Registration Decision RD2010-14

Pyroxsulam

(publié aussi en français)

3 December 2010

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario
K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

HC Pub: 100497

ISBN: 978-1-100-16870-8 (978-1-100-16871-5)
Catalogue number: H113-25/2010-14E (H113-25/2010-14E-PDF)

Registration Decision for Pyroxsulam

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 Pyroxsulam Technical Herbicide and Simplicity Herbicide, containing the technical grade active ingredient pyroxsulam, to control broadleaf and grassy weeds in spring wheat and durum wheat using ground or aerial application equipment.

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 proposed for full registration in the consultation document[1]: Proposed Registration Decision PRD2010-15, *Pyroxsulam*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for pyroxsulam and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2010-15. This decision is consistent with the proposed registration decision stated in PRD2010-15.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2010-15, *Pyroxsulam* and Evaluation Report ERC2010-04, *Pyroxsulam* that contain 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 acceptable[3] 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 value[4] 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 *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 (e.g. children) as well as organisms in the environment (e.g. 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 Pesticide and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is Pyroxsulam?

Pyroxsulam is the active ingredient in the end-use product Simplicity Herbicide. Simplicity Herbicide is a postemergence herbicide, i.e., a herbicide applied after the crop has emerged from the ground, which is applied to spring wheat and durum wheat using ground or aerial application equipment to control broadleaf and grassy weeds. Pyroxsulam inhibits the plant enzyme acetolactate synthase (ALS) in target weeds.

Health Considerations

Can Approved Uses of Pyroxsulam Affect Human Health?

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

Exposure to pyroxsulam may occur through diet (food and water), or when handling or 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. 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 products containing pyroxsulam are used according to label directions.

Both the technical grade active ingredient, Pyroxsulam Technical Herbicide, and the end-use product, Simplicity Herbicide, are considered to be potential skin sensitizers; consequently, the label statement "Potential Skin Sensitizer" is required. The end-use product, Simplicity Herbicide, was considered to be of slight acute toxicity by the inhalation route and moderately irritating to eyes and skin, resulting in the requirement for the label statements "Warning Poison" and "Eye and Skin Irritant".

Pyroxsulam was not genotoxic and did not cause cancer in animals. There were no indications that pyroxsulam caused damage to the developing fetus, the reproductive system, or the nervous system. Health effects in animals given daily doses of pyroxsulam over long periods of time included effects on the liver.

A risk assessment is conducted to ensure that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests. The dose levels used to assess risks are established to protect the most sensitive human population (e.g., children and nursing mothers). Only those uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Residues in Water and Food

Dietary risks from food and water are not of concern

Reference doses define levels to which an individual can be exposed over a single day (acute) or lifetime (chronic) and expect no adverse health effects. Generally, dietary exposure from food and water is acceptable if it is less than 100% of the acute reference dose or chronic reference dose (acceptable daily intake). An acceptable daily intake is an estimate of the level of daily exposure to a pesticide residue that, over a lifetime, is believed to have no significant harmful effects.

Aggregate dietary intake estimates (food plus water) revealed that the general population and infants, the subpopulation which would ingest the most pyroxsulam relative to body weight, are expected to be exposed to less than 1% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from pyroxsulam is not of concern for all population sub-groups. The lifetime cancer risk from the use of pyroxsulam on wheat is considered acceptable.

Animal studies revealed no acute health effects of pyroxsulam. No endpoint of concern attributable to a single dose was identified. Consequently, a single dose of pyroxsulam is not likely to cause acute health effects in the general population (including infants and children).

The Food and Drugs Act (FDA) 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 FDA purposes through the evaluation of scientific data under the Pest Control Products Act (PCPA). Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Residue trials conducted throughout Canada using pyroxsulam on wheat were acceptable. The MRLs for this active ingredient can be found in the Science Evaluation section of Evaluation Report ERC2010-04, *Pyroxsulam*.

Occupational Risks From Handling Simplicity Herbicide

Occupational risks are not of concern when Simplicity Herbicide is used according to the proposed label directions, which include protective measures.

Farmers and custom applicators who mix, load or apply Simplicity Herbicide as well as field workers re-entering freshly treated fields can come in direct contact with Simplicity Herbicide residues on the skin. Therefore, the label specifies that anyone mixing/loading and applying Simplicity Herbicide must wear coveralls over a long sleeved shirt and long pants, chemical-resistant gloves, socks and chemical-resistant footwear. During mixing and loading, eye protection is also required. Taking into consideration these label statements, the number of applications and the expectation of the exposure period for handlers and workers, risk to these individuals are not a concern.

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

Environmental Considerations

What Happens When Pyroxsulam Is Introduced Into the Environment?

Pyroxsulam can pose a risk to terrestrial and aquatic vascular plants, and the formulation Simplicity Herbicide can pose a risk to amphibians; therefore, spray buffer zones are required during application.

