Registration Decision RD2012-10

Imazapyr

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Registration Decision for Imazapyr and Ares Herbicide

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 Imazapyr Technical Herbicide and Ares Herbicide, containing the technical grade active ingredients imazapyr and imazamox, to control broadleaf and grassy weeds in Clearfield canola (e.g., canola varieties with the Clearfield trait), Clearfield canola quality *Brassica juncea* (e.g., canola quality *Brassica juncea* varieties with the Clearfield trait), and Clearfield lentils (e.g., lentil varieties with the Clearfield trait).

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 document[1] Proposed Registration Decision PRD2011-12, *Imazapyr*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for imazapyr and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2011-12, *Imazapyr*. This decision is consistent with the proposed registration decision stated in PRD2011-12, *Imazapyr*.

For more details on the information presented in this Registration Decision, please refer to PRD2011-12, *Imazapyr*, which 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 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 Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What is Imazapyr?

Imazapyr is an active ingredient in the end-use product Ares Herbicide. Ares Herbicide contains the active ingredients imazapyr at 15 grams per litre and imazamox at 33 grams per litre of product. Ares Herbicide is a post-emergence herbicide, i.e., a herbicide applied after weeds and crops have emerged from the ground, which is applied using ground application equipment to Clearfield canola (e.g., canola varieties with the Clearfield trait), Clearfield canola quality *Brassica juncea* (e.g., canola quality *Brassica juncea* varieties with the Clearfield trait), and Clearfield lentils (e.g., lentil varieties with the Clearfield trait) to control broadleaf and grassy weeds. Imazapyr inhibits the plant enzyme acetolactate synthase in target weeds. Chlorosis and tissue necrosis may not be apparent in some plant species until two weeks after application.

Health Considerations

Can Approved Uses of Imazapyr Affect Human Health?

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

Potential exposure to imazapyr may occur through the 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 (e.g., 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 imazapyr products are used according to label directions.

In laboratory animals, the technical grade active ingredient imazapyr was of low acute toxicity by the oral and dermal routes, but was of slight toxicity via the inhalation route. Imazapyr was non-irritating to the skin and did not cause an allergic skin reaction, but was severely irritating to the eye. Consequently, the hazard signal words "CAUTION POISON" and "DANGER – EYE IRRITANT" are required on the label.

The acute toxicity of the end-use product Ares Herbicide containing imazapyr as well as technical imazamox was low via the oral, dermal and inhalation routes of exposure. It was minimally irritating to the eye and slightly irritating to the skin. Ares Herbicide did not cause an allergic skin reaction.

There was no indication that imazapyr caused damage to the nervous system or immune system. Imazapyr did not cause birth defects in animals and there were no effects on the ability to reproduce. There was no indication of target organ toxicity. There was no evidence to suggest that imazapyr damaged genetic material or caused cancer at doses relevant to humans. Health effects in animals given repeated doses of imazapyr over long periods of time were early deaths and decreased survivorship.

When imazapyr was given to pregnant or nursing animals, no effects on the developing fetus or juvenile animal were observed, indicating that the young are not more sensitive to imazapyr than the adult animal.

The risk assessment protects against the effects of imazapyr by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Residues in Water and Food

Dietary risks from food and water are not of concern

Aggregate dietary intake estimates (food plus drinking water) revealed that the general population and children 1-2 years old, the subpopulation which would ingest the most imazapyr relative to body weight, are expected to be exposed to 0.00% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from imazapyr is not of concern for all population sub-groups. There is no evidence that imazapyr is carcinogenic; therefore, a cancer dietary assessment is not required.

Animal studies revealed no acute health effects. Consequently, a single dose of imazapyr is not likely to cause acute health effects in the general population (including infants and children).

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 a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Residue trials conducted throughout Canada using imazapyr on Clearfield canola and Clearfield lentils were acceptable. The MRLs for this active ingredient can be found in the Science Evaluation section of PRD2011-12, *Imazapyr*.

Occupational Risks From Handling Ares Herbicide

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

Farmers and custom applicators who mix, load or apply Ares Herbicide as well as field workers re-entering freshly treated fields can come in direct contact with imazapyr residues on the skin. Therefore, the label specifies that anyone mixing and loading Ares Herbicide must wear a long-sleeved shirt, long pants, chemical-resistant gloves and goggles or a face shield. In addition, the label specifies that anyone applying Ares Herbicide must wear a long-sleeved shirt and long pants. The label also requires that workers do not enter treated fields for 12 hours after application. Taking into consideration these label statements, the number of applications and the expectation of the exposure period for handlers and workers, the risk to these individuals is 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 Imazapyr Is Introduced Into the Environment?

Imazapyr poses a potential risk to non-target terrestrial plants. Therefore, risk-reduction measures including precautionary label statements and buffer zones must be observed.

The environmental fate and environmental toxicology of imazapyr are described in PRVD2008-10, *Imazapyr*.

Imazapyr will pose negligible risk to earthworms, bees, birds and wild mammals under conditions of field use. The risk to aquatic organisms is also negligible. Imazapyr poses a potential risk to non-target terrestrial plants. This risk can be mitigated by precautionary label statements and the establishment of terrestrial buffer zones for the protection of these habitats.

Value Considerations

What Is the Value of Ares Herbicide ?

Ares Herbicide contains the active ingredients imazapyr at 15 grams and imazamox at 33 grams per litre of product. Ares Herbicide is a post-emergence herbicide which is applied using ground application equipment to Clearfield canola (e.g., canola varieties with the Clearfield trait), Clearfield canola quality *Brassica juncea* (e.g., canola quality *Brassica juncea* varieties with the Clearfield trait), and Clearfield lentils (e.g., lentil varieties with the Clearfield trait) to control broadleaf and grassy weeds. Ares Herbicide provides an alternative to control of annual grassy and broadleaved weeds specifically in Clearfield crops and provides control of wild oat (including Group 1 and Group 8 resistant biotypes), green foxtail (including Group 1 and Group 3 resistant biotypes), volunteer wheat (all varieties except those with the Clearfield trait), volunteer barley, Japanese brome and Persian darnel.

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 Ares 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 imazapyr on the skin or through inhalation of spray mists, anyone mixing and loading Ares Herbicide must wear a long-sleeved shirt, long pants, chemical-resistant gloves and goggles or a face shield, and anyone applying Ares Herbicide must wear a long-sleeved shirt and long pants. In addition, standard label statements to protect against drift during application were added to the label.

Environment

Key risk-reduction measures for the protection of the environment include precautionary label directions and buffer zones for the new end-use product Ares Herbicide:

- Toxicity statement for non-target terrestrial plants;
- Terrestrial buffer zone of 1 metre for field sprayer application, based on imazapyr toxicity. However, as Ares Herbicide contains also the active ingredient imazamox, a terrestrial buffer zone of 11 metres for field sprayer application based on imazapyr toxicity supersedes the default 1-metre buffer zone for imazapyr.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2011-12 —*Imazapyr)* 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).

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 Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision, healthcanada.gc.ca/pmra) or contact the PMRA's Pest Management Information Service.

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