United States Environmental Protection Agency Office of Prevention, Pesticides and Toxic Substances (7501C)



Pesticide Fact Sheet

Name of Chemical: Sulfentrazone

Reason for Issuance: Registration of a New Chemical

Date Issued: February 27, 1997

1. Description of the Chemical

Generic Name: N-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-

5-oxo-1H-1,2,4-triazol-1-yl]phenyl]methanesulfonamide

Common Name: Sulfentrazone

Trade Name: Authority

EPA Shaughnessy Code: 129081

Chemical Abstracts

Service (CAS) Number: 122836-35-5

Year of Initial

Registration: 1997

Pesticide Type: Herbicide

Chemical Family: Aryl Triazolinone

U.S. Producer: FMC Corporation

2. <u>Use Patterns and Formulations</u>

Application Sites: Soybeans

Types of Formulations: 92.2% technical

39.6% flowable liquid end-use 75.0% water dispersible granule

end-use

47.0% water dispersible granule end-use
46.9% water dispersible granule end-use

Types and Methods of Application: Ground application using standard commercial sprayers

Application Rates: Application rates for soybeans range from 0.25 to 0.375 pounds active ingredient per acre in preemergency, preplant incorporated, no-till and minimum till applications.

Carrier: Water, crop oil concentrate, non-ionic surfactant

3. <u>Science Findings</u>

Summary Science Statements

Based upon a battery of acute toxicity studies, Authority Herbicide (technical product) is classified as Toxicity Category III. Sulfentrazone is not carcinogenic. However, under the conditions of the studies reviewed, sulfentrazone caused developmental and reproductive toxicity. The results of these studies elicited a high level of concern, since the developmental toxicity studies demonstrated embryo/fetal toxicity at treatment levels that were not maternally toxic, and significant toxic effects were observed primarily in the second generation animals of the reproduction study. Because these animals had been exposed to sulfentrazone in utero, the possibility that the observed reproductive toxicity resulted from a developmental and/or genotoxic mechanism was suggested.

<u>Chemical Characteristics</u> - Technical Grade

Physical State - Solid

Color - Tan

Odor - Faint sulfur-like

Melting Point - 120-122°C

Density - 0.53 g/ml at 20°C

Solubility - 7.8 X 10² (pH 7)

Vapor Pressure - 1 X 10⁻⁹ mmHg at 25°C

Dissociation Constant - 6.56

Octanol/Water Partition Coefficient - $K_{ow} = 9.8$ at pH 7

pH - 4.78

Toxicology Characteristics

Acute Toxicity - Sulfentrazone Technical

Acute Oral Toxicity in Rats - $LD_{50} > 2855$ mg/kg in males and females; Toxicity Category III

Acute Dermal Toxicity in Rats - $LD_{50} > 2000$ mg/kg in males and females; Toxicity Category III

Acute Inhalation Toxicity in Rats - $LC_{50} > 4.13$ mg/l in males and females; Toxicity Category III

Primary Eye Irritation in Rabbits - Corneal opacity, iritis, diffuse irritation within 24 hr., clearing by day 4; Toxicity Category III

Primary Dermal Irritation in Rabbits - No erythema or edema after 4-hour exposure; Toxicity Category IV

Primary Dermal Sensitization in Guinea-Pigs - Did not exhibit any sensitization potential.

<u>Acute Toxicity</u> - End-Use Products

The end-use products containing sulfentrazone, Authority 4 F Herbicide, Authority 75 DF Herbicide, Authority BL Herbicide, and Authority Broadleaf Herbicide, resulted in acute toxicity classification of III or IV in all areas of acute toxicity testing. The end-use products carry the signal word "CAUTION" to reflect toxicity category III.

Subchronic Toxicity

A 90-day feeding study in rats resulted in a lowest-observed-effect level (LOEL) of 65.8 mg/kg/day in males and 78.1 mg/kg/day in females, and a no-observed-effect level (NOEL) of 19.9 mg/kg/day in males and 23.1 mg/kg/day in females.

A 90-day feeding study in mice resulted in a LOEL of 108.4 mg/kg/day for males and 143.6 mg/kg/day in females, and a NOEL of 60.0 mg/kg/day for males and 79.8 mg/kg/day for females.

A 90-day feeding study in dogs resulted in a NOEL of 28 mg/kg/day and a LOEL of 57 mg/kg/day for males and 73 mg/kg/day for females.

