United States
Environmental Protection
Agency

Office of Prevention, Pesticides
and Toxic Substances
(7501C)

Pesticide Fact Sheet

Name of Chemical: Cloransulam-methyl
Reason for Issuance: Conditional Registration
Date Issued: October 29, 1997

DESCRIPTION OF CHEMICAL

Generic Name:	N-(2-carboxymethyl-6-chlorophenyl)-5-ethoxy-7-fluoro-(1,2,4)-triazolo[1,5c]-pyrimidine-2-sulfonamide
Common Name:	cloransulam-methyl
Trade Names:	Cloransulam-methyl Technical FirstRate Herbicide
EPA Chemical Code:	129116
Chemical Abstracts Service (CAS) Number:	147150-35-4
Year of Initial Registration:	1997
Pesticide Type:	Herbicide
Chemical Family:	Triazolopyrimidine sulfonanilide
U.S. and Foreign Producers:	DowElanco 9330 Zionsville Road Indianapolis, IN 46268-1054

USE PATTERNS AND FORMULATIONS

Cloransulam-methyl is applied to the soil surface or incorporated preemergence or postemergence in soybeans to control broadleaf weeds. It will be formulated as a 84% water dispersable granular in water soluble packaging. FirstRate Herbicide will be applied by ground only at 0.6 to 0.75 ounces per acre. The maximum use rate of 0.40 lb cloransulam-methyl per acre.

Cloransulam-methyl Technical is a 97.5% manufacturing use product.

SCIENCE FINDINGS

SUMMARY SCIENCE STATEMENTS

Adequate chemistry, toxicological, ecological effects, and environmental fate data have been submitted and reviewed to support the conditional registration of FirstRate Herbicide on soybeans for a period of four years.

The technical cloransulam-methyl product is classified in toxicity category III [CAUTION] based on acute dermal toxicity, acute inhalation toxicity, and eye irritation studies. The formulated end use product is classified in toxicity category III [CAUTION] based on the acute dermal toxicity and eye irritation studies.

Cloransulam-methyl was shown to be negative in assays for mouse micronucleus assay, in two cytogenetic assays, and in a cultured chinese hamster ovary cell study.

Developmental toxicity studies in the rat and rabbit demonstrated no developmental effects. In the rat the No Observed Effect Level (NOEL) for maternal and developmental toxicity was 1000 milligrams/kilogram(mg/kg)/day (Highest Dose Tested [HDT]). In rabbit, the NOELs for maternal toxicity was 100 mg/kg/day and for developmental toxicity was 300 mg/kg. In a two-generation rat reproduction study, the parental systemic NOEL was 10 mg/kg/day and the reproductive and developmental NOEL was 100 mg/kg/day.

In a 90-day mouse feeding study the NOEL was 50 mg/kg/day males. In a 21-day rabbit dermal study the dermal irritation NOEL was equal or greater than 1000 mg/kg/day and the systemic NOEL was equal to 500 mg/kg/day. In a 1-year dog chronic feeding study the NOEL was 10 mg/kg/day and the LOEL was 50 mg/kg/day based on hepatocellular hypertrophy and accumulation of pigment, and increased activity of alkaline phosphatase and alanine aminotransferase liver enzymes and decrease in albumin and total bilirubin.

In the rat Chronic Feeding / Carcinogenicity study the NOEL was equal to 75 mg/kg/day and the Lowest Observed Effect Level (LOEL) was 325 mg/kg/day based on significant increase in hemoglobin, hematocrit, and red cell count in males, activities of the liver enzymes aspartate and alanine aminotransferase as well as alkaline phosphatase were decreased in males, cholesterol was decreased in females, specific gravity of urine was decreased in females, increased relative wight in liver and relative weight of testes in males, males exhibited an increased incidence of

collecting duct hypertrophy and females exhibited increased incidence of vacuolation in the kidney. There was no evidence of carcinogenicity for cloransulam-methyl in this study. In the mouse carcinogenicity study the NOEL was 10 mg/kg/day and the LOEL was 108 mg/kg/day based on based on a decrease in renal tubule vacuolation in male mice, increased size of centrilobular and midzonal hepatocytes accompanied by altered tinctorial properties in females and centrilobular hepatocyte hypertrophy in males. Total tumor incidence (adenoma + carcinoma) was not increased by dosing with cloransulam-methyl.

