Regulatory Decision Document RDD99-01

Sulfosulfuron Herbicide

This Decision Document has been prepared on sulfosulfuron herbicide as part of the ongoing effort to make regulatory information more widely available. Input from a number of specialists and other interested parties is reflected in this document. Based on the review of all available information and in consideration of the input received, a regulatory decision has been made to grant registration for the use of sulfosulfuron in Western Canada for control of wild oats and certain broadleaf weeds in wheat.

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1.0 Introduction

This Decision Document is the final stage in the Pest Management Regulatory Agency's (PMRA) regulatory decision-making process concerning the use of sulfosulfuron (Sundance®) herbicide on wheat.

2.0 Regulatory Decision

Based on the considerations outlined in the following text, the PMRA has granted registration for the application of sulfosulfuron on wheat using ground equipment.

3.0 Background

The PMRA has been reviewing a registration submission for application of sulfosulfuron in wheat. The sulfosulfuron assessment is noteworthy in that it is the first chemical that goes beyond the North American Free Trade Agreement (NAFTA) Technical Working Group Joint Review initiative and has been reviewed cooperatively on an international basis. The assessment also served as a learning opportunity to appraise the international dossier structure and format being developed through the Organisation for Economic Co-operation and Development (OECD), using a practical example.

Canada, the United States, Australia and the European Union (EU), with Ireland as lead EU country, cooperated in this pilot project that built on previous North American Joint Review/Workshare experience and international harmonization interests focused through the OECD.

The assessment and regulatory processes are well advanced in all participating countries and within the OECD infrastructure. Canada and Ireland are among the first countries in a position to register this product within the OECD. Sulfosulfuron has previously had interim registration and temporary tolerances in the U.S. Final U.S. Environmental Protection Agency (U.S. EPA) approvals, including harmonized maximum residue limits (MRLs), are expected later this spring.

This cooperative review project reflects a worldwide approach by the manufacturer and regulatory agencies in evaluating information as well as a commitment to the flexibility and cooperation essential in making international harmonization feasible. The cooperative review is key to avoiding trade irritants by allowing harmonized MRLs or tolerances to be developed among countries.

Sulfosulfuron was assessed within the PMRA 25% faster than the established standard for a new active ingredient (a.i.). This saving reflects the efficiencies gained through international cooperation and exchange, and use of each other's reviews. While relatively modest, it is

nevertheless significant for an initial pilot, and is particularly important since it positions sulfosulfuron to be available for the 1999 growing season. This approach did not compromise the protection of human health or the environment, as the work was divided and the studies examined in detail by participating agencies.

4.0 Comments and Responses

A total of four responses was received by the Agency concerning the Proposed Regulatory Decision Document (PRDD) published on December 29, 1998. All of the comments were from the public or public interest sector and related to environmental impact considerations. Many comments were generic in nature, i.e., broadly relevant to herbicides in general and/or the sulfonylurea group of herbicides. The Agency has consolidated and summarized the comments received and is providing a response to each comment.

4.1 Analytical Methods

Comments on PRDD Sections 2.3.4 and 2.3.5

1. *Currently there are no analytical methods which can measure low concentrations in the environment.*

2. *Sulfonylureas affect the vegetative growth and reproduction at very low doses, often below detection level.*

Response **Methodology to Detect Acetolactate Synthase-Inhibiting Herbicides in the Environment**

Sulfosulfuron is a member of the sulfonylurea family of herbicides used widely throughout the world for control of broadleaf and grass weeds in a range of crops including cereals and corn. The fundamental mode of action for sulfosulfuron and indeed all sulfonylurea herbicides entails inhibition of acetolactate synthase (ALS) an essential enzyme in aliphatic amino acid synthesis.

There are several active ingredients from this chemical family currently registered in Canada and the U.S. They share a common characteristic of biological activity at very low rates, e.g., typical rates for effective weed control are in grams of active ingredient per hectare. Recognizing these properties, commentary regarding the ability to detect these materials in the natural environment at low levels and effects on non-target plants is quite legitimate.

Analytical methods for the determination of sulfonylurea herbicides at low concentrations are available in the published literature with detection limits of 5* and 50 parts per trillion** in water and soil, respectively. The limits of detection are lower than the effect levels, demonstrated in studies received on terrestrial and aquatic plants. Registrants are attempting to further develop more sensitive methods to measure the residues at low concentrations.

4.2 Environmental Fate

Comments on PRDD Section 5.1.2

1. *The maximum accumulation of residues of sulfosulfuron in two soils (type, pH, location?) over a 360-day period (in laboratory studies) was 21% of the applied amount. This seems to indicate persistence of the product.*

2. *The reported* DT_{90} *values show that it takes a considerably longer period of time for 90% of the residues to dissipate, which indicates a potential for residue carryover into the next year.*

3. *Registration of a "moderately persistent" herbicide is inappropriate.*

Response **Persistence of Sulfosulfuron in Soils**

Biotransformation studies conducted under laboratory conditions with U.S. soils indicated a maximum accumulation of 21% of applied amount. The soils used were a sandy loam from California (pH 7.6) and a silt loam from Illinois (pH 6.8). Canadian field studies indicated, however, that sulfosulfuron is slightly to moderately persistent in soils.

