Registration Decision RD2014-11

Flumioxazin

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Registration Decision for Flumioxazin

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 Flumioxazin Technical and Flumioxazin 51WDG Herbicide to control weeds in numerous crops, and Flumioxazin 0.25G Herbicide to control weeds in container grown ornamentals.

An evaluation of available scientific information found that, under the approved conditions of use, the products have value and do 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 PRD2013-20, *Flumioxazin*. This registration decision[2] describes this stage of the PMRA's regulatory process for flumioxazin and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2013-20. This decision is consistent with the proposed registration decision stated in PRD2013-20.

For more details on the information presented in this registration decision, please refer to PRD2013-20 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 (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 Flumioxazin?

Flumioxazin is an active ingredient in the end-use products Flumioxazin 51WDG Herbicide and Flumioxazin 0.25G Herbicide. Flumioxazin belongs to the *N*-phenylphthalimide chemical family and is a Weed Science Society of America Group 14 herbicide. The mode of action is the inhibition of the enzyme protoporphyrinogen oxidase . This enzyme is part of the chlorophyll biosynthesis pathway, and its inhibition leads to a loss of chlorophyll and carotenoids, and irreversible damage to cell membrane function and structure. Sensitive plants emerging from soils treated with the herbicide flumioxazin become necrotic and die shortly after exposure to sunlight.

Health Considerations

Can Approved Uses of Flumioxazin Affect Human Health?

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

Potential exposure to flumioxazin may occur through 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 those uses where 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 flumioxazin products, according to label directions.

Flumioxazin technical grade active ingredient and the end-use products, Flumioxazin 0.25G Herbicide and Flumioxazin 51WDG Herbicide showed a potential for slight toxicity by the inhalation route in animals. Because of this, the label statement: CAUTION – POISON, is required. Flumioxazin did not cause cancer in animals and was not genotoxic. There was also no indication that flumioxazin caused damage to the nervous system. There were significant effects on fetal development. The first signs of toxicity in animals given daily doses of flumioxazin over longer periods of time were effects on the blood, and liver and bile systems. The risk assessment protects against these effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

When flumioxazin was given to pregnant animals, effects on the developing fetus were observed at doses that were not toxic to the mother, indicating that the fetus was more sensitive to flumioxazin than the adult animal. Because of this observation, extra protective measures were applied during the risk assessment to further reduce the allowable level of human exposure to flumioxazin.

Residues in Water and Food

Aggregate dietary intake estimates (food plus water) revealed that women 13-49 years old, the most sensitive population group to flumioxazin, are expected to be exposed to ≤5.5% of the acceptable daily intake, and children 1-2 years old, the population group that would ingest the most flumioxazin relative to body weight, are expected to be exposed to ≤3.7% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from flumioxazin is not of concern for all segments of the population. Flumioxazin is not carcinogenic; therefore, a chronic cancer dietary risk assessment is not required.

A single dose of flumioxazin is not likely to cause acute health effects in the general population (including infants and children). An aggregate (food and water) dietary intake estimate for females 13-49 years old used less than 15% of the acute reference dose, which is 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 a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Residue trials conducted throughout the United States, using flumioxazin on potatoes, dry bulb onions, soybeans, apples, pears, peaches, plums, cherries, blueberries, grapes, strawberries, and asparagus were acceptable. The MRLs for this active ingredient can be found in the Science Evaluation section of the proposed registration decision, PRD2013-20.

Occupational Risks From Handling Flumioxazin 51WDG Herbicide or Flumioxazin 0.25G Herbicide

Occupational risks are not of concern when Flumioxazin 51WDG Herbicide or Flumioxazin 0.25G Herbicide are used according to the label directions, which include protective measures.

Farmers, custom applicators, or ornamental nursery operators who mix, load or apply Flumioxazin 51WDG Herbicide or Flumioxazin 0.25G Herbicide, as well as field workers re-entering freshly treated fields, bare ground non-crop areas, and nurseries can come in direct contact with flumioxazin residues on the skin. Therefore, the labels specify that anyone mixing/loading and applying Flumioxazin 51WDG Herbicide or Flumioxazin 0.25G Herbicide must wear Personal Protective Equipment . The label also requires that workers do not enter treated crop areas until 12 hours after application. Also, no entry is allowed into treated, non-crop bare ground use areas until the sprays have dried. Taking into consideration these label statements, the number of applications, and the expectation of the exposure period for handlers and workers, it was determined that exposures to these individuals are not a concern.