Chronic Toxicity

A 1-year feeding oral study was performed on dogs. The induction of normochromic microcytosis in animals fed diets containing 1800 ppm test material, although compensated by increased red cell production, reflects an adverse treatment-related effect. The microcytosis may have arisen from the inhibition of heme synthesis as indicated by the presence of brown to yellow/brown pigmentation in hepatocytes and reticuloendothelial cells of the liver. The microcytosis induced by sulfentrazone justifies an oral LOEL of 61.2 mg/kg/day for males and 61.9 mg/kg/day for females. The NOEL is 24.9 mg/kg/day for males and 29.6 mg/kg/day for females.

A 18-month feeding/carcinogenicity study in mice resulted a LOEL of 160.5 mg/kg/day in males and 198.0 mg/kg/day in females, based upon treatment-related decreases in hemoglobin and hematocrit. The NOEL is 93.9 mg/kg/day in males and 116.9 mg/kg/day in females.

A 2-year feeding/carcinogenicity study in rats resulted in a LOEL of 82.8 mg/kg/day in males and 67.0 mg/kg/day in females, and a NOEL of 40.0 mg/kg/day in males and 36.4 mg/kg/day in females. There was no evidence of carcinogenicity in this study.

Reproductive/Developmental Toxicity

A developmental toxicity study in rats resulted in a maternal (systemic) LOEL of 50.0 mg/kg/day based upon increased relative spleen weight and splenic extramedullary hematopoiesis. The maternal (systemic) NOEL is 25.00 mg/kg/day. The developmental (fetal) LOEL is 25.0 mg/kg/day based upon 1) decreased mean fetal weight and 2) retardation in skeletal development as evidenced by an increased number of litters with any variation and by decreased numbers of caudal vertebral and metacarpal ossification sites. The developmental (fetal) NOEL is 10.0 mg/kg/day.

Evidence of treatment-related developmental toxicity consisted of decreased fetal viability, decreased fetal body weight, and increased incidence of fetal alterations, comprised, for the most part, of skeletal malformations and variations. A supplementary prenatal oral developmental toxicity study in rats confirmed the maternal and fetal findings of the previously conducted study and did not alter the study conclusions.

In a dietary two-generation reproduction study in rats resulted in the systemic and reproductive/developmental NOEL of 14 mg/kg/day for males and 16 mg/kg/day for females.

Mutagenicity

A reverse gene mutation assay in <u>Salmonella</u> <u>typhimurium</u> yielded negative results, both with and without metabolic activation.

A mouse lymphoma forward gene mutation assay yielded negative results with equivocal results

without activation.

A mouse micronucleus assay test was negative following intraperitoneal injection of 340 mg/kg.

Metabolism

A metabolism study in rats resulted in the administered dose and nearly all radioactivity excreted in the urine, indicating nearly complete absorption. Most of the test article was eliminated by urine and feces within 72 hours, and appeared to be independent of dose and sex.

Environmental Characteristics

Acceptable information from environmental fate studies with respect to the persistence and mobility of sulfentrazone under laboratory and field conditions has been reviewed. Based on the current environmental fate data base, sulfentrazone has the following characteristics: 1) moderately soluble, 2) not susceptible to hydrolysis, 3) extremely susceptible to direct photolysis in water, 4) very stable to photolysis on soil, 5) aerobic half-life of 1.5 years, 6) anaerobic half-life of 9 years, 7) very high mobility in soil (average $K_{oc} = 43$, Kd < 1), and 8) low volatility from soils and water. With these properties, it appears that sulfentrazone is highly mobile and persistent, and has a strong potential to leach into groundwater and move offsite to surface water.

The primary routes of dissipation are through direct aqueous photolysis and leaching. Direct photolysis would only be an effective dissipation pathway in clear shallow waters because sulfentrazone is stable to hydrolysis and biodegradation. Low soil/water partitioning (average $K_{oc} = 43$, Kd < 1) indicates that most sulfentrazone runoff is through dissolution in runoff water, as opposed to adsorption to eroding soil. It also indicates that most sulfentrazone will be partitioned in the water column instead of in the suspended and bottom sediments.

Mechanism of Pesticidal Action

Sulfentrazone control weeds by process of protoporphyrinogen oxidase inhibition (membrane disruption), a mode-of-action commonly referred to as PPO inhibition. Sulfentrazone is primarily taken up by the roots of treated plants. Plants emerging from treated soil turn necrotic and die after exposure to light. Foliar contact causes rapid desiccation and necrosis of exposed plant tissue. Shoot-root soil placement studies indicate that sulfentrazone is primarily absorbed by the roots of the plant following soil applications.

Potential to Contaminate Groundwater

A groundwater exposure estimate for sulfentrazone was conducted based on findings from a prospective groundwater monitoring study in North Carolina. Although the study was incomplete, enough data were collected to confirm that sulfentrazone leaches substantially to groundwater in areas with sandy soils.

