Registration Decision RD2014-12

Diflufenzopyr-sodium

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Registration Decision for Diflufenzopyr-sodium

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 Sodium Diflufenzopyr Technical Herbicide and the end-use product Overdrive Herbicide, containing the technical grade active ingredients diflufenzopyr-sodium and dicamba, to control broadleaf weeds in pasture, rangeland and non-cropland situations such as railroad, utility, pipeline and highway rights-of-way, railroad crossings, roadside, petroleum tank farms, non-agriculture fencerows and airports.

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 PRD2011-05, *Diflufenzopyr-sodium.* This registration decision[2] describes this stage of the PMRA's regulatory process for diflufenzopyr-sodium and summarizes the Agency's decision, the reasons for it, and provides, in Appendix I, the comment received during the consultation process as well as the PMRA's response to this comment. This decision is consistent with the proposed registration decision, stated in PRD2011-05.

For more details on the information presented in this registration decision, please refer to PRD2011-05, 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.

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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 Are Diflufenzopyr-sodium and Overdrive Herbicide?

Diflufenzopyr-sodium is an active ingredient in the end-use product Overdrive Herbicide. Overdrive Herbicide contains the active ingredients dicamba at 50% and diflufenzopyr-sodium at 20%. Overdrive is a postemergence herbicide (a herbicide applied after weeds and crops have emerged from the ground), which is applied using ground application equipment to pasture, rangeland and non-cropland situations such as railroad, utility, pipeline and highway rights-of-way, railroad crossings, roadside, petroleum tank farms, non-agriculture fencerows and airports, for the control of broadleaf weeds. Diflufenzopyr-sodium inhibits the transport of naturally occurring auxin and synthetic auxin-like compounds, like dicamba, in sensitive plants. When diflufenzopyr-sodium is applied with dicamba, it focuses translocation of dicamba to the growing points of the plant and providing weed control at lower rates of dicamba than when dicamba is applied alone.

Health Considerations

Can Approved Uses of Diflufenzopyr-sodium Affect Human Health?

Diflufenzopyr-sodium is unlikely to affect your health when used according to label directions.

Potential exposure to diflufenzopyr-sodium 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 (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 diflufenzopyr-sodium products are used according to label directions.

In laboratory animals technical diflufenzopyr-sodium was of low acute toxicity via oral, dermal and inhalation routes of exposure. It was not irritating when applied to the skin, but was minimally irritating to the eye. It did not produce an allergic skin reaction. The end-use product Overdrive Herbicide, containing diflufenzopyr-sodium and dicamba, was slightly acutely toxic via the oral route, and of low toxicity via the dermal and inhalation routes of exposure. It was minimally irritating to the skin, mildly irritating to the eye and caused an allergic skin reaction. Consequently, the hazard signal words: CAUTION – POISON, CAUTION – EYE IRRITANT and POTENTIAL SKIN SENSITIZER, are required on the label.

Diflufenzopyr-sodium did not cause cancer in animals and did not damage genetic material. There was also no indication that diflufenzopyr-sodium caused damage to the nervous system or birth defects. Health effects in animals given repeated doses of diflufenzopyr-sodium over longer periods of time included lower body weight and effects indicative of mild compensatory anaemia.

When diflufenzopyr-sodium was given to pregnant animals, effects of a serious nature on the developing fetus (embryo/fetal loss) were observed at doses that were toxic to the mother.

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.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Aggregate dietary intake estimates (food plus water) revealed that the general population and children 1-2 years old, the subpopulation which would ingest the most diflufenzopyr-sodium relative to body weight, are expected to be exposed to less than 1.0% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from diflufenzopyr-sodium is not of concern for all population subgroups.

Animal studies revealed no acute health effects. Consequently, a single dose of diflufenzopyr-sodium 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 the United States of America using diflufenzopyr-sodium on pasture and rangeland grasses were acceptable. The MRLs for this active ingredient can be found in the Science Evaluation section of the proposed registration decision, PRD2011-05.

Risks in Residential and Other Non-Occupational Environments

Entry by the public into treated commercial areas is considered acceptable.

Potential for bystander exposure is considered minimal due to the restricted nature of many of the non-cropland areas, and is expected to be significantly less than exposures estimated for operators and workers.

