Registration Decision RD2015-16

Spiroxamine

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6607 D
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

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Registration Decision for Spiroxamine

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 Spiroxamine Technical Fungicide and Impulse 500 EC Fungicide containing the technical grade active ingredient spiroxamine, to control powdery mildew (*Uncinula necator*, syn. *Erysiphe necator*) on grape.

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 PRD2015-14, *Spiroxamine*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for spiroxamine and summarizes the Agency's decision, and the reasons for it. The PMRA received no comments on PRD2015-14. This decision is consistent with the proposed registration decision stated in PRD2015-14.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2015-14, *Spiroxamine* 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.

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. 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 Spiroxamine?

Spiroxamine is a sterol biosynthesis inhibitor fungicide with systemic activity. This active ingredient provides control of powdery mildew caused by the ascomycetous fungus, *Uncinula necator* (syn. *Erysiphe necator*) in grapes.

Health Considerations

Can Approved Uses of Spiroxamine Affect Human Health?

Spiroxamine is unlikely to affect human health when Impulse 500 EC Fungicide is used according to label directions.

Potential exposure to spiroxamine may occur through the diet (food and water) or when handling and applying the end-use product Impulse 500 EC Fungicide. 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-containing products are used according to label directions.

In laboratory animals, the technical grade spiroxamine was moderately to highly acutely toxic by the oral route and slightly acutely toxic by the dermal and inhalation routes of exposure. Spiroxamine was non-irritating to the eyes, but moderately irritating to the skin. Spiroxamine caused an allergic skin reaction. Based on the acute toxicity data, the signal words and hazard statements DANGER – POISON, SKIN IRRITANT and POTENTIAL SKIN SENSITIZER are required on the label.

Impulse 500 EC Fungicide, containing spiroxamine, was moderately acutely toxic by the oral route, of low dermal toxicity, and slightly acutely toxic by the inhalation route. It was severely irritating to the eye and moderately irritating to the skin. It caused an allergic skin reaction. Based on the acute toxicity data, signal words and hazard statements DANGER – POISON, EYE and SKIN IRRITANT, POTENTIAL SKIN SENSITIZER and their associated symbols are required on the product label.

Health effects in animals given repeated doses of spiroxamine included effects on the liver, lining of the gastrointestinal and urogenital tracts, the eye and body weight. Spiroxamine did not cause cancer in animals and did not damage genetic material. There was no indication that spiroxamine caused damage to the nervous or immune systems.

When spiroxamine was given to pregnant or nursing animals, it delayed the development of the fetuses and offspring at doses that were toxic to the mother.

The risk assessment protects against the effects of spiroxamine 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 total population and children one to two years old, the subpopulation which would ingest the most spiroxamine relative to body weight, are expected to be exposed to less than 31% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from spiroxamine is not of health concern for all population subgroups.

The risk assessment is protective of both the non-cancer effects and potential tumor formation.

Acute dietary (food plus drinking water) intake estimates for the total population and all population subgroups were less than 33% of the acute reference dose, and are not of health concern. The highest exposed subpopulation was children one to two years old.

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 in the United States and other countries using spiroxamine on grapes and bananas are acceptable. The MRLs for this active ingredient can be found in the Science Evaluation of PRD2015-14.

Occupational Risks From Handling Impulse 500 EC Fungicide

Occupational risks are not of concern when Impulse 500 EC Fungicide is used according to the proposed label directions, which include protective measures.

Farmers and custom applicators who mix, load or apply Impulse 500 EC Fungicide, as well as field workers re-entering freshly treated vineyards, can come in direct contact with spiroxamine residues on the skin or through inhalation of spray mists. Therefore, the label specifies that anyone mixing, loading and applying Impulse 500 EC Fungicide, or involved in equipment clean-up and repairs, must wear long pants, a long-sleeved shirt, chemical-resistant gloves made of waterproof material, socks, shoes and goggles. In addition, all applicators driving an open-cab tractor must wear a chemical-resistant headgear (includes Sou'Wester hats or large brimmed waterproof hats and hoods with sufficient neck protection).