Cloransulam-methyl is classified as a "Not Likely" carcinogen based on the lack of carcinogenicity in rats and mice.

The Reference Dose (RfD) for cloransulam-methyl is 0.1 mg/kg/day. This value is based on the systemic NOEL of 10 mg/kg/day in the dog chronic feeding study with a 100-fold safety factor to account for interspecies extrapolation and intraspecies variability

A DRES chronic exposure analysis was conducted using tolerance level residues and 100 percent crop treated information to estimate the Theoretical Maximum Residue Contribution (TMRC) for the general population and 22 subgroups. The chronic analysis showed that exposure from the tolerances in or on soybeans for non-nursing infants (the subgroup with the highest exposure) would be 0.033% of the Reference Dose (RfD). The exposure for the general U.S. population would be 0.007% of the RfD.

Tolerances are established for the for residues of the herbicide cloransulam-methyl, N-(2-carboxymethyl-6-chlorophenyl)-5-ethoxy- 7-fluoro-(1,2,4)-triazolo[1,5c]-pyrimidine-2-sulfonamide, plus its acid, cloransulam, calculated as parent ester in or on soybean seed at 0.02 parts per million (ppm), soybean forage at 0.1 ppm, and soybean hay at 0.2 ppm.

For the aggregate dietary exposures from food and drinking water, the percentage of the RfD utilized for non-nursing infants (the subgroup with the highest exposure) would be 0.216% of the RfD. The exposure would be less than 0.061% the RfD for females 20 years old (not pregnant - not nursing). Even though these risks represent the worst-case scenario there appears to be no aggregate risk concern associated with the use of cloransulam-methyl on soybeans.

Cloransulam-methyl hydrolysis is pH dependent. Cloransulam-methyl photolyzed rapidly in water with a half life of 22 minutes Photolysis on soil more slowing with half lives, corrected for metabolism, of 30 to 70 days. The apparent transformation half-

life in aerobic soils was estimated at 9 to 13 days. The transformation half-life of cloransulam-methyl residues under anaerobic aquatic conditions was approximately 16 days.

The structurally-similar transformation products occur in aerobic and anaerobic metabolism studies and appear persistent under anaerobic conditions. Cloransulam-methyl is highly mobile while the major transformation product also appears to be mobile in soils. Cloransulam-methyl dissipated relatively rapidly from the upper 15 cm of bare ground plots. Transformation products indicate that metabolism and photolysis are likely to be major routes of transformation of cloransulam-methyl in the field. Leaching may play an important role in dissipation of cloransulam-methyl from the surface layer. So while cloransulam-methyl and its transformation products are likely to be only of slight persistence in the surface, the chemicals may become more persistent when leached into the subsurface. A label Groundwater Application Advisory is required and prospective groundwater monitoring studies are a condition of registration.

Cloransulam-methyl was shown to be practically non-toxic to birds, practically non-toxic to small mammals, practically non-toxic to bees, practically non-toxic to slightly toxic to fresh water organisms, and practically non-toxic to estuarine / marine organisms. Cloransulam-methyl can be toxic to non-target plants from movement off the treatment site. Environmental hazard precautionary statements are required. Tier II Phytotoxicity Studies for the cloransulam-methyl transformation compounds cloransulam, 5-hydroxy-cloransulam and 5-hydroxy-cloransulam-methyl are required as a condition of registration.

CHEMICAL CHARACTERISTICS

Empirical Formula:	$C_{15}H_{13}O_5N_5SClF$
Molecular Weight:	429.82
Color:	off-white
Physical State:	powder at 20°C
Odor:	slight mint
Melting Point:	216 - 218°C
Density at	

(20°C): 1.538

Solubility g/liter:
distilled water - 16 parts per million (ppm)
buffered pH 5 - 3 ppm
buffered pH 7 - 184 ppm
buffered pH 9 - 0.343 g/100mL
acetone - 0.436 g/100mL
acetonitrile - 0.550 g/100mL
dichloromethane - 0.698 g/100mL
ethylacetate - 0.098 g/100mL
hexane - < 10 ppm
methanol - 0.047 g/100mL
octanol - < 10 ppm
toluene - 14 ppm

Vapor Pressure: 3×10^{-16} mmHg at 25° C

Dissociation Constant: 4.81 at 20° C

Octanol/Water partition coefficient: Log K_{ow} = 1.12 at pH 5
-.365 at pH 7
-1.24 at pH 8.5
0.268 distilled water

pH: 3.0 (9.8% dispersed in water)