The 90 percent dissipation (DT_{90}) values calculated from the field data indicated the time required for 90% dissipation of the pesticide applied. They serve to flag a potential for carryover. However, examination of the Canadian field data (measured concentrations) indicated that there was a maximum carryover of only 15% of applied amount at the end of a 192-day period. Estimation of soil concentrations from annual 15% carryover over a ten-year period indicated no substantial accumulation in soil which would lead to any consequent effects in the environment.

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* D'Ascenzo, G., A. Gentili, S. Marchese, A. Marino and D. Perret. 1998. Multi-residue method for determination of post-emergence herbicides in water by high performance liquid chromatography (HPLC)/electron-specific ionization/mass spectrometry (MS) in positive ionization mode. Environ. Sci. Technol. 2:1340–1347.

** Li, T.T.L., D.A. Campbell, P.K. Bennett and J. Henion. 1996. Acceptance criteria for ultra-trace HPLC-Tandem MS: Qualitative and quantitative determination of sulfonylurea herbicides in soil. Anal. Chem. 68:3397–3404.

Comments on PRDD Section 5.1.4

4. Sulfosulfuron and its transformation products were primarily detected in the upper 0- to15-cm soil layer, and they have a low potential to leach to groundwater.

and PRDD Section 5.1.6

5. On the basis of laboratory adsorption and soil column leaching studies, sulfosulfuron, sulfonamide, and desmethyl can be classified as having high potential for mobility in soils.

Response

The adsorption and soil column leaching studies were conducted under laboratory conditions and indicated a potential for mobility. This potential was, however, not realized under field conditions. Laboratory studies are designed, often in a worst-case scenario, to determine the potential for a particular process to occur. On the other hand, field studies are designed to approximate actual use conditions and include integration of all dissipative processes, including transformation and transport. It is not unusual for field results to indicate less potential than laboratory results.

4.3 Impact on Non-target Plants

Comments on PRDD Section 6.1.7

1. Data provided for the plant terrestrial risk assessment only includes ten terrestrial crop species. Sulfonylureas affect the vegetative growth and reproduction at very low doses, often below detection level. Additional testing should be required to assess effects of sulfosulfuron on non-crop species, including emergent wetland species, both at seedling and reproductive stages.

2. The potential effect(s) on non-target plants have not been adequately addressed. Particular attention should be paid to critical times of exposure, e.g., during reproduction. The guidelines for non-target plant toxicity developed by the Canadian Wildlife Service (CWS) should be followed explicitly.

Response

Neither testing of non-crop species nor testing for reproductive effects on plants is a requirement internationally. As these issues are being examined under NAFTA and the

OECD, there may be different requirements in the future. The work of the CWS is being considered in discussions in these fora.

Comment

3. Sulfonylureas are not exceptionally toxic to woody plants. The size difference alone between a radish (most sensitive plant species) and a tree would suggest that more deposition would be required to produce an effect on a tree.

Response

There have been several reports of effects of sulfonylurea herbicides on orchards via drift from neighbouring treated fields. As no data were submitted on effects/toxicity to woody plants, available data from crop species were extrapolated to all non-crop plants. Plant size is not a factor in this extrapolation.

4.4 Risk Assessment

Comments on PRDD Section 6.4.2

1. The median lethal concentration (LC_{50}) to duckweed is 0.001 mg active ingredient per litre (a.i./L) and the predicted concentration in prairie pond water from runoff is 0.0034 mg a.i./L.

Response

The assessment of risk to non-target aquatic plants was done using a worst-case scenario (no observed effect concentration [NOEC] 0.0005 mg a.i./L). Sulfosulfuron is only slightly and moderately persistent under aerobic and anaerobic conditions, respectively, in aquatic systems (Sections 5.2.3 and 5.2.4). The proposed buffer zone of 6 m will provide a reasonable margin of safety against drift and runoff to aquatic systems.

Comment

2. Aquatic risk assessments for sulfosulfuron were based on NOEC/no observed effect level (NOEL) values rather than lowest observed effect concentration (LOEC) values, which would be more appropriate for risk management calculations. Endpoint information should be included on the pesticide label with use precautions.

Response

The PMRA has determined that NOEC/NOEL values are more appropriate endpoints for the risk assessment with aquatic organisms. Using these values provides greater protection to the aquatic organisms than using LOEC values.

Label statements, such as "this product is toxic to aquatic plants", provide suitable information on toxicity to users. More detailed endpoint information will be available in PMRA regulatory documents.

4.5 Data Requirements

Comment

1. The toxicity of the pesticide product, i.e., including the surfactant should be evaluated.

Response **Evaluation of Inerts as well as the Active Ingredient**

Environmental impact is initially assessed through a series of laboratory studies focusing on the active ingredient.