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

For people who enter treated fields for “pick-your-own” activities, exposure is expected to be short-term even though this activity may be performed once or several times per year. Taking into consideration the label requirements, the risk to people that enter treated fields to pick apples, pears, highbush blueberries, or strawberries is not of concern.

Environmental Considerations

What Happens When Flumioxazin is Introduced Into the Environment?

Flumioxazin enters the environment when used on various crops and ornamentals for weed control. In soil, flumioxazin breaks down in the presence of bacteria and is not likely to persist for long periods. Flumioxazin is not expected to volatilize into the atmosphere and is not expected to move through soil and reach groundwater. When flumioxazin breaks down it does not form any other major residues in soil.

Although the use pattern for flumioxazin does not include direct application to water, the possibility that aquatic systems will be exposed to flumioxazin and its breakdown products, directly or indirectly, cannot be ruled out. Flumioxazin can enter the aquatic environment through spray drift and runoff from treated fields. In aquatic systems, flumioxazin breaks down rapidly in the presence of bacteria and sunlight. Any major breakdown products are not likely to persist in the aquatic environment. Flumioxazin and its breakdown products are unlikely to accumulate in fish.

The use of the granular formulation of flumioxazin (Flumioxazin 0.25 G) may pose a risk to terrestrial and aquatic organisms, including small mammals, algae and aquatic plants. Precautionary statements are required on the product labels to identify and mitigate the risks. Advisory runoff statements on the label may minimize the risk from runoff.

The use of the spray formulation of flumioxazin (Flumioxazin 51 WDG) may pose a risk to terrestrial and aquatic organisms, including arthropods, terrestrial plants, algae and aquatic plants. Precautionary statements are required on the product labels to identify and mitigate the risk from spray drift to beneficial arthropods and plants. Also, terrestrial spray buffer zones of 5 to 25 meters and aquatic buffer zones of up to 5 metres are required to protect sensitive non-target plant species from spray drift. Advisory runoff statements on the label may minimize the risk from runoff.

Value Considerations

What Is the Value of Flumioxazin 51WDG Herbicide and Flumioxazin 0.25G Herbicide?

Flumioxazin 51WDG Herbicide provides pre-emergence control or suppression of common lamb's quarters, redroot pigweed, common ragweed, green pigweed, eastern black nightshade, hairy nightshade, green foxtail, kochia, Canada fleabane, and dandelion in non-crop areas, field-grown coniferous and deciduous ornamental trees, mint, soybean, dry-bulb onion, field pea, pome fruit, grape, highbush and lowbush blueberries, stone fruit, nut tree, asparagus, potato, field pepper, celery, strawberry and suppression of moss in lowbush blueberry**.**

With the exception of ornamentals, Flumioxazin 51WDG Herbicide represents a new mode of action for pre-emergence weed control for all uses listed on the label. Therefore, the registration of Flumioxazin 51WDG will provide a key tool in weed resistance management in the labelled crops.

Flumioxazin 0.25G Herbicide provides pre-emergence control or suppression of specific broadleaf weeds in container-grown ornamentals.

Weed management is critical in container-grown ornamental production. Containers that are overrun with weeds become less marketable, as consumers a want clean, weed-free product. There are very few herbicides registered for use in container-grown ornamentals.

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 labels of Flumioxazin 51WDG Herbicide and Flumioxazin 0.25G Herbicide to address the potential risks identified in this assessment are as follows:

Key Risk-Reduction Measures

Human Health

Since there is a concern with users coming into direct contact with flumioxazin on the skin or through inhalation of spray mists, anyone mixing, loading, applying, and involved in clean-up or repair activities with Flumioxazin 51WDG Herbicide or Flumioxazin 0.25G Herbicide must wear the recommended personal protective equipment. Standard label statements to protect against spray drift during application are included on the label. A restricted-entry interval was required for postapplication hand-line irrigation after over-the-top application to field-grown coniferous trees and trees grown for reforestation.

Environment

Mitigative measures are required to protect sensitive terrestrial and aquatic habitats from the use of flumioxazin. These mitigative measures include precautionary statements on the label as well as appropriate buffer zones to protect sensitive habitats from spray drift.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2013-20) 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) or contact the PMRA's Pest Management Information Service.

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