

Re-evaluation Decision

RVD2023-11

Nucleopolyhedrovirus for Douglas-Fir Tussock Moth and Neodiprion abietis Nucleopolyhedrovirus, and Their Associated End-use Products

Final Decision

(publié aussi en français)

6 June 2023

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

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ISSN: 1925-1017 (print) 1925-1025 (online)

Catalogue number: H113-28/2023-11E (print version) H113-28/2023-11E-PDF (PDF version)

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Re-evaluation Decision for Nucleopolyhedrovirus for Douglas-Fir Tussock Moth and *Neodiprion abietis* Nucleopolyhedrovirus, and their Associated End-use Products

Under the authority of the *Pest Control Products Act*, all registered pesticides must be regularly re-evaluated by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they continue to meet health and environmental standards and continue to have value. The re-evaluation considers information from various sources such as data and information from pesticide manufacturers and other regulatory agencies, as well as comments received during public consultations. Health Canada applies internationally accepted risk assessment methods as well as risk management approaches and policies.

Nucleopolyhedrovirus for Douglas-fir tussock moth and *Neodiprion abietis* nucleopolyhedrovirus are naturally occurring baculoviruses, registered in Canada for use as microbial pest control agents. Nucleopolyhedrovirus for Douglas-fir tussock moth is used for the control of Douglas-fir tussock moth and the suppression of white marked tussock moth on forest trees, in woodlands, along rights-of-way, in tree nurseries, in seed orchards, and in areas that are less than half a hectare with high-value trees or ornamental trees. *Neodiprion abietis* nucleopolyhedrovirus is used for the management of balsam fir sawfly larvae (*Neodiprion abietis*) in forestry sites and on field-grown conifers, including Christmas trees. Currently registered products containing nucleopolyhedrovirus for Douglas-fir tussock moth and *Neodiprion abietis* nucleopolyhedrovirus can be found in the <u>Pesticide Product Information</u> <u>Database</u> and in Appendix I.

The Proposed Re-evaluation Decision PRVD2022-20, Nucleopolyhedrovirus for Douglas-Fir Tussock Moth and *Neodiprion abietis* Nucleopolyhedrovirus and Their Associated End-use Products¹ containing the evaluation of nucleopolyhedrovirus for Douglas-fir tussock moth and *Neodiprion abietis* nucleopolyhedrovirus underwent a 90-day consultation period ending on 24 January 2023. PRVD2022-20 proposed continued registration of nucleopolyhedrovirus for Douglas-fir tussock moth and *Neodiprion abietis* nucleopolyhedrovirus for nucleopolyhedrovirus for Douglas-fir tussock moth and *Neodiprion abietis* nucleopolyhedrovirus products for sale and use in Canada, with label updates to meet current labelling standards (Appendix II and III).

No comments were received during the consultation period. Therefore, this decision is consistent with the proposed re-evaluation decision stated in PRVD2022-20, which lists all information used as the basis for the re-evaluation decision.

This document presents the final re-evaluation decision² for the re-evaluation of nucleopolyhedrovirus for Douglas-fir tussock moth and *Neodiprion abietis* nucleopolyhedrovirus, including the label updates required to meet the current labelling standards. All products containing nucleopolyhedroviruses for Douglas-fir tussock moth or *Neodiprion abietis* nucleopolyhedroviruses that are registered in Canada are subject to this re-evaluation decision.

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*.

Re-evaluation Decision for Nucleopolyhedrovirus for Douglas-Fir Tussock Moth and *Neodiprion abietis* Nucleopolyhedrovirus

Health Canada has completed the re-evaluation of nucleopolyhedrovirus for Douglas-fir tussock moth and *Neodiprion abietis* nucleopolyhedrovirus. Under the authority of the *Pest Control Products Act*, Health Canada has determined that continued registration of products containing nucleopolyhedroviruses for Douglas-fir tussock moth and *Neodiprion abietis* nucleopolyhedroviruses are acceptable with the label updates (Appendix II and III). An evaluation of available scientific information found that uses of nucleopolyhedroviruses for Douglas-fir tussock moth and *Neodiprion abietis* nucleopolyhedroviruses products meet current standards for protection of human health and the environment and have acceptable value with the label updates (Appendix II and III).