Pyroxsulam enters the environment when used as a herbicide on wheat. It is stable to hydrolysis but can phototransform in shallow, clear, water bodies. Pyroxsulam is non-persistent to slightly persistent in aerobic soil and in water. It is however considered persistent under anaerobic conditions. Pyroxsulam and its transformation products are expected to leach through the soil profile beyond 30 cm in some soils and therefore may be expected to enter groundwater. Based on Canadian field studies, residues of pyroxsulam and its transformation products are not expected to significantly carry over into the next growing season. Based on its low volatility, pyroxsulam residues are not expected in the air.

Pyroxsulam and its major transformation products present a negligible risk to wild mammals, birds, earthworms, bees and other arthropods, aquatic invertebrates, fish, and green algae. However, given that pyroxsulam is a herbicide, it is expected to adversely affect terrestrial plants in adjacent areas. Spray buffer zones of 2 metres for ground application and 55 to 65 metres for aerial application (depending on application equipment) are required to protect nearby terrestrial plants from the effects of spray drift. Pyroxsulam can potentially affect aquatic vascular plants in adjacent areas, while an aromatic petroleum distillate in the end-use product, Simplicity Herbicide, can potentially affect amphibians in adjacent areas. Therefore, a spray buffer zone of 1 metre is required to protect aquatic vascular plants and amphibians from the effects of spray drift.

Value Considerations

What Is the Value of Simplicity Herbicide?

Simplicity Herbicide, a postemergence herbicide, controls wild oats and broadleaf weeds in spring wheat and durum wheat.

A single application of Simplicity Herbicide provides effective control of a range of broadleaf weeds and wild oats in spring wheat and durum wheat. It is also compatible with integrated weed management practices and with conservation tillage and conventional crop production systems. Because Simplicity Herbicide is applied after weeds have emerged, producers can better assess whether the herbicide is necessary or suitable for particular weed species. Simplicity Herbicide provides an alternative to Group 1 herbicides, which are of concern given the spread of ACCase-resistant wild oats.

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 being proposed on the label of Simplicity Herbicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Because there is a concern with users coming into direct contact with Simplicity Herbicide on the skin, anyone mixing, loading and applying Simplicity Herbicide must wear coveralls over a long sleeved shirt and long pants, chemical-resistant gloves, socks and chemical-resistant footwear. During mixing and loading, eye protection is also required. In addition, standard label statements to protect against drift during application were added to the label.

Environment

Spray drift of pyroxsulam and the end-use product Simplicity Herbicide can pose a risk to terrestrial plants, aquatic vascular plants and amphibians. To mitigate the risk from the effects of spray drift, a buffer zone of 1 metre is required for the protection of sensitive freshwater habitats, and buffer zones of 2 to 65 metres, depending on the type of application equipment, are required to protect sensitive terrestrial habitats. These buffer zones are specified on the product label.

Other environmental concerns associated with pyroxsulam and Simplicity Herbicide are: the leaching potential of pyroxsulam and its transformation products; runoff; and the aromatic petroleum distillate present as a component in the formulation. These concerns are mitigated with label statements on the product label.

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 objection[5] 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 Pesticide and Pest Management portion of Health Canada's website (Requesting a Reconsideration of Decision, healthcanada.gc.ca/pmra) or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

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

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Document Number: 1283061
Reference: 2005, Analytical method and validation for the determination of active ingredient and process impurities in XDE-742 technical by liquid chromatography, Data Numbering Code: 2.13.1 Confidential Business Information

PMRA Document Number: 1283063
Reference: 2005, Analytical method and validation for the determination of residual solvent in XDE-742 technical by gas chromatography, Data Numbering Code: 2.13.1 Confidential Business Information

PMRA Document Number: 1752299
Reference: 2008, Manufacturing plant location, Conditional to full registration, Pyroxsulam Technical Herbicide 28886, Data Numbering Code: 2.2 Confidential Business Information

PMRA Document Number: 1752300
Reference: 2009, Samples of analytical standards, Conditional to full registration, Pyroxsulam Technical Herbicide 28886, Data Numbering Code: 2.15

PMRA Document Number: 1876955
Reference: 2010, Batch analysis study for Pyroxsulam Technical [n-(5,7-dimethoxy[1,2,4] triazolo [1,5-a]pyrimidin-2-yl)-2-methoxy-4-(trifluoromethyl)-3-pyridinesulfonamide], Data Numbering Code: 2.13.3 Confidential Business Information

2.0 Environment

PMRA Document Number: 1752301
Reference: 2008, Octanol-water partition coefficient study, Data Numbering Code: 8.5

PMRA Document Number: 1752302
Reference: 2008, XDE-742 acute toxicity to the freshwater diatom (*Navicula pelliculosa*), Pyroxsulam Technical 28886, Data Numbering Code: 9.8.2