitled, "Spray Nozzle Classification by Drop Spectra". Refer to that publication for additional information. Regardless of droplet size, if applications are made improperly or under unfavorable environmental conditions off target movement will occur. (see Wind, Temperature and Humidity, and Temperature Inversion sections in this label)."

"Controlling Droplet Size

Volume: Use high flow rate nozzles that produce medium droplets to apply the highest practical spray volume."

Pressure: Use the lower spray pressures recommended for the nozzle and do not exceed the manufacturer's recommended pressure. Higher pressure reduces droplet size and does not improve canopy penetration. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure.

Number of nozzles: Use the minimum number of nozzles that provide uniform coverage.

Nozzle orientation: Orienting nozzles so that the spray is released backwards parallel to the air-stream will produce larger droplets than other orientations. Significant deflection from the horizontal will reduce droplet size and increase drift potential.

Nozzle type: Use a nozzle type that is designed for the intended application. Do not use air inducting or flood type nozzles.

Ground Boom Application Height: Applications must not be made at a height greater than 4 feet above the top of the largest plants. Making applications at the lowest possible height reduces exposure of droplets to evaporation and wind."

"Swath Adjustment

When applications are made with a cross wind, the swath will be displaced downwind. Therefore, on the up and downwind edges of the field, the applicator must compensate for this displacement by adjusting the path of the aircraft upwind. Swath adjustment distance should increase with increasing drift potential (higher wind, smaller drops, etc.)."

"Wind

Variable wind speeds with changing directions may pose the largest potential for drift damage if crops other than rice are adjacent to the field to be sprayed. Drift potential is lowest between wind speeds of 2 to 8 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application must be avoided if wind speed is below 2 mph due to variable wind direction and high inversion potential. Note: local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect drift."

"Temperature and Humidity

When making applications in low relative humidity, set up equipment to produce larger droplets to compensate for evaporation, but they still should remain within the medium droplet size category. Droplet evaporation is most severe when conditions are both hot and dry."

"Temperature Inversions

Do not spray at times when spray particles may be entrained into a temperature inversion layer. If inversion conditions are suspected, consult with local weather services before making an application. Applications must not occur during temperature inversion, because drift potential is high. Temperature inversions restrict vertical air mixing, which causes small, suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a connected cloud (under low wind conditions) indicates an inversion, while smoke that moves upwards and rapidly dissipates indicates good vertical air mixing."

"Sensitive Areas

The pesticide must only be applied when the potential for drift to adjacent sensitive areas (e.g., residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g., when wind is blowing away from the sensitive areas)."

• Additional Language Required for Aerial Applications to Rice:

"Aerial Drift Reduction Advisory:

The following aerial drift reduction advisory information must be followed to avoid off- target drift movement from aerial applications to agricultural field crops.

- 1. Do not spray if wind speed is greater than 8 mph or less than 2 mph. If sensitive crops or plants are downwind, extreme caution must be used under all conditions.
- 2. The distance between the outermost nozzles on the boom must not exceed 3/4 the length of the wingspan or rotor.
- 3. Nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees. Where states have more stringent regulations, they must be observed.
- 4. Do not apply under conditions involving possible drift to food, forage or other plantings that might be damaged or the crops thereof rendered unfit for sale, use or consumption.
- 5. When making tank mixture applications follow the most restrictive label directions, including application buffer zones, of each product in the mixture.
- 6. Nozzles should be at a minimum of 10 inches below the trailing edge of the wing on a fixed wing aircraft to prevent spray particles from being released into turbulent air. For some use patterns, reducing the effective boom length to less than 3/4 of the wingspan or rotor length may further reduce drift without reducing swath width.
- 7. Applications should not be made at a height greater than 10 feet above the top of the largest plants unless a greater height is required for aircraft safety. Making applications at the lowest height that is safe reduces exposure of droplets to evaporation and wind."

"For aerial applications, do not apply imazosulfuron within a 1/4 mile of emerged cotton or non-STS soybeans and do not apply within 100 feet of any other non-target crop."

"Aerial application is permitted for rice crop treatments only."

C. Public Interest

The use of imazosulfuron on tomatoes and peppers (bell & non-bell) are considered by the Agency to be minor uses. The Agency believes that the registration of sustainable pest control technology for specialty crops and minor uses is beneficial to growers, food processors, and the general public and is, therefore, in the public interest. The public benefits by having high-quality food at reasonable prices. Imazosulfuron provides another tool to users for the control of several broadleaf weeds and sedges in turfgrass and food crops, including difficult-to-control yellow nutsedge (*Cyperus esculentus*) and purple nutsedge (*Cyperus rotundus*), as well as pre-emergent and post-emergent control of ducksalad (*Heteranthera spp.*) and Texasweed (*Caperonia palustris*), both of which are significant weed problems in rice production.

Imazosulfuron has an excellent human toxicity profile, demonstrating low acute, subchronic and chronic toxicity in the submitted animal studies. There is no evidence that it causes developmental or reproductive toxicity, neurotoxicity, carcinogenicity or immunotoxicity; and no evidence of increased susceptibility of infants or children to imazosulfuron. Due to imazosulfuron's lack of dermal toxicity, low acute inhalation toxicity, and low vapor pressure, the pesticide poses very low risk to workers or homeowners applying the pesticide or to people entering areas that have been treated with imazosulfuron.

Imazosulfuron poses low risk to aquatic animals, and to birds and mammals on an acute exposure basis. While chronic exposure RQs for birds and mammals slightly exceed the LOC, EPA believes the actual risk to birds and mammals from chronic exposure to imazosulfuron is low. As with all herbicides, imazosulfuron poses risk to non-target plants; however, the RQs for non-target plants compare favorably with other herbicides, and the mitigation language for end-use product labels should help to mitigate risk to non-target plants.

Based on these considerations, the Agency believes that the registration of imazosulfuron is in the public's interest.

Contact Person at EPA

162-1

Kable Bo Davis Product Manager Herbicide Branch Registration Division (7505P) Office of Pesticide Programs Environmental Protection Agency Aerial Rios Building 1200 Pennsylvania Ave., NW Washington, DC 20460

Aerobic soil metabolism

DISCLAIMER: The information presented in this Pesticide Fact Sheet is for informational purposes only and may not be used to fulfill data requirements for pesticide registration and reregistration.

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MRID	Citation Reference
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MRID	Citation Reference
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MRID	Citation Reference
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