The label also requires that workers do not enter treated fields for:

- 12 hours after application to conduct activities such as transplanting, scouting, hand pruning, hand weeding, propagating, bird control and trellis repairs;
- 3 days to conduct activities such as hand set irrigation;
- 17 days to conduct activities, such as tying/training, hand harvesting and leaf pulling; and 24 days to conduct activities such as girdling and turning.

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 are not expected to be of 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 Spiroxamine Is Introduced Into the Environment?

When used according to label directions, spiroxamine is not expected to pose an unacceptable risk to the environment. Labelled risk reduction measures mitigate potential risks posed by spiroxamine to freshwater/marine/estuarine organisms.

Spiroxamine will enter the environment when applied as Impulse 500 EC Fungicide on grapes for the control of powdery mildew. Spiroxamine breaks down in the environment mainly through soil microbial activities and is not expected to persist for long periods of time. Spiroxamine is considered to have low potential to move through the soil and enter groundwater. However, it does have the potential to enter aquatic environments through surface runoff and spray drift. Spiroxamine dissolves readily in water but is expected to move into sediments in aquatic

environments. Spiroxamine is not expected to enter the atmosphere in large amounts and is not expected to be transported long distances from where it was applied. Spiroxamine is unlikely to accumulate in the tissues of organisms.

Spiroxamine presents a negligible risk to most terrestrial organisms including earthworms, honeybees, birds, and vascular plants. If exposed to high enough levels, it could pose a reproductive risk to mammals, a chronic risk to certain aquatic organisms (for example, amphibians, freshwater fish, freshwater invertebrates,) and an acute risk to amphibians, as well as freshwater and marine algae. Statements to inform the user of the potential hazards to mammals and aquatic organisms as well as spray buffer zones to protect sensitive aquatic habitats are required on the label.

Value Considerations

What Is the Value of Impulse 500 EC Fungicide ?

Impulse 500 EC Fungicide is a foliar applied conventional fungicide for use on grapes to control powdery mildew. It has a low to medium risk for resistance development. It will address a high priority disease as identified by Canadian growers.

Impulse 500 EC Fungicide has demonstrated good control of powdery mildew on grape, and its availability offers growers a new mode of action for resistance management. This product can be incorporated into integrated pest management programs with other chemical and cultural controls for disease and resistance management.

Measures to Minimize Risk

Registered pesticide product labels 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 Impulse 500 EC Fungicide 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 spiroxamine on the skin or through inhalation of spray mists, anyone mixing, loading and applying Impulse 500 EC Fungicide, or involved in equipment clean-up and repairs, must wear long pants, a long-sleeved shirt, chemical-resistant gloves made of waterproof material, socks, shoes and goggles. In addition, all applicators driving an open-cab tractor must wear chemical-resistant headgear.

Chemical-resistant headgear includes Sou'Wester hats or large brimmed waterproof hats and hoods with sufficient neck protection. Furthermore, workers re-entering freshly treated vineyards to perform postapplication activities are required to respect the following restricted-entry intervals (REIs):

Re-Entry Activity	Restricted-Entry Interval
Transplanting, scouting, hand pruning, hand weeding, propagating, bird control, trellis repairs	12 hours[1]
Irrigation (hand set)	3 days
Tying/training, hand harvesting, leaf pulling	17 days
Girdling, turning	24 days

[1] A minimum of 12 hours is applicable for all agricultural workers to allow residues to dry and vapors to dissipate, hence limiting potential effects such as irritation or allergic reactions.

In addition, standard label statements to protect against drift during application are on the label.

Environment

Statements to inform the user of the potential hazards to mammals and aquatic organisms as well as spray buffer zones to protect sensitive aquatic habitats are required on the label. Spray buffer zones of 1 to 40 metres are required to protect sensitive freshwater habitats, and spray buffer zones of 2 to 35 metres are required to protect sensitive estuarine/marine habitats. These spray buffer zones are to be specified on the product label.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2015-14) 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 Pesticide and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

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