Stability: Stable after 28 days at room temperature alone and 122°F alone and with 304 and 306 stainless steel, mild steel, brass, ferric chloride and magnesium chloride

TOXICOLOGY CHARACTERISTICS

FirstRate Herbicide
(End-Use Product)

Acute Oral Toxicity (rats): LD50 > 5000 mg/kg
Toxicity Category: IV

Acute Dermal

Toxicity (rabbits):	LD50 > 2000 mg/kg
Toxicity Category:	III
Primary Eye Irritation (rabbits):	Moderate eye irritant
Toxicity Category:	III
Primary Skin Irritation (rabbits):	Slight dermal irritant
Toxicity Category:	IV
Dermal Sensitization (guinea pigs):	Negative

Cloransulam-methyl Technical
(manufacturing use product)

Acute Oral Toxicity (rats):	LD50 > 5000 mg/kg
Toxicity Category:	IV
Acute Dermal Toxicity (rabbits):	LD50 > 2000 mg/kg
Toxicity Category:	III
Acute Inhalation Toxicity (rats):	LC50 > 3.77 mg/l
Toxicity Category:	III
Primary Eye Irritation (rabbits):	Slight eye irritant
Toxicity Category:	III

Primary Skin Irritation (rabbits):	Non-irritating
Toxicity Category:	IV
Dermal Sensitization (guinea pigs):	Negative
Acute Oral Neurotoxicity (rat):	Systemic NOEL ≥ 2000 mg/kg - Highest Dose Tested (HDT)
90-day dietary (mice):	NOEL = 50 mg/kg/day (males) LOEL = 100 mg/kg/day for males based on increased levels of alkaline phosphatase and increased liver weights and an increase in the size of hepatocytes.
21-day dermal (rabbit):	Dermal Irritation NOEL ≥ 1000 mg/kg/day Systemic NOEL = 500 mg/kg/day Systemic LOEL = 1000 mg/kg/day based on decreased red cell count, hemoglobin and hematocrit, anisocytosis and macrocytosis of red cells for females.
Developmental Toxicity (rabbit):	Maternal NOEL = 100 mg/kg/day Maternal LOEL = 300 mg/kg/day based on reduced weight gain, food efficiency, increased abortions, and cesarean section observations. Developmental NOEL = 300 mg/kg/day (HDT)
Developmental Toxicity (rat):	Maternal NOEL = 1000 mg/kg/day (HDT) Developmental NOEL = 1000 mg/kg/day (HDT)
Two Generation Reproduction (rat):	Parental Systemic NOEL = 10 mg/kg/day Parental Systemic LOEL = 100 mg/kg/day based

	on hypertrophy of the collecting ducts and vacuolation consistent with fatty changes. Reproductive and Developmental NOEL = 100 mg/kg/day Reproductive and Developmental LOEL = 500 mg/kg/day based on decreased live pups and increased pup deaths.
1 Year Chronic Feeding (dog):	NOEL = 10 mg/kg/day LOEL = 50 mg/kg/day based on hepatocellular hypertrophy and accumulation of pigment, and increased activity of alkaline phosphatase and alanine aminotransferase liver enzymes and decrease in albumin and total bilirubin.
Chronic Feeding/ Carcinogenicity (rat):	NOEL = 75 mg/kg/day LOEL = 325 mg/kg/day based on significant increase in hemoglobin, hematocrit, and red cell count in males, activities of the liver enzymes aspartate and alanine aminotransferase as well as alkaline phosphatase were decreased in males, cholesterol was decreased in females, specific gravity of urine was decreased in females, increased relative wight in liver and relative weight of testes in males, males exhibited an increased incidence of collecting duct hypertrophy and females exhibited increased incidence of vacuolation in the kidney. There was no evidence of carcinogenicity for cloransulam-methyl in this study.
Carcinogenicity (mouse):	NOEL = 10 mg/kg/day LOEL = 108 mg/kg/day based on a decrease in renal tubule vacuolation in male mice, increased size of centrilobular and midzonal hepatocytes accompanied by altered tinctorial properties in females and centrilobular hepatocyte hypertrophy in males. Total tumor incidence (adenoma + carcinoma) was not increased by dosing with cloransulam-methyl.
Carcinogenicity:	According to the new proposed guidelines for

Carcinogen Risk Assessment (April, 1996), the appropriate descriptor for human carcinogenic potential of cloransulam-methyl is "Not Likely" based on the lack of carcinogenicity in rats and mice.