Typically, toxicity studies are conducted with the technical active well in advance of decisions on formulation. The PMRA can request studies with the formulated product on a case-by-case basis if there are reasons for concern. In this case, there were no concerns that triggered studies with the formulated product. Similarly, as Sundance® is mixed with Merge®, a surfactant that has been widely used for several years without reports of adverse effects, toxicity studies with the spray mixture were not required.

Comments on PRDD Section 6.1.6

2. Toxicity to fungal species was not examined. It would be inappropriate to register a product which disrupts the important ecological role, in agricultural and natural habitats, that these species play.

3. An assessment of toxicity to soil micro-organisms, including soil-borne pathogens, was not considered.

Response **Toxicity to Fungal Species and Soil Micoorganisms**

In the past, data on soil micro-organisms have been required. These data did not reveal any long-lasting detrimental effects on the soil microbial community. Therefore, these studies are no longer required. In the case of sulfosulfuron, there are studies on its effects on soil

microbial biomass and nitrogen transformations, which were reviewed by the EU. According to their reviews, sulfosulfuron had no significant effect on soil microbial biomass and nitrogen transformations in soils at the proposed maximum application rate. These parameters are good indicators of soil microbial activity, fungi included. In support of the EU findings, the PMRA had previously arrived at similar conclusions regarding the effects of three other sulfonylurea herbicides on soil microbes.

Comments on PRDD Sections 6.2.5 and 6.4.2

4. The company should be required to provide data for prairie species of submerged macrophytes, given the persistence of sulfosulfuron in water (see Sections 5.2.3 and 5.2.4).

Response **Toxicity to Submerged Macrophytes**

Sulfosulfuron is only slightly and moderately persistent under aerobic and anaerobic conditions, respectively, in aquatic systems (Sections 5.2.3 and 5.2.4). The NOEC rather than LC_{50} for aquatic plants was used in risk assessment. This will provide adequate protection to the submerged macrophytes. Therefore, the PMRA does not require data on macrophytes.

Comment

5. The toxicity to amphibians was not examined.

Response **Toxicity to Amphibians**

The PMRA does not require testing of pesticides with amphibians, but does require buffer zones to be established around any sensitive terrestrial and/or aquatic system including wetlands. These buffer zones minimize the risk to potentially sensitive species, such as amphibians.

4.6 Label Statements

Comments on PRDD Section 6.5

Buffer zone restrictions on pesticide labels are becoming an increasing source of dissatisfaction among pesticide users who view label buffer zones as restrictions for the sake of restrictions with little relevance to responsible product use. The label for sulfosulfuron and other products should provide users with all of the information available to support safe and effective application.

Response

The PMRA believes that the buffer zones are appropriate. They allow the product to be used in a way that protects the environment. The PMRA will continue to work with provincial regulators to provide guidance and to ensure that they understand the importance of buffer zones.

4.7 Integrated Pest Management and Non-chemical Alternatives

Comment

Alternatives to chemical pesticides were not examined (or at least discussed) in the pre-registration process. In particular, integrated weed management options should be considered and recommended for the weed species targeted.

Response

Generic information related to integrated weed management (IWM) and production practices which could be implemented in cereals is readily available from provincial extension. This information applies to all herbicides including sulfosulfuron. In addition, there have been several excellent review articles written on IWM specific to cereals under Canadian conditions.

4.8 Resistance

Comment

There is a high potential for development of resistance to ALS inhibitors.

Response

The PMRA is aware of the importance of delaying the development of resistance to herbicides as well as other pesticides that are registered in Canada.

The Sundance® label identifies the product as a Group 2 mode of action herbicide (inhibition of ALS) according to the herbicide grouping system, and provides the applicator with directions on resistance management strategies.

4.9 Post-registration Monitoring

Comments

1. *Methods and plans to track the dispersal and effect of ALS-inhibiting herbicides must be in place. The PMRA and the registrant have responsibilities to track pesticide post-registration, and that cannot be guaranteed at this point.*

2. *Data regarding shelterbelt sensitivities can be gathered as part of a post-registration monitoring exercise and additional research can be completed prior to product renewal.*

Response

The PMRA believes that buffer zones offer sufficient protection to sensitive non-target plant species and that monitoring as a condition of registration is not required.

Acronyms

a.i./L	active ingredient per litre
ALS	acetolactate synthase
CWS	Canadian Wildlife Service
DT_{90}	90 percent dissipation
EU	European Union
HPLC	high-performance liquid chromatography
IWM	integrated weed management
LC_{50}	median lethal concentration
LOEC	lowest observed effect concentration
MRL	maximum residue limit
MS	mass spectrometry
NAFTA	North American Free Trade Agreement
NOEC	no observed effect concentration
NOEL	no observed effect level
OECD	Organisation for Economic Co-operation and Development
PMRA	Pest Management Regulatory Agency
PRDD	Proposed Regulatory Decision Document
U.S. EPA	United States Environmental Protection Agency