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Registration Decision

RD2010-05

Saflufenacil

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Registration Decision for Saflufenacil

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of saflufenacil technical (Kixor) and its end use products Heat WG, Eragon and Integrity, containing the technical grade active ingredient saflufenacil to control broadleaf weeds in lentils, soybean, barley, canary seed, chickpea, field corn, sweet corn, oats, dried field peas, wheat (spring, durum and winter) and in chemfallow.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document¹: Proposed Registration Decision PRD2009-18, *Saflufenacil*. This Registration Decision² describes this stage of the PMRA's regulatory process for saflufenacil and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2009-18. This decision is consistent with the proposed registration decision stated in PRD2009-18.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2009-18, *Saflufenacil* that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable³ if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value⁴ when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

¹ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*

² "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

³ "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

⁴ "Value" as defined by subsection 2(1) of *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What is Saflufenacil?

Saflufenacil is a herbicidal compound which inhibits the protoporphyrinogen-IV oxidase enzyme in sensitive plants. The result is build-up of phytotoxic intermediates, rapid development of chlorotic to necrotic symptoms and ultimately plant death. This compound is efficacious against broadleaf weeds.

Saflufenacil is regarded as a Weed Science Society of America Group 14 or Herbicide Resistance Action Committee Group E herbicide.

Heat WG and Eragon contain the active ingredient saflufenacil at 70%. Integrity contains saflufenacil at 68 grams per litre of product and dimethenamid-P at 600 grams per litre of product.

Health Considerations

Can Approved Uses of Saflufenacil Affect Human Health?

Saflufenacil is unlikely to affect your health when used according to label directions.

Exposure to saflufenacil may occur through diet (food and water) or when handling and applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population, such as children and nursing mothers. Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when using saflufenacil products according to label directions.

Saflufenacil end-use products Heat WG and Eragon cause dermal irritation in rabbits. Integrity is a dermal and eye irritant as well as a potential skin sensitizer. All end-use formulations are of low acute toxicity by the oral, dermal, and inhalation routes of exposure.

When tested in laboratory animals, technical saflufenacil was not genotoxic, oncogenic, neurotoxic, or toxic to the reproductive system. Repeat administration of saflufenacil resulted in microcytic hypochromic anemia affecting the red blood cell parameters.

In the rat developmental toxicity study, saflufenacil delayed the development of fetuses and resulted in an increased incidence of the skeletal malformation (bent scapula) at a dose that was not toxic to the dams. No adverse developmental effects were observed in the rabbit developmental toxicity study. The identified offspring toxicity in the absence of maternal toxicity and the occurrence of skeletal formation in the rat developmental toxicity study are taken into consideration in the assessment of risk to infants and children.

The risk assessment protects against these effects by ensuring levels of human exposure are well below the lowest dose at which these effects occur in animal studies.

Residues in Water and Food

Dietary risks from food and water are not of concern

Aggregate dietary intake estimates (food plus water) revealed that the general population, including infants, the subpopulation which would ingest the most saflufenacil relative to body weight, are expected to be exposed to less than 24.4% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from saflufenacil is not of concern for all population subgroups.

A single dose of saflufenacil is not likely to cause acute health effects in the general population or in women aged 13-49 years. The aggregate (food and water) dietary intake estimates were 44.37% of the reference dose for females 13-49 years old and $\leq 0.61\%$ of the reference dose for all other population subgroups, which are not a health concern.

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Food containing pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Results proved acceptable from residue trials conducted throughout Canada and the United States using saflufenacil on legume vegetables (Crop Group 6), citrus fruits (Revised Crop Group 10), pome fruits (Crop Group 11), stone fruits (Crop Group 12), tree nuts (Crop Group 14), cereal grains (Crop Group 15), grapes, sunflower seeds and cotton. The MRLs for this active ingredient can be found in the Science Evaluation section of Proposed Registration Decision PRD2009-18, *Saflufenacil*.

Occupational Risks From Handling Heat WG, Eragon and Integrity

Occupational risks are not of concern when Heat WG, Eragon and Integrity are used according to the proposed label directions, which include protective measures.

Farmers and pesticide applicators mixing, loading or applying Heat WG, Eragon and Integrity as well as field workers re-entering freshly treated fields can come in direct contact with Heat WG, Eragon and Integrity on the skin or through inhalation of spray mists.

Therefore, the labels will specify appropriate personal protective equipment such as long-sleeved shirt, long pants, chemical-resistant gloves, shoes plus socks, coveralls, chemical-resistant coveralls, goggles or face shield, or engineering control for anyone conducting specific tasks with one of the end-use products of saflufenacil. Full details are provided in the risk-reduction measures for human health.