Mutagenicity: In a mouse micronucleus assay no lethality or evidence of target tissue cytotoxicity and no significant increase in frequency of micro nucleated polychromatic erythrocytes were observed. In two cytogenetic assays, cloransulam-methyl did not induce either cytotoxic or clastogenic effects in rat lymphocytes. In a cultured chinese hamster ovary cell study, cloransulam-methyl was neither cytotoxic nor mutagenic.

Metabolism: A rat metabolism study showed that radio labeled cloransulam-methyl was excreted mainly via urine in females and urine and feces in males. Less than 0.1% of administered dose was found in any tissue at 72 hours post-dose.

ECOLOGICAL CHARACTERISTICS

Avian Acute Toxicity:

Bobwhite Quail: LD_{50} > 2250 mg/kg bw

Avian Dietary Toxicity:

Bobwhite Quail: 5-day LC_{50} > 5620 ppm
Mallard Duck: 5-day LC_{50} > 5620 ppm

Freshwater Fish Acute Toxicity:

Bluegill Sunfish 96-hr LC_{50} > 154 ppm
Rainbow Trout: 96-hr LC_{50} > 86 ppm

Freshwater Invertebrate Toxicity:

Daphnia magna 48-hr LC50 = 98 ppm

Estuarine and Marine Organisms Toxicity:

Silver Side (*Menidia beryllina*) 96-hr LC50 > 121 ppm

Non-Target Insects Toxicity:

Honey Bee Acute Contact	LD50 > 25 µg ai/bee

Seedling Emergence and Vegetative Vigor for Cloransulam-methyl Technical (Tier II)

Seedling Emergence:

Monocot - Corn	EC_{25}/EC_{05} = 0.25 (lb ai/acre) - phytotoxicity
Monocot - Ryegrass	EC_{25}/EC_{05} = 0.178 (lb ai/acre) - phytotoxicity
Monocot - Wheat	EC_{25}/EC_{05} = 0.046 (lb ai/acre) - all parameters similar
Monocot - Onion	EC_{25}/EC_{05} = 0.016 (lb ai/acre) - shoot length
Dicot - Carrot	EC_{25}/EC_{05} = 0.0054 (lb ai/acre) - phytotoxicity
Dicot - Pinto Bean	EC_{25}/EC_{05} = 0.046 (lb ai/acre) - Parameters similar
Dicot - Radish	EC_{25}/EC_{05} = 0.046 (lb ai/acre) - shoot fresh weight
Dicot - Soybean	EC_{25}/EC_{05} = 0.046 (lb ai/acre) - shoot length
Dicot - Tomato	EC_{25}/EC_{05} = 0.0076 (lb ai/acre) - shoot fresh weight
Dicot - Cotton	EC_{25}/EC_{05} = 0.040 (lb ai/acre) - phytotoxicity

Vegetative Vigor

Monocot - Corn	EC_{25} = 0.0053 (lb ai/acre) - shoot fresh weight
Monocot - Onion	EC_{25} = 0.0122 (lb ai/acre) - phytotoxicity
Monocot - Ryegrass	EC_{25} = 0.026 (lb ai/acre) - shoot fresh weight
Dicot - Cotton	EC_{25} = 0.0067 (lb ai/acre) - phytotoxicity

Dicot - Carrot	EC_{25} = 0.0054 (lb ai/acre)	- phytotoxicity
Dicot - Pinto Bean	EC_{25} = 0.0098 (lb ai/acre)	- shoot fresh weight
Dicot - Radish	EC_{25} = 0.0002 (lb ai/acre)	- shoot fresh weight
Dicot - Soybean	EC_{25} = 0.023 (lb ai/acre)	- shoot length weight
Dicot - Tomato	EC_{25} = 0.0006 (lb ai/acre)	- shoot fresh weight

Nontarget Aquatic Plant Toxicity (Tier II):

Vascular Plants	
Duckweed *Lemna gibba*	EC_{50}/EC_{05} = 0.00312 ppm
Nonvascular Plants	
Green algae *Selenastrum capricornuium*	EC_{50}/EC_{05} = 0.00346 ppm

Cloransulam-methyl was shown to be practically non-toxic to birds, practically non-toxic to small mammals, practically non-toxic to bees, practically non-toxic to slightly toxic to fresh water organisms, and practically non-toxic to estuarine / marine organisms. For terrestrial plants, radish is the most sensitive dicot and onion the most sensitive monocot and the ryegrass the most sensitive monocot in the vegetative vigor test. For aquatic plants, green algae was the most sensitive nonvascular species and duckweed the most sensitive vascular species.