Risk mitigation measures

Registered pesticide product labels include specific directions for use. Directions include risk mitigation measures to protect human health and the environment and must be followed by law. The required updated label statements, as a result of the re-evaluation of nucleopolyhedrovirus for Douglas-fir tussock moth and *Neodiprion abietis* nucleopolyhedrovirus, are summarized below. Refer to Appendix II and III for details.

Label improvements to meet current standards:

Human health

• Update to standard label statements (wording related to personal protective equipment, first aid, spray drift, directions for use and the addition of a re-entry interval.).

Environment

• Updates to standard label statements (wording related to disposal).

Next steps

To comply with this decision, the required label amendments must be implemented on all product labels no later than 24 months after the publication date of this decision document. Accordingly, both registrants and retailers will have up to 24 months from the date of this decision document to transition to selling the product with the newly amended labels. Similarly, users will also have the same 24-month period from the date of this decision document to transition to using the newly amended labels, which will be available on the Public Registry.

Refer to Appendix I for details on specific products impacted by this decision.

Other information

Any person may file a notice of objection³ regarding this decision on nucleopolyhedrovirus for Douglas-fir tussock moth and *Neodiprion abietis* nucleopolyhedrovirus and its associated enduse products within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides section of the Canada.ca website (Request a Reconsideration of Decision) or contact Health Canada's <u>Pest Management Information Service</u>.

The relevant confidential test data on which the decision is based (as referenced in PRVD2022-20) are available for public inspection, upon application, in Health Canada's Reading Room. For more information, please contact Health Canada's <u>Pest Management Information Service</u>.

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

Appendix I Registered Products containing Nucleopolyhedrovirus for Douglas-Fir Tussock Moth or *Neodiprion abietis* Nucleopolyhedrovirus in Canada

Table 1Registered products containing Nucleopolyhedrovirus for Douglas-Fir
Tussock Moth requiring (label) amendments1

Registration number	Marketing class	Registrant	Product name	Formulation type	Guarantee
17786	R	Natural Resources Canada (FPM)	Virtuss Nucleopolyhedrovirus Biological Insecticide	Wettable Powder	2.5% (Contains at least 1×10^{10} Polyhedral Inclusion Bodies (PIBs) of <i>Orgyia</i> <i>pseudotsugata</i> nucleopolyhedrovi rus per gram)
19293	R	Natural Resources Canada (FPM)	Tm Biocontrol-1 Nucleopolyhedrovirus Biological Insecticide	Wettable Granules	Contains at least 7.05×10^9 PIBs per gram
20290	Т	Natural Resources Canada (FPM)	Tm Biocontrol-1 Nuclear Polyhedrosis Virus Biological Insecticide	Wettable Powder	3.5% (Contains at least 70 million activity units per gram)
29106	Т	Natural Resources Canada (FPM)	Virtuss Technical Active Nucleopolyhedrovirus Biological Insecticide	Wettable Powder	2.5% (Contains at least 1×10^{10} PIBs of <i>Orgyia</i> <i>pseudotsugata</i> nucleopolyhedrovi rus per gram)

T = Technical; R = restricted

¹ as of 31 January 2023, excluding discontinued products or products with a submission for discontinuation.

Table 2Registered products containing Neodiprion abietis nucleopolyhedrovirus
requiring (label) amendments1

Registration number	Marketing Class	Registrant	Product name	Formulation type	Guarantee
28303	Т	Natural Resources Canada (CDQ)	Abietiv Technical	Suspension	4×10^9 PIBs per milliliter
28304	R	Natural Resources Canada (CDQ)	Abietiv Flowable Biological Insecticide	Suspension	4×10^9 PIBs per milliliter

T = Technical; R= restricted

¹as of 31 January 2023, excluding discontinued products or products with a submission for discontinuation.

Appendix II Label amendments for products containing Nucleopolyhedrovirus for Douglas-Fir Tussock Moth

Information on labels of currently registered products should not be removed unless it contradicts the label statements provided below.

Label updates for technical grade active ingredients

I. Under PRECAUTIONS section, update PPE with:

"Wear a long-sleeved shirt, long pants, protective eyewear (goggles), waterproof gloves, socks and shoes and a NIOSH-approved particulate filtering facepiece respirator with any N, R or P filter when handling and during all clean-up/repair activities."

