

RD2008-06

Registration Decision

Bispyribac-sodium

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Table of Contents

Overview	L
Registration Decision for Bispyribac-sodium1	L
What Does Health Canada Consider When Making a Registration Decision?	
What Is Bispyribac-sodium? 2	2
Health Considerations)
Environmental Considerations	
Value Considerations	ŀ
Measures to Minimize Risk	
Other Information	;
References	5

Overview

Registration Decision for Bispyribac-sodium

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the <u>Pest</u> <u>Control Products Act</u> and Regulations, is granting full registration for the sale and use of Bisypribac-sodium Technical and Velocity SP Herbicide containing the technical grade active ingredient bisypribac-sodium for use on sod farms and golf courses for the reduction of annual bluegrass in turf.

Current scientific data from the registrant and scientific reports were evaluated to determine if, under the proposed 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 document¹: Proposed Registration Decision, *Bispyribac-sodium* (PRD2008-02). This Registration Decision² describes this stage of the PMRA's regulatory process for Bisypribac-sodium Technical and Velocity SP Herbicide and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2008-02. This decision is consistent with the proposed registration decision stated in PRD2008-02.

For more details on the information presented in this Registration Decision, please refer to the Science Evaluation section of PRD2008-02.

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 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.³ The Act also requires that products have value⁴ 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 of humans (e.g. children) as well as organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present 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 PMRA's website at <u>www.pmra-arla.gc.ca</u>.

What Is Bispyribac-sodium?

Bispyribac-sodium is a postemergence herbicide, i.e. a herbicide applied to emerged plants. It is applied to turf using ground application equipment to reduce the presence of annual bluegrass, a common invasive turf weed. Bispyribac-sodium inhibits the synthesis of key amino acids causing susceptible plants to stop growing and die within about two to three weeks.

Health Considerations

Can Approved Uses of Bispyribac-sodium Affect Human Health?

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

Exposure to bispyribac-sodium may occur when handling and applying the product. When assessing health risks, two key factors are considered: the level at which 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 (e.g. 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 using bispyribac-sodium products according to label directions.

Health effects in animals given daily doses of bispyribac-sodium over long periods of time included effects on the liver, bile duct, gall bladder and urinary bladder. When bispyribac-sodium was given to pregnant animals, effects on the developing fetus were observed at doses that were toxic to the mother, indicating that the fetus is no more sensitive to bispyribac-sodium than the adult animal. Bispyribac-sodium was not genotoxic and did not cause cancer, damage the nervous system or have reproductive effects. The risk assessment is conducted to ensure 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.

The use of Velocity SP Herbicide is limited to non-food/feed situations. It is not anticipated that the use of Velocity SP Herbicide will result in dietary risk from food and/or water.

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

Pesticide applicators mixing, loading or applying Velocity SP Herbicide, as well as field workers re-entering freshly treated areas, can come in direct contact with bispyribacsodium on the skin or through inhalation of spray mists. Therefore, the label will specify that anyone mixing, loading or applying Velocity SP Herbicide must wear a long-sleeved shirt, long pants, chemical-resistant gloves, shoes and socks. The label also specifies that all unprotected persons must be kept out of operation areas or areas where there may be drift. Taking into consideration these label requirements and that occupational exposure is expected to be brief, risk to applicators or workers is not a concern.

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

Environmental Considerations

What Happens When Bispyribac-sodium Is Introduced Into the Environment?

Bispyribac-sodium is toxic to aquatic and terrestrial plants; therefore, buffer zones are required during application.

Bispyribac-sodium enters the environment when used as a herbicide on turf. Bispyribacsodium is slightly persistent in soil and moderately persistent in water and sediment systems. Based on its low volatility, residues of bispyribac-sodium are not expected in the air. Based on physical and chemical factors of bispyribac-sodium, including its moderate persistence and moderate to high mobility in soil, bispyribac-sodium has the potential to move into surface and groundwater through runoff and leaching.

Bispyribac-sodium presents a low risk to wild mammals, birds, earthworms, bees, aquatic invertebrates and fish. Given that bispyribac-sodium is a herbicide, it is expected to adversely affect terrestrial plants in areas adjacent to where it is being used, as well as aquatic plants and some species of algae. Therefore, a buffer zone of five metres is required to protect nearby terrestrial plants from the effects of spray drift. Similarly, a buffer zone of one metre is required to protect aquatic plants and algae from the potential effects of spray drift.

Value Considerations

What Is the Value of Bispyribac-sodium?

Bispyribac-sodium, a postemergence herbicide, reduces the presence of annual bluegrass in turf.

Multiple applications of bispyribac-sodium, formulated as Velocity SP Herbicide, reduce the presence of annual bluegrass in turf. As bispyribac-sodium is only applied to turf infested with annual bluegrass, golf course superintendents and sod farmers can readily determine whether application of this herbicide is necessary.

Bispyribac-sodium is the only herbicide available in Canada to combat annual bluegrass in turf.

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 are required by law to be followed.

The key risk-reduction measures being proposed on the label of Velocity SP 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 bispyribac-sodium on the skin, anyone handling Velocity SP Herbicide must wear a long-sleeved shirt, long pants, chemical-resistant gloves, shoes and socks.

Environment

• Velocity SP Herbicide cannot be sprayed within five metres of susceptible non-target terrestrial plant species, nor within one metre of susceptible aquatic plant species. The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublands) and sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands).

Method of Application	Buffer Z	ones (metres) Requi	red for the Protection of:
	Freshwate	r habitat of depths:	Terrestrial habitat
	Less than 1 m	Greater than 1 m	
Field sprayer*	1	1	5

For field sprayer application, buffer zones can be reduced with the use of drift-reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy, the labelled buffer zone can be reduced by 30%.

Other Information

- 1. The relevant test data on which the decision is based (as referenced in this document) 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 (<u>pmra_inforserv@hc-sc.gc.ca</u>).
- 2. Any person may file a notice of objection⁵ regarding this registration decision within 60 days from the date of publication of this Registration Decision Document. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Requesting a Reconsideration of Decision, http://www.pmra-arla.gc.ca/english/pubreg/reconsideration-e.html) or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_inforserv@hc-sc.gc.ca).

⁵

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

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5.0 Value

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B. ADDITIONAL INFORMATION CONSIDERED

i) Published Information

1.0 Value

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