Based on the toxicity to non-target terrestrial and aquatic organisms and the modeled exposure data, the use of cloransulam-methyl poses minimal risk to all aquatic organisms (fish, invertebrates, and plants) and to terrestrial animals, including birds, mammals and beneficial insects as well. Cloransulam-methyl is a herbicide and can have adverse growth effects on non-target endangered species of terrestrial plants. DowElanco is participating in the Endangered Species Task Force that is gathering information on the locations of all endangered species relative to areas used for agriculture.

To reduce the risk to non-target plants the following statements are required on the label:

Avoid all direct or indirect contact with non-target plants.

Do not apply near desirable vegetation and allow adequate distance between target area desirable plants to minimize exposure.

Do not apply under conditions which favor runoff or wind erosion of soil containing FirstRate Herbicide to non-target areas.

To prevent off-site movement due to runoff or wind erosion:
- Avoid treating powdery dry or light sandy soils when conditions are favorable for wind erosion. Under these conditions, the soil surface should first be settled by rainfall or irrigation.
- Do not apply to imperious substrates such as paved or highly compacted surfaces or frozen or snow cover ground.
- Do not apply to soils when saturated with water.
- Do not use tail water from the first flood or furrow irrigation of treated fields to treat non target crops unless at least 1/2 inch of rain fall has occurred between application and first irrigation.

Do not apply when weather conditions favor drift to non target sites. To minimize spray drift to non target areas:
- Use low pressure application equipment capable of producing a large droplet spray.
- Do not use nozzles that produce fine-droplet spray.
- Minimize drift by using sufficient spray volume to ensure adequate coverage with large droplet size sprays.
- Keep ground-driven spray boom as low as possible above the target surface.
- Spray when conditions are calm or wind speed is low. Do not apply when wind is gusting or steady wind speed is greater than 10 mph.

The following statement must appear in the Environmental Hazards section of the label: "Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark.Do not contaminate water by disposal of waste waters."

ENVIRONMENTAL CHARACTERISTICS

The susceptibility of cloransulam-methyl to hydrolysis is pH dependent. The parent is stable at pH 5, degraded slow at pH 7, and hydrolyzed rapidly at ph 9. Cloransulam-methyl photolyzed rapidly in water with a half life of 22 minutes (pH 7). Photolysis on soil more slowing with half lives, corrected for

metabolism, of 30 to 70 days. With the low reported octanol/water coefficient cloransulam-methyl is not expected to accumulated significantly in fish.

Under aerobic conditions transformation of cloransulam-methyl in soil was initially rapid but slowed over time. The apparent transformation half-life in aerobic soils was estimated at 9 to 13 days. The transformation half-life of cloransulam-methyl residues under anaerobic aquatic conditions was approximately 16 days.

The structurally-similar transformation products, cloransulam, 5-hydroxy-cloransulam-methyl and 5-hydroxy-cloransulam occurred in aerobic and anaerobic metabolism studies. Sulfonamide and cloransulam-methyl fluorethenyl were found in anaerobic conditions. Cloransulam-methyl fluorethenyl appears persistent under anaerobic conditions.

Cloransulam-methyl is highly mobile while the major transformation product also appears to be mobile in soils. Cloransulam-methyl dissipated relatively rapidly from the upper 15 cm of bare ground plots. Transformation products indicate that metabolism and photolysis are likely to be major routes of transformation of cloransulam-methyl in the field. The timing of rainfall or irrigation in relation to dissipation at each test site and laboratory mobility data suggest that leaching may play an important role in dissipation of cloransulam-methyl from the surface layer. So while cloransulam-methyl and its transformation products are likely to be only of slight persistence in the surface, the chemicals may become more persistent when leached into the subsurface.

Due to concerns about the mobility and potential persistence of cloransulam-methyl and its structurally-similar, biologically active transformation products in the subsurface and ground water, and surface water the following label statements are required:

Groundwater Advisory

> This chemical and its transformation products demonstrate the properties and characteristics associated with chemical detected in ground water. The use of this chemical in areas where soils are permeable particularly where the water table is shallow, may result in ground-water contamination.