Occupational Risks From Handling Overdrive Herbicide

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

Workers who mix, load or apply Overdrive Herbicide as well as workers re-entering treated areas can come in direct contact with dicamba and diflufenzopyr-sodium residues on the skin. Therefore, the label specifies that anyone mixing/loading and applying Overdrive Herbicide must wear chemical-resistant gloves, long-sleeved shirt, long pants, socks and shoes as well as protective eyewear during mixing and loading. The label also requires that workers do not enter treated areas for 12 hours after application in pasture and rangeland. For all other applications, workers must wait until sprays have dried before re-entering treated areas. Taking into consideration these label statements, the number of applications and the expected exposure period for handlers and workers, the risk to workers handling Overdrive Herbicide is not 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 Diflufenzopyr-sodium is Introduced Into the Environment?

Diflufenzopyr-sodium poses a potential risk to aquatic organisms and terrestrial plants, therefore, risk-reduction measures must be observed.

Diflufenzopyr-sodium is non-persistent in soil. Therefore, accumulation in soil and carryover are not expected to be significant. Diflufenzopyr-sodium can enter aquatic systems by spray drift or runoff. It is slightly persistent in the aquatic environment. Based on its low volatility, diflufenzopyr-sodium residues are not expected in the air. There is low potential for bioaccumulation of diflufenzopyr-sodium.

Diflufenzopyr-sodium is expected to pose a risk to aquatic organisms and terrestrial vascular plants. As such, mitigative measures must be taken to minimise adverse effects on plant populations and aquatic organisms. Diflufenzopyr-sodium presents negligible risk to wild birds and mammals, bees and other arthropods.

To minimize potential exposure, spray buffer zones are required. The width of these buffer zones are specified on the product label.

Value Considerations

What Is the Value of Overdrive Herbicide?

Overdrive Herbicide contains the active ingredients dicamba at 50% and diflufenzopyr-sodium at 20% . Overdrive Herbicide is a postemergence herbicide, which is applied using ground application equipment to pasture, rangeland and non-cropland situations to control common ragweed, lady's thumb, lamb's-quarters, redroot pigweed, tall water hemp, velvetleaf, wild buckwheat, biennial wormwood, Canada thistle (top growth control), sweet clover (top growth control), vetch (top growth control), dandelion (top growth suppression) and leafy spurge (top growth suppression).

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 Overdrive 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 Overdrive Herbicide on the skin, anyone mixing, loading and applying Overdrive Herbicide must wear a long-sleeved shirt, long pants, shoes and socks, chemical-resistant gloves as well as protective eyewear during mixing and loading. The label also requires a restricted-entry interval (REI) of 12 hours for workers re-entering treated pasture and rangeland. For all other applications, workers must wait until sprays have dried before re-entering treated areas. In addition, standard label statements to protect against drift during application were added to the label.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2011-05) 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.*

Appendix I Comment and Response

Comment

The application rates used during the pasture and rangeland crop field trials were calculated incorrectly: “On page 30, Table 6 (Crop Field Trials on Pasture and Rangeland Grasses), the PMRA notes “During all trials, each treated plot received one spray application of diflufenzopyr-sodium (BAS 662 01 H; co-formulation of diflufenzopyr-sodium and dicamba) at 0.078-0.083 kg a.e./ha.” The application rate is incorrect. The application rate was 0.112 kg a.e./ha diflufenzopyr (0.109- 0.15 kg a.e./ha). A common mistake is to use the percent of diflufenzopyr (DFFP) in the formulated product (20%) to calculate the amount of DFFP in the 0.35 lb total active ingredient applied per acre (A). DFFP comprises 28.57% of the active ingredient in the formulated product (0.2/0.7 = 0.2857). Therefore, with 0.35 lb a.e./A total active applied, then 35 lb a.e./A × 0.2857 = 0.1 lb a.e./A DFFP. This is equivalent to 0.112 kg a.e./ha.”

Response

The PMRA acknowledges the error in the calculation of the application rates for diflufenzopyr-sodium. The formulated product has a guarantee of 20.4% diflufenzopyr and 49.4% dicamba, for a total of 69.8% total actives. Thus, the application rates were revised using the fraction of diflufenzopyr in the formulated product (20.4% ÷ 69.8% = 0.292). The revised rates ranged from 0.111-0.118 kg a.e./ha but are slightly different from the calculations as indicated in the above comment (0.109-0.15 kg a.e./ha) due to rounding-off of the guarantee of the fraction of dicamba in the formulated product. These revised application rates for diflufenzopyr-sodium do not have any impact on the regulatory decision.