Taking into consideration the label requirements and that occupational exposure is expected to be short- to intermediate-term because this herbicide may be applied to any given crop only twice per year, risk to farmers, applicators or workers is not a concern.

For bystanders, exposure is expected to be much less than that of field workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

For postapplication, exposure is expected to be minimal because Heat WG, Eragon and Integrity are applied directly to the ground using a groundboom sprayer either before the crop has been planted or after it has been planted but before emergence. Therefore, health risks to workers entering treated fields are not of concern.

Environmental Considerations

What Happens When Saflufenacil is Introduced into the Environment?

Saflufenacil and its degradates have high potential to reach groundwater. Without risk-reduction measures, saflufenacil may impact non-target terrestrial plants adjacent to the treatment area.

Saflufenacil is degraded by both chemical reactions and microorganisms in soil and aquatic systems. The rate of degradation is enhanced by sunlight. Saflufenacil is non-persistent to slightly persistent in soil and moderately persistent in aquatic systems. Saflufenacil and its degradates are mobile in soil and have high potential to reach groundwater. Saflufenacil does not bioconcentrate and is therefore unlikely to bioaccumulate.

Risks to non-target terrestrial plants as a result of spray drift have been identified in areas adjacent to the treatment area. There are no concerns about saflufenacil or its transformation products affecting any other non-target organisms.

Risks to aquatic plants and amphibians have been identified for the Integrity formulation, which is a co-formulation of saflufenacil and another herbicide, dimethenamid-P.

Value Considerations

What Is the Value of Heat WG, Eragon and Integrity?

Saflufenacil, a postemergence and a residual herbicide, controls a broad spectrum of broadleaf weeds in lentils, soybean, barley, canary seed, chickpea, field and sweet corn, oats, dried field peas, wheat (spring, durum and winter) and in chemfallow.

A single application of saflufenacil provides effective control of several broadleaf weeds including kochia, Canada fleabane, lamb's quarters, redroot pigweed, round-leaved mallow, stinkweed, volunteer Canola (all herbicide tolerant types including Roundup Ready), wild buckwheat, wild mustard, common ragweed and velvetleaf; it also suppresses dandelion.

Saflufenacil is compatible with integrated weed management practices, conservation tillage and conventional crop production systems. As saflufenacil is applied after weed emergence, growers are able to assess whether the herbicide is suitable for the particular weed species present.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of Heat WG, Eragon and Integrity to address the potential risks identified in this assessment are as follows:

Key Risk-Reduction Measures

Human Health

As there is a concern with users coming into direct contact with Heat WG, Eragon and Integrity on the skin or through inhalation of spray mists, anyone mixing, loading and applying Heat WG, Eragon and Integrity must wear appropriate personal protective equipment.

Integrity

Wear a long-sleeved shirt, long pants, chemical-resistant gloves and shoes plus socks during mixing, loading, clean-up and repair. In addition, wear goggles or face shield during mixing and loading. Applicators must wear a long-sleeved shirt, long pants and shoes plus socks.

Custom applicators performing mixing, loading and application must wear chemical-resistant coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, and goggle or face shield during mixing and loading.

Heat WG and Eragon

Wear coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves and shoes plus socks during mixing, loading, clean-up and repair. In addition, wear goggles or face shield during mixing and loading. Applicators must wear a long-sleeved shirt, long pants, coveralls and shoes plus socks.

Custom handlers treating corn fields must wear chemical-resistant coveralls over a long-sleeved shirt, long pants and chemical-resistant gloves during mixing, loading, application, clean-up and repair and, additionally, goggles or a face shield during mixing and loading. Custom applicators performing mixing, loading, and application must use a closed mixing and loading system.

In addition, standard label statements to protect against drift during application were added to the labels.

Environment

To mitigate risks from the use of saflufenacil to non-target terrestrial plants, spray buffer zones are required to protect terrestrial habitats adjacent to the treatment area. The sizes of the buffer zones range from 4 to 15 metres for application rates ranging 18 to 100 grams of saflufenacil per hectare.

To mitigate risks to aquatic plants and amphibians from the use of Integrity, a spray buffer zone of one metre is required on the Integrity label to protect aquatic habitats adjacent to the treatment areas.

Other Information

1. The relevant test data on which the decision is based (as referenced in this document) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).
2. Any person may file a notice of objection⁵ regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website under Request a Reconsideration of Decision (www.hc-sc.gc.ca/cps-spc/pest/protect-proteger/publi-regist/index-eng.php#rrd) or contact the PMRA's Pest Management Information Service.

⁵ As per subsection 35(1) of the *Pest Control Products Act*.

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3.0 Environment

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4.0 Value

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B. Additional Information Considered

i) Published Information

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