Surface Water Advisory

> This chemical can contaminate surface water through spray drift.

Under some conditions, this chemical, and/or its transformation products, may have a high potential for runoff into surface water (primarily via dissolution in run off water) for several weeks post-application. Vulnerable Conditions include poorly draining or wet soils with readily visible slopes toward adjacent surface waters, frequently flooded area, areas over-laying extremely shallow ground water, areas with in-field canals or ditches that drain to surface-water, areas not separated or adjacent surface waters with vegetated filter strips, and areas over-laying tile drainage systems that drain to surface water.

Proper Handling Instructions

This product may not be mixed or loaded within 50 feet of any wells (including abandoned wells and drainage wells), sink holes, perennial or intermittent streams and rivers, and natural or impounded lakes and reservoirs. This setback does not apply to properly capped or plugged abandoned wells and does not apply to impervious pad or properly diked mixing/loading areas.

Operations that involve, mixing, loading, rinsing, or washing this product into or from pesticide handling or application equipment or contained within 50 feet of any well are prohibited unless conducted on an imperious pad constructed to withstand the weight of the heaviest load that may be positioned on or moved across the pad. Such a pad shall be designed and maintained to contain any product spills or equipment leaks, container or equipment rinse or washwater, and rainwater that may fall on the pad. Surface water shall not be allowed either flow over or from the pad, which means the pad must be self contained. The pad shall be sloped to facilitate material removal. An unroofed pad shall be of sufficient capacity shall be of sufficient capacity to contain at a minimum 110% of the capacity of the largest pesticide container or application equipment on the pad. A pad that is covered by a roof of sufficient size to completely exclude precipitation from contact with the pad shall have a minimum containment capacity of 100% of the capacity of the largest pesticide container or application equipment on the pad. Containment capacities as described above shall be maintained at all times. The above specific minimum containment capacities do not apply to vehicles when delivering pesticide shipments to the mixing/loading site. States may have in effect additional requirements regarding wellhead setbacks and operational containment.

Do not apply this product through any type of irrigation

system.

Do not use flood irrigation to apply or incorporate this product.

Product must be used in a manner which will prevent back siphoning in wells, spills or improper disposal of excess pesticide, spray mixtures or rinsates.

Prospective groundwater monitoring studies are a condition of registration. The Health Level in water for cloransulam-methyl and/or its acid, cloransulam, is 1000 ppb based on an RfD of 0.1 mg/kg bw/day, and a 10 kg child consuming 1 Liter of water of day. An Ecotoxicity Level will be determined, if necessary, upon receipt and review of the Tier II Phytotoxicity Studies required as a condition of registration. DowElanco agreed to exposure reductions if residues of cloransulam-methyl occur at or above 50% of the health level (500 ppb) in public and private wells. DowElanco will develop modeling scenarios for each of the prospective groundwater monitoring sites simulating conditions over a maximum of 100 years.

TOLERANCE ASSESSMENT

Tolerances are established for the for residues of the herbicide cloransulam-methyl, N-(2-carboxymethyl-6-chlorophenyl)-5-ethoxy- 7-fluoro-(1,2,4)-triazolo[1,5c]-pyrimidine-2-sulfonamide, plus its acid, cloransulam, calculated as parent ester in or on soybean seed at 0.02 parts per million (ppm), soybean forage at 0.1 ppm, and soybean hay at 0.2 ppm.

AGGREGATE EXPOSURES

In examining aggregate exposure, Food Quality Protection Act (FQPA) directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures. The primary non-food sources of exposure the Agency looks at include drinking water (whether from groundwater or surface water), and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

1. From Food and Feed Uses

The Reference Dose (RfD) for cloransulam-methyl is 0.1 mg/kg/day. This value is based on the systemic NOEL of 10 mg/kg/day in the dog chronic feeding study with a 100-fold safety factor to account for interspecies extrapolation and intraspecies variability.

A DRES chronic exposure analysis was conducted using tolerance level residues and 100 percent crop treated information to estimate the Theoretical Maximum Residue Contribution (TMRC) for the general population and 22 subgroups. The chronic analysis showed that exposure from the tolerances in or on soybeans for non-nursing infants (the subgroup with the highest exposure) would be 0.033% of the Reference Dose (RfD). The exposure for the general U.S. population would be 0.007% of the RfD.

