Registration Decision RD2015-13

Bicyclopyrone

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Registration Decision for Bicyclopyrone

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 Bicyclopyrone Technical, the manufacturing concentrate products Bicyclopyrone Wet Paste I and Bicyclopyrone Wet Paste II, and the end-use product SYNA16003 Herbicide, containing the technical grade active ingredient bicyclopyrone, to control specific weeds in field, sweet and seed corn. Also granted full registration is Acuron Herbicide, containing the active ingredients bicyclopyrone, atrazine, s-metolachlor and mesotrione to control specific weeds in field, sweet and seed corn.

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 PRD2015-02, *Bicyclopyrone*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for bicyclopyrone and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2015-02, *Bicyclopyrone.* This decision is consistent with the proposed registration decision stated in PRD2015-02, *Bicyclopyrone.*

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2015-02, *Bicyclopyrone* 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 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.

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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 (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 Bicyclopyrone?

Bicyclopyrone is a Group 27 Herbicide. It acts in susceptible plants by inhibiting the biosynthesis of carotenoids and leading to the destruction of chlorophyll. The mode of action of bicyclopyrone is shared with several other commercial herbicide active ingredients, specifically, mesotrione, isoxaflutole, topramezone, tembotrione and pyrasulfatole. Bicyclopyrone is efficacious against select broadleaf weeds as well as proso millet (a difficult to control grassy weed).

SYNA16003 Herbicide contains the active ingredient bicyclopyrone at 200 grams per litre of product and Acuron Herbicide contains bicyclopyrone at 7.1 grams, mesotrione at 28.5 grams, atrazine at 120 grams and s-metolachlor at 257 grams per litre of product.

Health Considerations

Can Approved Uses of Bicyclopyrone Affect Human Health?

Products containing bicyclopyrone are unlikely to affect your health when used according to label directions.

Potential exposure to bicyclopyrone may occur through the diet (food and water) or when handling and applying the products. 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 (for example, 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 pesticide products containing bicyclopyrone are used according to label directions.

In laboratory animals, the technical grade active ingredient bicyclopyrone was of low acute toxicity by the oral, dermal and inhalation routes. Bicyclopyrone was minimally irritating to the eye, non-irritating to the skin, and did not cause an allergic skin reaction.

The end-use product, SYNA16003 Herbicide was of low acute toxicity via the oral, dermal and inhalation routes. It was non-irritating to the skin and minimally irritating to the eyes. SYNA16003 Herbicide caused an allergic skin reaction; consequently, the hazard statement "POTENTIAL SKIN SENSITIZER" is required on the label for this end-use product.

The end-use product, Acuron Herbicide was slightly acutely toxic via the oral route, was of low acute toxicity via the dermal and inhalation routes and minimally irritating to the eye. It was moderately irritating to the skin and caused an allergic skin reaction. Based on the above findings, the signal words and hazard statements "WARNING, POISON, SKIN IRRITANT and POTENTIAL SKIN SENSITIZER" are required on the label.

There was some indication that bicyclopyrone caused damage to the nervous system in dogs only. There were no effects on the immune system. Health effects in animals given repeated doses of bicyclopyrone included effects on the liver, kidney, eyes, and on body weight. There was no evidence to suggest that bicyclopyrone damaged genetic material.

When bicyclopyrone was given to pregnant or nursing animals, effects (malformations) on the developing fetus were observed at doses that were not toxic to the mother, indicating that the young were more sensitive to bicyclopyrone than the adult animal.

The risk assessment protects against the effects of bicyclopyrone 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 drinking water are not of health concern.

Aggregate dietary intake estimates (food plus drinking water) revealed that the general population and infants, the subpopulation which would ingest the most bicyclopyrone relative to body weight, are not expected to be exposed to greater than 100% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from bicyclopyrone is not of health concern for all subpopulations, including infants.

Bicyclopyrone is not carcinogenic; therefore, a cancer dietary risk assessment is not required.

Acute dietary (food plus drinking water) intake estimates for females 13 to 49 years old were 97% of the acute reference dose (ARfD), and is not of health concern. The general population and all other population subgroups were less than 1% of the ARfD, and are not of 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 a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Residue trials conducted on corn (field, sweet and pop) throughout the United States, and on sugarcane in Australia using bicyclopyrone are acceptable. The MRLs for this active ingredient can be found in the Science Evaluation of PRD2015-02, *Bicyclopyrone*.

Acuron Herbicide is formulated with the active ingredients mesotrione, atrazine, s-metolachlor and the safener benoxacor. These active ingredients are already registered for use in Canada.

Occupational Risks From Handling SYNA16003 Herbicide and Acuron Herbicide

Occupational risks are not of concern when SYNA16003 Herbicide and Acuron Herbicide are used according to the proposed label directions, which include protective measures.