II. Under DISPOSAL section, update current statement with:

"For information on disposal of unused, unwanted product, contact the manufacturer or the provincial regulatory agency. Contact the manufacturer and the provincial regulatory agency in case of a spill and for clean-up of spills."

Label updates for restricted class end-use products

III. Under PRECAUTIONS section, update the PPE with:

"Wear a long-sleeved shirt, long pants, protective eyewear (goggles), waterproof gloves, socks and shoes and a NIOSH-approved particulate filtering facepiece respirator with any N, R or P filter when handling, mixing/loading or applying the product and during all clean-up/repair activities. When applicators use a closed system (e.g., enclosed cab), the applicator requirement for waterproof gloves, protective eyewear (goggles) and a NIOSH-approved particulate filtering respirator with any N, R, or P filter may be waived. When reduced personal protective equipment is worn, waterproof gloves and the facepiece respirator must be immediately available for use in an emergency such as a spill or equipment breakdown."

IV. Under PRECAUTIONS section, add the label statement as follows:

"PREVENT ACCESS BY UNAUTHORIZED PERSONNEL"

V. Under PRECAUTIONS section, update the current drift statement with:

"Apply only when the potential for drift to areas of human habitation or other areas of human activity such as parks, school grounds, and playing fields is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings."

VI. Under the DIRECTIONS FOR USE section, add the label statement as follows:

"DO NOT allow worker entry into treated areas for 4 hours or until sprays have dried unless wearing waterproof gloves, long-sleeved shirt, long pants, socks and shoes."

Appendix III Label Amendments for products containing *Neodiprion abietis* nucleopolyhedrovirus

Information on labels of currently registered products should not be removed unless it contradicts the label statements provided below.

Label updates for technical grade active ingredients

I. Under PRECAUTIONS section update the PPE with:

"Wear a long-sleeved shirt, long pants, protective eyewear (goggles), waterproof gloves, socks and shoes and a NIOSH-approved particulate filtering facepiece respirator with any N, R or P filter when handling and during all clean-up/repair activities."

II. Under DISPOSAL section, update the current statement with:

"For information on disposal of unused, unwanted product, contact the manufacturer or the provincial regulatory agency. Contact the manufacturer and the provincial regulatory agency in case of a spill and for clean-up of spills."

III. Under FIRST AID section, update the statements as per the PMRA Guidance Document, First Aid Labelling Statements, March 2022:

"If swallowed Call a poison control centre or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control centre or doctor. Do not give anything by mouth to an unconscious person. If on skin or clothing – Take off contaminated clothing. Rinse skin immediately with plenty of water for 15–20 minutes. Call a poison control centre or doctor for treatment advice. If inhaled – Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouthto-mouth, if possible. Call a poison control centre of doctor for further treatment advice. If in eyes – Hold eye open and rinse slowly and gently with water for 15–20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control centre or doctor for treatment advice."

Label updates for restricted class end-use products

IV. Under PRECAUTIONS section, update the PPE with:

"Wear a long-sleeved shirt, long pants, protective eyewear (goggles), waterproof gloves, socks and shoes and a NIOSH-approved particulate filtering facepiece respirator with any N, R or P filter when handling, mixing/loading or applying the product and during all clean-up/repair activities. When applicators use a closed system (e.g., enclosed cab

and/or cockpit), the applicator requirement for waterproof gloves, protective eyewear (goggles) and a NIOSH-approved particulate filtering respirator with any N, R, or P filter may be waived. When reduced personal protective equipment is worn, waterproof gloves and the facepiece respirator must be immediately available for use in an emergency such as a spill or equipment breakdown."

V. Under PRECAUTIONS section add the label statement as follows:

"PREVENT ACCESS BY UNAUTHORIZED PERSONNEL"

VI. Under PRECAUTIONS section add the label statement as follows:

"Apply only when the potential for drift to areas of human habitation or other areas of human activity such as parks, school grounds, and playing fields is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings."

VII. Under the DIRECTIONS FOR USE section add the label statement as follows:

"DO NOT allow worker entry into treated areas for 4 hours or until sprays have dried unless wearing waterproof gloves, long-sleeved shirt, long pants, socks and shoes."