The analysis for cloransulam-methyl is a worst case estimate of dietary exposure with all residues at tolerance levels and 100 percent of the commodities assumed to be treated with cloransulam-methyl. Even without refinements, the chronic dietary exposure to cloransulam-methyl appears to be minimal.

2. From Potable Water

As a worst case screen, upper bound estimates (acute/chronic) of the concentration of cloransulam-methyl that might be found in surface water have been calculated with the GENEEC screening model program. For soybeans, based on the assumption of one ground application at the maximum application rate 0.40 lb a.i./A), GENEEC calculates the peak (acute) concentration in runoff water adjacent to the application area to be ppb and the chronic concentration to be 1.83 ppb. Based on the estimated exposures to cloransulam-methyl from drinking water, the percentage of the RfD utilized for non-nursing infants (the subgroup with the highest exposure) would be 0.183% of the Reference Dose (RfD). The exposure for a pregnant female would be 0.061% of the RfD.

For the aggregate dietary exposures from food and drinking water, the percentage of the RfD utilized for non-nursing infants (the subgroup with the highest exposure) would be 0.216% of the RfD. The exposure would be less than 0.061% the RfD for females 20 years old (not pregnant - not nursing). EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Even though these risks represent the worst-case scenario there appears to be no aggregate risk concern associated with the use of cloransulam-methyl on soybeans.

3. From Non-Dietary Uses

There are no non-food uses of cloransulam-methyl registered. No non-dietary exposures are expected for the general population.

4. Cumulative Exposure to Substances with Common Mechanism of Toxicity

For cloransulam-methyl, EPA has not conducted a detailed review of common mechanism yet to determine whether it is appropriate, or how to include this chemical in a cumulative risk assessment. After EPA develops a methodology for apply common mechanism of toxicity issues to risk assessments, the Agency will develop a process (either as part of the periodic review of pesticides or otherwise) to reexamine these tolerance decisions. The Agency has determined that there are no metabolites of toxicological concern associated with cloransulam-methyl. Cloransulam-methyl is a triazolopyrimidine sulfonamide herbicide. Another member of this class is Flumetsulam. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, cloransulam-methyl does not appear to produce a toxic metabolite produced by other substances. Therefore, EPA has not assumed that cloransulam-methyl has a common mechanism of toxicity with other substances.

DETERMINATION OF SAFETY FOR INFANTS AND CHILDREN

FQPA provides that EPA shall apply an additional safety factor for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the data base, unless EPA determines that such an additional factor is not necessary to protect the safety of infants and children. An additional Uncertainty Factor to account for possible increased sensitivity of children to cloransulam-methyl was not used because the pre- and post-natal toxicology data base for cloransulam-methyl is complete with respect to current toxicological data requirements. The results of these studies indicate that infants and children are not more sensitive to exposure, based on the results of the oral rat and rabbit developmental toxicity studies and the 2-generation reproductive toxicity study in rats.

OCCUPATIONAL EXPOSURE

EPA has concluded using the parental NOEL of 10 mg/kg/day from the 2-generation reproduction study in rats that the Margin of Exposure (MOE) for occupational exposure between 2,500 and 14,000. A MOE of 100 is generally accepted as showing an adequate margin of safety. The available evidence does not indicate any evidence of significant toxicity from intermediate term dermal or inhalation routes of exposure.

An occupational chronic risk assessment is not appropriate since worker exposure from application to soybeans once a year

does not occur often enough to be considered a chronic exposure i.e. a continuous exposure that occurs for at least several months.

SUMMARY OF DATA GAPS

1. Tier II Phytotoxicity Studies for cloransulam, 5-hydroxy-cloransulam, and 5-hydroxy-cloransulam-methyl [GLN 123-1 & 123-2]

2. Prospective Groundwater Monitoring Studies

PUBLIC INTEREST FINDING

FirstRate Herbicide is highly effective at controlling three weeds that are very common through out soybean product areas - common cocklebur, giant ragweed and common ragweed. Due to low use rates and the alternative herbicides that will be replaced, the total herbicide volume applied to soybeans will likely to be reduced. FirstRate Herbicide will allow flexibility in crops that can be planted the season following applications. For post-emergent applications First Rate Herbicide will have lower product costs than alternative herbicides.

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