Farmers and custom applicators who mix, load and apply SYNA16003 Herbicide and Acuron Herbicide as well as field workers re-entering freshly treated fields can come in direct contact with bicyclopyrone residues on the skin. Therefore, the SYNA16003 Herbicide label specifies that anyone mixing/loading must use closed mixing and loading equipment, and must wear a long-sleeved shirt and long pants, chemical-resistant gloves, socks, shoes, and eye protection. During application, clean-up and repair, workers must wear coveralls over a long-sleeved shirt and long pants, socks, and shoes. In addition, workers must wear chemical-resistant gloves during clean-up, repair, or if contact with spray nozzles is necessary. The Acuron Herbicide label specifies that anyone mixing, loading or applying the herbicide, and during clean-up and repair, must wear coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, and shoes with socks. In addition, when mixing/loading, workers must wear a faceshield. Chemical-resistant gloves are not required during application. The label also requires that workers do not enter treated fields for 15 days after application of SYNA16003 Herbicide, and 12 days after application of Acuron Herbicide, for hand setting irrigation equipment. For all other tasks, 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, risks 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 Bicyclopyrone Is Introduced Into the Environment?

When used according to the label directions, bicyclopyrone is not expected to pose an unacceptable risk to the environment.

SYNA16003 and Acuron Herbicides, containing bicyclopyrone, can enter non-target terrestrial and aquatic habitats through spray drift and can enter aquatic habitats through run-off and leaching when used as a foliar spray on field, sweet and seed corn. In the terrestrial environment bicyclopyrone breaks down and is not expected to persist or accumulate over time. Breakdown of the molecule occurs mainly through reacting with sunlight and soil microbial activities. Bicyclopyrone is soluble in water and can move through the soil profile, and potentially reach ground water. In aquatic environments, bicylopyrone breaks down more slowly in the aquatic environment but does not accumulate. It may break down more rapidly, however, in the presence of sunlight in clear, shallow water.

Bicyclopyrone is unlikely to enter the atmosphere and be transported to areas far removed from where it was applied.

Bicyclopyrone is not expected to accumulate in plant and animal tissues.

Bicyclopyrone presents a negligible risk to aquatic organisms and most terrestrial organisms including birds, mammals, earthworms, parasitoid arthropods and honeybees. When bicyclopyrone is used at the labelled application rates it could pose a risk to certain non-target terrestrial plants if they are exposed to high enough concentrations. Therefore, mitigation measures, such as spray buffer zones, are required in order to minimize potential exposure of non-target terrestrial plants and, thereby, risk to the environment. When bicyclopyrone is used in accordance with the label and the required risk reductions measures are applied, the reduced environmental exposure is deemed adequate and risks are considered to be acceptable. Hazard statements for aquatic organisms and non-target terrestrial plants are required on product labels.

Value Considerations

What Is the Value of SYNA16003 Herbicide and Acuron Herbicide?

Proso millet is a difficult-to-control annual grassy weed and chemical control options are limited in corn.

There are currently no herbicides registered for use in corn that have residual soil activity on proso millet. Furthermore, the use pattern for SYNA16003 Herbicide is such that multiple weed control “options” are available for growers, including a two-pass weed control system (residual soil application followed by a planned post-emergent application), a one-pass post-emergent system, which would combine the residual capabilities of bicyclopyrone with the burndown ability of a glyphosate tank-mix partner, or a one-pass pre-emergent or post-emergent system

with Primextra II Magnum Herbicide (Registration Number 25730) or Lumax EZ Herbicide (Registration Number 30964). Accordingly, the flexibility available with the proposed use pattern will provide a certain level of value to users of SYNA16003 Herbicide.

The combination of four active ingredients in Acuron Herbicide yields a product that can provide season-long control of a number of broadleaf and grassy weeds as well as provide early season suppression of proso millet in field, seed and sweet corn.

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 SYNA16003 Herbicide and Acuron 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 SYNA16003 Herbicide and Acuron Herbicide on the skin or through inhalation of spray mists, the SYNA16003 Herbicide label specifies that anyone mixing/loading must use closed mixing and loading equipment, and wear a long-sleeved shirt and long pants, chemical-resistant gloves, socks, shoes, and eye protection. During application, clean-up and repair, workers must wear coveralls over a long-sleeved shirt and long pants, socks and shoes. In addition, workers must wear chemical-resistant gloves during clean-up, repair, or if contact with spray nozzles is necessary. The Acuron Herbicide label specifies that anyone mixing, loading or applying the herbicide, and during clean-up and repair, must wear coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, and shoes with socks. In addition, when mixing/loading, workers must wear a faceshield. Chemical-resistant gloves are not required during application. In addition, the Acuron Herbicide label contains a spray-drift reduction statement for exposure protection in areas of human habitation.

Environment

Standard hazard statements for non-target organisms including aquatic organisms and non-target terrestrial plants.

Standard statements to inform users of conditions that may favour runoff and leaching
Spray buffer zones to protect habitats from drift

A statement advising that bicyclopyrone could potentially reach groundwater, particularly in areas where soils are permeable and/or the depth to the water table is shallow.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2015-02, *Bicyclopyrone* 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 Pesticides and Pest Management section of the Health Canada website (Request a Reconsideration of Decision) or contact the PMRA Pest Management Information Service.

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