Ecological Characteristics

Terrestrial

Sulfentrazone is practically non-toxic to birds on an acute oral and with an LD_{50} greater 2250 mg/kg. Sulfentrazone is practically non-toxic to birds on an avian dietary basis with an LD_{50} greater 5620 ppm. Mammalian results indicate that sulfentrazone is slightly toxic to small mammals on an acute oral basis.

Aquatic

Sulfentrazone is practically non-toxic to the rainbow trout (LC_{50}) greater 120 ppm) and slightly toxic to the bluegill sunfish (93.8 ppm). The results indicate that sulfentrazone is slightly toxic to fish on an acute basis. The chronic results indicate that sulfentrazone significantly affects young fish survival and growth at aquatic concentrations as low as 5.93 ppm. Sulfentrazone is slightly toxic to aquatic invertebrates on an acute basis.

The results from data from chronic freshwater invertebrates indicate that survival of young daphnids is adversely affected at sulfentrazone concentrations as low as 0.51 ppm. The results from acute estuarine and marine animals study are incomplete but indicate that sulfentrazone is highly toxic to estuarine/marine organisms.

Plants

Being a pre-plant and pre-emergent herbicide, sulfentrazone is expected to prevent the successful emergence of non-target terrestrial and semi-aquatic plants through soil that has been exposed. The proposed use is not expected to pose an unacceptable risk to non-target terrestrial or aquatic animals.

For nontarget terrestrial plant Tier II seedling emergence, the results indicate that lettuce is the most sensitive dicot and oat is the most sensitive monocot. For Tier II vegetative vigor, cucumber is the most sensitive dicot and onion is the most sensitive monocot.

For aquatic plant testing the results indicate that duckweed is the most sensitive aquatic plant species.

4. <u>Summary of Regulatory Position and Rationale</u>

Available data provide adequate information to support the conditional registration of Authority herbicide as a technical product, Authority 4 F herbicide, Authority 75 DF herbicide, Authority Broadleaf herbicide, and Authority BL herbicide for use on soybean seed, in cereal grains (excluding sweet corn), forage, straw, hay, grain, stover, bran and hulls.

The registrant will add statements to the end use labels to mitigate the risk to groundwater and will conduct further prospective groundwater studies to further address the Agency's concerns.

Use, Formulation, Manufacturing Process or Geographic Restrictions:

Environmental Hazards

This pesticide is toxic to marine/estaurine invertebrates. Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Drift and runoff may be hazardous to terrestrial and aquatic plants in neighboring areas. Do not contaminate water when disposing of equipment washwaters or rinsate.

Groundwater Advisory and Labeling-Off of Soil Type: This chemical is known to leach through soil into ground water under certain conditions as a result of label use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination.

Do not use on coarse soils classified as sand which have less than 1% organic matter."

Surface Water Advisory: Sulfentrazone can contaminate surface water through spray drift. Under some conditions, sulfentrazone may also have a high potential for runoff into surface water (primarily via dissolution in runoff water), for several to many months post-application. These include poorly draining or wet soils with readily visible slopes toward adjacent surface waters, frequently flooded areas, areas overlying extremely shallow ground water, areas with in-field canals or ditches that drain to surface water, areas not separated from adjacent surface waters with vegetated filter strips, and areas over-lying tile drainage systems that drain to surface waters."

Use Directions - General Precautions

Do not use on crops other than soybeans.

Use only ground application equipment. Do not apply by air.

Do not apply this product through any type of irrigation system.

Do not flood irrigation to apply or incorporate this product.

Do not apply when wind speed exceeds 10 mph nor with a spray pressure exceeding 40 psi.

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.

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 of this product into or from pesticide handling or application equipment or containers within 50 feet of any well are prohibited unless conducted on an impervious 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 to 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 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."

<u>Use Directions - Soybeans - Preemergence</u> - Apply only one preemergence application, not to exceed 0.375 lb ai/acre per year, up to 30 days before crop emergence. Can also be applied during or after planting, but before the crop emerges.

<u>Use Directions - Soybeans - Preplant Incorporated</u> - Apply only one preplant incorporated application, not to exceed 0.375 lb ai/acre per year, up to 30 days prior to planting soybeans.

5. <u>Summary of Data Gaps</u>

Toxicology Data:

- 1. 21-day dermal study in rabbits
- 2. <u>In vivo</u> cytogenetics dominant lethal assay in rats

Residue Chemistry Data:

- 1. Wheat processing study
- 2. Additional rice field trials
- 3. Residue data for sorghum aspirated grain fractions

Ecological Effect Data:

1. Acute oyster toxicity study

6. Contact Person at EPA

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