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Proposed Registration Decision

Neodiprion abietis Nucleopolyhedrovirus Newfoundland Strain

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Overview

Proposed 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 proposing 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.

Abietiv Technical (Registration No. 28303) and Abietiv Flowable Biological Insecticide (Registration No. 28304) are conditionally registered in Canada. The detailed review of these products can be found in Regulatory Note REG2006-10, *Neodiprion abietis Nucleopolyhedrovirus Newfoundland Strain.* The current applications were submitted to convert Abietiv Technical and Abietiv Flowable Biological Insecticide from conditional registration to full registration.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of Abietiv Technical and Abietiv Flowable Biological Insecticide.

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[1] 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 proposed conditions of registration. The Act also requires that products have value[2] 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 human populations

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act.*

2 "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."

(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.pmra-arla.gc.ca.

Before making a final registration decision on *Neodiprion abietis* nucleopolyhedrovirus Newfoundland strain, the PMRA will consider all comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision[4] on *Neodiprion abietis* nucleopolyhedrovirus Newfoundland strain, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to those comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation in this consultation document.

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 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.

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[3] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

[4] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

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 that 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 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, 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

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 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 apply the end-use product directly to freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs, ditches and wetlands), estuaries or marine habitats. Users are also advised not to contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

Next Steps

Before making a final registration decision on *Neodiprion abietis* nucleopolyhedrovirus Newfoundland strain, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

At the time the PMRA makes its registration decision, it will publish a Registration Decision document on *Neodiprion abietis* nucleopolyhedrovirus Newfoundland strain (based on the Science Evaluation in this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Neodiprion abietis nucleopolyhedrovirus (NeabNPV) Newfoundland Strain

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active microorganism	Polyhedral inclusion bodies (PIBs) of balsam fir sawfly nucleopolyhedrovirus (NPV) Newfoundland strain
Function	Viral insecticide
Binomial name	PIBs of *Neodiprion abietis* nucleopolyhedrovirus (NeabNPV) Newfoundland strain
Taxonomic designation	
Family	*Baculoviridae*
Genus	Nucleopolyhedrovirus
Patent status information	N/A
Nominal purity of active ingredient	4.0×10^9 PIBs/mL
Identity of relevant impurities of toxicological, environmental and/or other significance	The technical grade Abietiv Technical does not contain any impurities or microcontaminants known to be Toxic Substances Management Policy (TSMP) Track 1 substances. The product must meet microbiological contaminants release standards, and no mammalian toxins are known to be produced by the technical grade of the active ingredient, Abietiv Technical.

1.2 Physical and Chemical Properties of the Active Ingredients and End-Use Product

Technical Product—Abietiv Technical

Property	Result
Colour	Brown
Odour	Musty
Physical state	Suspension
Specific gravity	1.00 g/mL

Property	Result
Viscosity	1.0 centipoise
Corrosion character (oxidizing or reducing action)	Not corrosive

End-Use Product—Abietiv Flowable Biological Insecticide

Property	Result
Colour	Brown
Odour	Musty
Physical state	Suspension
Formulation type	Suspension
Guarantee	4.0×10^9 PIBs/mL
Formulants	The product does not contain any USEPA List 1 formulants or formulants known to be TSMP Track 1 substances.
Container material and description	High density polyethylene (40 mL–20 L)
Corrosion character (oxidizing or reducing action)	Not corrosive
Density/bulk density/specific gravity	1.0 g/mL
pH (in solution)	neutral
Storage stability	Information on storage stability indicated that Abietiv was stable at 4°C for up to 2.5 years.

1.3 Directions for Use

A 20% aqueous solution of molasses serves as the carrier for Abietiv Flowable Biological Insecticide. For preparation of spray solution add between 1 and 3 mL of Abietiv Flowable Biological Insecticide in each 10 L of the molasses solution. Use the higher rate under higher pest pressure. The spray solution will yield a rate of 1 to 3 billion (10^9) polyhedral inclusion bodies (PIBs) of *Neodiprion abietis* Nucleopolyhedrovirus when applied at a rate of 2.5 L per hectare. For example, 40 mL of Abietiv Flowable Biological Insecticide mixed with 400 L of 20% aqueous molasses and applied at a rate of 2.5 L per hectare will yield a rate of 1 billion PIBs of *Neodiprion abietis* Nucleopolyhedrovirus per hectare. To be effective, larvae must ingest foliage with deposits of Abietiv Flowable Biological Insecticide. Uniform spray deposit coverage of the foliage is essential for optimal efficacy.

1.4 Mode of Action

Neodiprion abietis Nucleopolyhedrovirus causes a lethal disease in larvae of the balsam fir sawfly, *Neodiprion abietis*. Larval infection begins with ingestion of polyhedral inclusion bodies (PIBs) containing the virus. In the alkaline environment of the larval midgut, the protein matrix of the PIBs is dissolved to release the virions that infect midgut epithelial cells. Viral replication occurs in the midgut epithelial cells and, in the later stages of infection, virions are occluded by polyhedrin protein to form new PIBs in the cell nucleus. Infected cells containing PIBs are sloughed off into the gut and out of the body where they can be ingested and subsequently infect other host insects. Death of the host insect normally occurs within one to two weeks of infection, during which time host feeding is reduced or completely suppressed.

2.0 Methods of Analysis

Data for methods of analysis were submitted in support of the initial registration of Abietiv Technical and Abietiv Flowable Biological Insecticide. Additional storage stability data were identified in the initial review as a requirement for conversion to full registration. A storage stability study was submitted and reviewed as part of the current review.

The storage stability of three batches of Abietiv Flowable Biological Insecticide stored at 4°C was assessed. Viability testing demonstrated that the product was stable over a period of up to 2.5 years at 4°C.

Refer to Regulatory Note REG2006-10, *Abietiv Neodiprion abietis Nucleopolyhedrovirus Newfoundland Strain*, for the evaluation results of the methods of analysis data submitted in support of the initial application.

3.0 Impact on Human and Animal Health

Refer to REG2006-10 for a detailed assessment of the toxicology, exposure and dietary risk database for Abietiv *Neodiprion abietis* Nucleopolyhedrovirus Newfoundland Strain and Abietiv Flowable Biological Insecticide.

4.0 Impact on the Environment

Refer to REG2006-10 for a detailed assessment of the environmental database for Abietiv *Neodiprion abietis* Nucleopolyhedrovirus Newfoundland Strain and Abietiv Flowable Biological Insecticide.

5.0 Value

Refer to REG2006-10 for a detailed assessment of the efficacy database for Abietiv Flowable Biological Insecticide.

6.0 Toxic Substances Management Policy Considerations

During the original review of Abietiv Technical and Abietiv Flowable Biological Insecticide, the PMRA had taken into account the federal Toxic Substances Management Policy and its Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*. It was determined that these products did not meet the TSMP Track 1 criteria. These products were also found not to contain any impurities of human health or environmental concerns and did not contain any USEPA or PMRA List 1 or 2 formulants.

7.0 Summary

All data requirements for Abietiv Technical and Abietiv Flowable Biological Insecticide have been fulfilled.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act*, is proposing 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 has resulted in the determination that, under the proposed conditions of use, the end-use product has value and does not present an unacceptable risk to human health or the environment.

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, N/A, MRID: N/A, DACO: M2.11