RD2009-05

Registration Decision

Neodiprion abietis Nucleopolyhedrovirus Newfoundland Strain

(publié aussi en français)

25 March 2009

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6605C
Ottawa, Ontario
K1A 0K9

Internet: pmra_publications@hc-sc.gc.ca
www.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

HC Pub: 8174

ISBN: 978-1-100-11492-7 (978-1-100-11493-4)
Catalogue number: H113-25/2009-5E (H113-25/2009-5E-PDF)

Overview

Registration Decision for *Neodiprion abietis* Nucleopolyhedrovirus Newfoundland Strain

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 Abietiv Technical and Abietiv Flowable Biological Insecticide containing the technical grade active ingredient *Neodiprion abietis* nucleopolyhedrovirus Newfoundland strain to reduce balsam fir sawfly populations on forest stands and woodlots.

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 PRD2008-11, *Neodiprion abietis Nucleopolyhedrovirus Newfoundland Strain*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for *Neodiprion abietis* nucleopolyhedrovirus Newfoundland strain and summarizes the Agency's decision, the reasons for it and provides, in Appendix I, a summary of comments received during the consultation process as well as the PMRA's response to these comments. This decision is consistent with the proposed registration decision stated in PRD2008-11.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2008-11, *Neodiprion abietis Nucleopolyhedrovirus Newfoundland Strain*, 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

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 the 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 (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 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 www.healthcanada.gc.ca/pmra.

What Is Neodiprion abietis Nucleopolyhedrovirus Newfoundland Strain?

Neodiprion abietis nucleopolyhedrovirus Newfoundland strain is a virus that causes a lethal disease in larvae of the balsam fir sawfly, *Neodiprion abietis*, when ingested by feeding larvae. Formulated as the end-use product Abietiv Flowable Biological Insecticide, it is applied to forest stands to decrease populations of balsam fir sawfly and thereby reduce feeding damage to balsam fir trees caused by this insect pest.

Health Considerations

Can Approved Uses of *Neodiprion abietis* Nucleopolyhedrovirus Newfoundland Strain Affect Human Health?

***Neodiprion abietis* nucleopolyhedrovirus Newfoundland strain is unlikely to affect your health when Abietiv Flowable Biological Insecticide is used according to the label directions.**

Exposure to *Neodiprion abietis* nucleopolyhedrovirus Newfoundland strain may occur during handling and application of Abietiv Flowable Biological Insecticide. When assessing health risks, several key factors are considered: the microorganism's biological properties (e.g. production of toxic byproducts), reports of any adverse incidents, its potential to cause disease or toxicity as determined in toxicological studies, and the levels to which people may be exposed relative to exposures already encountered in nature to other isolates of the microorganism.

Toxicology studies in laboratory animals describe potential health effects from large doses in an effort to identify any potential to cause disease or toxicity. When *Neodiprion abietis* nucleopolyhedrovirus Newfoundland strain was tested on laboratory animals, there were no signs it caused any significant toxicity or disease.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Abietiv Flowable Biological Insecticide is proposed for use only in forest stands. The establishment of a maximum residue limit is not required for *Neodiprion abietis* nucleopolyhedrovirus Newfoundland strain as it is not intended for application to food or feed crops. The acute oral toxicology data submitted by the applicant and the lack of production of known mammalian toxins—in addition to a long history of research, use and safety testing of baculoviruses—indicate that any inadvertent exposure poses minimal risk.

Baculoviruses are not generally recognized as aquatic microorganisms and are not expected to proliferate in aquatic habitats following direct or indirect exposure. Percolation through soil and municipal treatment of drinking water both reduce the possibility of exposure to *Neodiprion abietis* nucleopolyhedrovirus Newfoundland strain through drinking water.

Occupational Risks From Handling Abietiv Flowable Biological Insecticide

Occupational risks are not expected to be of concern when Abietiv Flowable Biological Insecticide is used according to the label directions, which include protective measures.

Users handling Abietiv Flowable Biological Insecticide can come into direct contact with *Neodiprion abietis* nucleopolyhedrovirus Newfoundland strain on the skin or in the eyes, or by inhalation. For this reason, the label specifies that mixers and loaders must wear a long-sleeved shirt, long pants, waterproof gloves, eye goggles, shoes and socks when handling this product. Specific personal protective equipment is not required for aerial applicators.

For bystanders, the exposure is expected to be much less than that of handlers, mixers and loaders, and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When *Neodiprion abietis* Nucleopolyhedrovirus Newfoundland Strain Is Introduced Into the Environment?

Environmental risks are not of concern.

The risk to non-target terrestrial and aquatic species is expected to be low based on the results of submitted studies and an absence of adverse effects reported in the published scientific literature with respect to other baculoviruses.

