Registration Decision RD2015-06

Flutriafol

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Registration Decision for Flutriafol

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Flutriafol Technical Fungicide and Fullback 125 SC Fungicide containing the technical grade active ingredient flutriafol to control fungal diseases on apples, grapes, strawberries and soybeans.

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 PRD2014-16, *Flutriafol*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for Flutriafol and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2014-16. This decision is consistent with the proposed registration decision stated in PRD2014-16.

For more details on the information presented in this Registration Decision, please refer to PRD2014-16, 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.

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.

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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 the *Pest Control Products Act.*

4 "Value" as defined by subsection 2(1) of the *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".

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.

What Is Flutriafol?

Flutriafol is a demethylase inhibitor fungicide with systemic activity. This active ingredient provides broad spectrum control of certain ascomycetes and rust fungi on a range of crops.

Health Considerations

Can Approved Uses of Flutriafol Affect Human Health?

Fullback 125 SC Fungicide, containing Flutriafol, is unlikely to affect your health when used according to label directions.

Potential exposure to flutriafol may occur through the diet (food and water) or when handling and applying the end-use product Fullback 125 SC 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 active ingredient flutriafol was of high acute toxicity by the oral route; consequently, the hazard signal words "DANGER – POISON" are required on the label. It was of low acute toxicity dermally and through inhalation exposure. Flutriafol was non-irritating to the skin, and did not cause an allergic skin reaction. Flutriafol was mildly irritating to the eyes; consequently, the hazard signal words "EYE IRRITANT" are required on the label.

The acute toxicity of the end-use product Fullback 125 SC Fungicide containing flutriafol was low via the oral, dermal and inhalation routes of exposure. It was minimally irritating to the eyes and slightly irritating to the skin. Fullback 125 SC Fungicide did cause an allergic skin reaction; consequently, the hazard signal words "POTENTIAL SKIN SENSITIZER" are required on the label.

Flutriafol did not cause cancer in animals and did not damage genetic material. There was no indication that flutriafol caused damage to the nervous system or immune system. Health effects in animals given repeated doses of flutriafol included effects on the liver, red blood cells, adrenal gland, spleen and on skeletal development. In all species investigated, flutriafol affected body weight, which was also often accompanied by reduced food consumption.

When flutriafol was given to pregnant or nursing animals, effects of a serious nature (mortality, skeletal malformations) were observed in the developing fetus and juvenile animal at doses that were toxic to the mother. The risk assessment protects against the effects of flutriafol 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 concern.

Refined aggregate dietary intake estimates (food plus drinking water) revealed that infants less than one year old, the subpopulation that would ingest the most flutriafol relative to body weight, are expected to be exposed to 29% of the acceptable daily intake, and females 13 to 49 years of age are expected to be exposed to 16% of the acceptable daily intake. Based on these estimates, the refined chronic dietary risk from flutriafol is not of concern for all population subgroups.

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

Refined acute dietary (food plus drinking water) intake estimate was 82% of the acute reference dose for all infants (less than 1 year old), the highest exposed subpopulation. The refined aggregate exposure from food and drinking water is considered acceptable for females 13 to 49 years of age at 42% of the acute reference dose.

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 and the United States using flutriafol on various crops are acceptable. The MRLs for this active ingredient can be found in PRD2014-16.

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

Farmers and custom applicators who mix, load or apply Fullback 125 SC Fungicide as well as field workers re-entering freshly treated fields can come in direct contact with flutriafol residues on the skin. Therefore, the label specifies that anyone mixing/loading and applying Fullback 125 SC Fungicide must wear a long-sleeved shirt and long pants, chemical-resistant gloves, and shoes plus socks. The label also requires that workers do not enter treated strawberry fields, soybean fields and apple orchards for 12 hours after application. In addition, the label requires that workers do not enter treated grape vineyards for 14 days after application to do cane turning and girdling; for 7 days to do tying, training and leaf pulling; and for 12 hours to do all other activities.

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 and people who enter fields to perform pick-your-own harvesting, exposure is expected to be much less than that for workers. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Flutriafol is Introduced into the Environment?

When Fullback 125 SC Fungicide is applied on field crops, some of it finds its way into soil and water. Flutriafol is persistent in soils and has a potential for long-term accumulation and residue carry over to the following crop season. It does not transform readily in soils as it is not broken down in the presence of sunlight, by microbes or by reacting with water. No major transformation products were detected in soils in laboratory and field studies.

Flutriafol is soluble in water and moderately to highly mobile in soils. Laboratory and field studies, along with conservative water modelling estimates indicated that it has a potential to leach and contaminate the groundwater.

The potential mobility and high persistence of flutriafol suggest that leaching is the most important route of dissipation of flutriafol in the environment. Expected environmental concentrations in runoff water generated using water models also indicated that flutriafol has a potential for transport in surface runoff water from treated areas to nearby aquatic systems.

In the aquatic environment, it moves from water to sediment and is persistent there. Flutriafol does not break down readily in the aquatic environment. No major transformation products were detected in the water or sediment phases.

Flutriafol does not accumulate in organisms.

Although properties of flutriafol indicate that it has a low potential to enter the atmosphere and travel long distances in the air, flutriafol has been detected at very low concentrations in Arctic ice cores, and in surface and groundwater in Ontario and British Columbia even though flutriafol has never been registered for use in Canada. These results indicate that flutriafol could have a potential to enter the atmosphere and travel long distances in the air.

Risk Characterization: Fullback 125 SC is applied by field sprayer and airblast sprayer on field crops. There is a potential for exposure to non-target terrestrial and aquatic habitats due to spray drift or runoff from the uses of Fullback 125 SC.

An assessment of the environmental risk for uses of Fullback 125 SC identified the following concerns:

- adverse effects on non-target terrestrial plants and wildlife habitat
- risk to amphibians and freshwater invertebrates

Value Considerations

What is the Value of Fullback 125 SC Fungicide?

Fullback 125 SC Fungicide is a broad-spectrum foliar fungicide for use on apple, strawberry, soybean and grapes.

Fullback 125 SC Fungicide has demonstrated good control of powdery mildew, rust diseases, apple scab and other economically important diseases. 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

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 Fullback 125 SC 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 flutriafol on the skin or through inhalation of spray mists, anyone mixing, loading and applying Fullback 125 SC Fungicide must wear a long-sleeved shirt and long pants, chemical-resistant gloves, and shoes plus socks. Workers are not allowed to enter treated strawberry fields, soybean fields and apple orchards for 12 hours after application and they are not allowed to enter treated grape vineyards for 14 days after application to do cane turning and girdling; for 7 days to do tying, training and leaf pulling; or for 12 hours to do all other activities. In addition, standard label statements to protect against drift during application were added to the label.

Environment

Flutriafol can pose a risk to non-target terrestrial plants and aquatic organisms. Label statements as well as spray buffer zones of 1 to 2 metres are required on the label to protect sensitive aquatic and terrestrial habitats.

Label statements are required on the label for Fullback 125 SC to inform users of the potential risks of leaching, persistence and carry-over of flutriafol.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2014-16) are available for public inspection, upon application, in the PMRA Reading Room (located in Ottawa). For more information, please contact the PMRA 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 Health Canada's 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.*