Neodiprion abietis nucleopolyhedrovirus Newfoundland strain occurs naturally. The use of Abietiv Flowable Biological Insecticide will not significantly increase background levels of the virus in the environment, and the potential increased risk to non-target organisms will be similarly non-significant. Furthermore, the host range of *Neodiprion abietis* nucleopolyhedrovirus Newfoundland strain is limited to arthropods in the hymenopteran order. Consequently, Abietiv Flowable Biological Insecticide is expected to pose little environmental risk when used according to the proposed label directions.

Value Considerations

What Is the Value of Abietiv Flowable Biological Insecticide?

Abietiv Flowable Biological Insecticide, containing the insect virus *Neodiprion abietis* nucleopolyhedrovirus, reduces populations of balsam fir sawfly (*Neodiprion abietis*).

A single application of *Neodiprion abietis* nucleopolyhedrovirus Newfoundland strain, formulated as Abietiv Flowable Biological Insecticide and applied by aerial spraying, can reduce populations of balsam fir sawfly larvae. Reducing populations of balsam fir sawfly larvae reduces the defoliation caused by larval feeding. One year of defoliation can cause several years of reduced tree growth, and more than one year of defoliation can cause tree mortality. Therefore, application of *Neodiprion abietis* nucleopolyhedrovirus Newfoundland strain can prevent serious losses in forest productivity.

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 on the label of Abietiv Flowable Biological Insecticide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

As with all microbial pest control products, there are concerns with skin irritation and with users developing allergic reactions through repeated high exposures to *Neodiprion abietis* nucleopolyhedrovirus Newfoundland strain.

Therefore, mixers and loaders of Abietiv Flowable Biological Insecticide must wear a long-sleeved shirt, long pants, waterproof gloves, eye goggles, shoes and socks when handling this product.

Environment

As a general precaution, users are advised not to use the end-use product to control aquatic pests. Users are also advised not to contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

Other Information

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 (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 PMRA's website (Requesting a Reconsideration of Decision, www.hc-sc.gc.ca/cps-spc/pest/protect-proteger/publi-regist/index-eng.php#rrd) or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

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

Appendix I Comments and Responses

1. A number of comments requested an explanation for limiting the application of Abietiv Flowable Biological Insecticide over aquatic habitats. The list of aquatic habitats in which Abietiv Flowable Biological Insecticide could not be applied was considered too restrictive.

   Response

   Although the health risks associated with drinking water exposure are negligible and aquatic ecosystem impacts are minimal, Abietiv Flowable Biological Insecticide is not intended for use in aquatic environments and such applications should be avoided where possible. To reinforce this intention, the PMRA will modify the proposed label language of Abietiv Flowable Biological Insecticide with the following statement under the **ENVIRONMENTAL PRECAUTIONS** section.

   > As this pesticide is not registered for the control of pests in aquatic systems, **DO NOT** use to control aquatic pests.

   This language is meant to replace the proposed language of:

   > **DO NOT** apply directly to freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands), estuaries or marine habitats.

   To avoid contamination of water bodies during cleaning and disposal activities, the following proposed language, which is in keeping with best practices, will remain on the Abietiv Flowable Biological Insecticide label.

   > **DO NOT** contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

2. A comment was received about the specific meteorological conditions for aerial applications (i.e. no applications when wind speed is greater than 16 km/h). The commenter stated that this specification was considered too restrictive as many aerial applicators in Canada do not have access to this technology. It was indicated that this label statement could “prevent the aerial application industry from working on strategies such as ‘optimization’ to improve target deposit and reduce off target drift.”

   Response

   Models used to calculate buffer zones take meteorological conditions into consideration. Given that buffer zones are not required for Abietiv Flowable Biological Insecticide, specifying the meteorological conditions is also not required. Instead, the PMRA will replace the proposed meteorological conditions (i.e. no applications when wind speed is greater than 16 km/h) with the following.

Apply only when meteorological conditions at the treatment site allow for complete and even coverage. Apply only when meteorological conditions are in compliance with local and/or provincial authorities.

3. A comment was received indicating that the aerial application terminology (i.e. use of appropriate marking devices) should be specific to technologies that are readily available and currently used by the aerial application industry.

Response

The PMRA recognizes that aerial application terminology may vary depending on the jurisdictions and available technologies. Consequently, the PMRA, in conjunction with stakeholders, will be discussing alternate wording or revisions to the current standard statement. The proposed label statement will remain until such time as alternate/revised wording is available.

References

A. List of Studies/Information Submitted by Registrant

1.0 The Active Ingredient, Its Properties and Uses

PMRA Document Number	Reference
1555885	2008, Abietiv (Sub. No. 2006-5583) Response to Query, DACO: M2.11