Proposed Re-evaluation Decision PRVD2022-20

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

Consultation Document

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Proposed re-evaluation decision

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

This document presents the proposed regulatory decision for the re-evaluation of nucleopolyhedrovirus for Douglas-fir tussock moth and *Neodiprion abietis* nucleopolyhedrovirus, including any proposed amendments (risk mitigation measures) to protect human health and the environment, as well as the science evaluation on which the proposed decision is based.

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 are listed in Appendix I.

Registered pesticide product labels include specific directions for use. Directions include risk mitigation measures to protect human health and the environment that must be followed by law. When the current label directions are followed, these products were shown to have value in providing a pest management solution, and potential risks to human health (occupational and bystander) and the environment are considered to be acceptable. As a result of the re-evaluation of nucleopolyhedrovirus for Douglas-fir tussock moth and *Neodiprion abietis* nucleopolyhedrovirus, label updates are proposed to meet the current labelling standards (Appendices II, III). Proposed label amendments include updates to personal protective equipment, first aid, spray drift, and disposal label statements, and the addition of a re-entry interval.

Under the authority of the *Pest Control Products Act* and based on an evaluation of currently available scientific information, products containing nucleopolyhedrovirus for Douglas-fir tussock moth and *Neodiprion abietis* nucleopolyhedrovirus (Appendix I) are being proposed for continued registration in Canada with the proposed updates to label directions (Appendices II, III).

All products containing nucleopolyhedrovirus for Douglas-fir tussock moth and *Neodiprion abietis* nucleopolyhedrovirus registered in Canada are subject to this proposed re-evaluation decision. This document is subject to a public consultation,[1] during which written comments and additional information may be submitted to PMRA Publications. The final re-evaluation decision will be published taking into consideration the comments and information received during the consultation period.

Next steps

The public, including the registrant and stakeholders, are encouraged to submit written comments and additional information during the 90-day public consultation period upon publication of this proposed re-evaluation decision.

All comments received during the 90-day public consultation period will be taken into consideration in preparation of the re-evaluation decision document,[2] which could result in revised risk mitigation measures. The re-evaluation decision document will include the final re-evaluation decision, the reasons for it and a summary of comments received on the proposed re-evaluation decision with Health Canada's responses.

Other information

When Health Canada makes its re-evaluation decision, it will publish a Re-evaluation Decision on nucleopolyhedrovirus for Douglas-fir tussock moth and *Neodiprion abietis* nucleopolyhedrovirus (based on the Science Evaluation of PRVD2022-20). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room.

Additional scientific information

Additional scientific data are not required at this time.

[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*.

Science evaluation

1.0 Human health assessment

Nucleopolyhedrovirus for Douglas-fir tussock moth and *Neodiprion abietis* nucleopolyhedrovirus are naturally occurring host-specific baculoviruses which pose little risk to human health and safety when used as directed (Canada, 2004 and 2006). They are registered in Canada for use as microbial pest control agents (MPCAs) against Douglas-fir tussock moth/white marked tussock moth and balsam fir sawfly larvae, respectively.

Nucleopolyhedrovirus for Douglas-fir tussock moth is of low acute toxicity via the oral, pulmonary, and dermal routes of exposure, not pathogenic via intraperitoneal injection, and not a dermal irritant (USEPA, 1996). Nucleopolyhedrovirus for Douglas-fir tussock moth is a severe eye irritant which may cause irreversible damage to the cornea, and is a potential sensitizer (Canada, 2004). Mammalian tissue culture assays were waived based on the lack of effects when testing nucleopolyhedrovirus for Douglas-fir tussock moth against amphibian and fish cell lines for infectivity, as well as the results of the testing of numerous baculoviruses against more than 50 cell lines, including mammalian cell lines, without any adverse effects being noted (USEPA, 1996).

Although the MPCA, nucleopolyhedrovirus for Douglas-fir tussock moth, is of low acute dermal toxicity and not a dermal irritant, these routes of exposure were identified as areas of concern by the USEPA due to the presence of insect hairs in end-use products. Hypersensitivity can occur from exposure to setae (hairs) of the larval stages of the target host insects. Currently, sufficient precautions, including personal protective equipment, are on the registered label to mitigate potential risk. However, personal protective equipment is proposed to be updated to reflect current standards (Appendix II).

Neodiprion abietis nucleopolyhedrovirus is of low acute toxicity via the oral, pulmonary and intravenous routes of exposure, is minimally to slightly irritating to the skin, is a potential skin sensitizer, and is not cytopathic to a range of mammalian cells, based on published studies and scientific rationale (Canada, 2006). An eye irritation study for *Neodiprion abietis* nucleopolyhedrovirus has not been submitted, thus a precautionary statement is required (Canada, 2006). Based on Health Canada's knowledge and familiarity with baculoviruses in general and information in the available published scientific literature, no further tissue culture testing is required to assess infection (overt, persistent, latent or abortive), transformation, and toxicity (Canada, 2006). Precautionary label statements are present on the end-use product to caution that the product is an eye irritant and potential sensitizer. Personal protective equipment is proposed to be updated to align with current labelling standards (Appendix III).

For the review of baculovirus active ingredients, Health Canada relied on human health and safety studies conducted on a variety of baculovirus species. The information included numerous acute oral, inhalation, intravenous injection, dermal toxicity, dermal irritation and tissue culture studies, as well as a scientific waiver to address potential infectivity of baculoviruses. For additional details refer to PRD2015-09 *Autographa californica* Nucleopolyhedrovirus FV11 and REG2006-10 Abietiv *Neodiprion abietis* Nucleopolyhedrovirus Newfoundland Strain.

Appropriate hazard statements are currently present on all product labels.

Nucleopolyhedrovirus for Douglas-fir tussock moth and *Neodiprion abietis* nucleopolyhedrovirus end-use products are restricted class products applied to forested areas and are not registered for use on food or feed crops. 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 nucleopolyhedrovirus for Douglas-fir tussock moth and *Neodiprion abietis* nucleopolyhedrovirus through drinking water. Users are also advised not to contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes. Therefore, drinking water contamination is considered unlikely (Canada, 2009). Dietary exposure is not anticipated and maximum residue limits are not required.

Occupational exposure to nucleopolyhedrovirus for Douglas-fir tussock moth and to *Neodiprion abietis* nucleopolyhedrovirus is expected during the mixing, loading, and application of the restricted products. The nucleopolyhedrovirus for Douglas-fir tussock moth products are applied by conventional hydraulic sprayers (ground application) or by fixed-wing or rotary aircraft (aerial application) to 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-valued trees or ornamental trees. The *Neodiprion abietis* nucleopolyhedrovirus product is applied by conventional ground application equipment, including airblast sprayers, to field-grown conifers, including Christmas trees, and by fixed-wing or rotary aircraft to forestry sites.

Potential occupational exposure is expected to be short-term and to occur via dermal, ocular, and inhalation routes for both MPCAs. Baculoviruses are naturally occurring. To mitigate dermal, ocular, and inhalation exposure, product labels currently require handlers to wear personal protective equipment (PPE) including a long-sleeved shirt and long pants, socks, shoes, gloves, respirator, eye goggles or face shield. However, PPE for end-use products containing these MPCAs are proposed to be updated for clarity and to reflect current standards (Appendices II, III). Postapplication risk is acceptable due to the low toxicity and lack of infectivity associated with these MPCAs, and the minimal postapplication exposure anticipated. However, it is proposed that a re-entry interval of four hours, or until sprays have dried, unless wearing a long-sleeved shirt, long pants, waterproof gloves, socks and shoes, is added to product labels, to align with current labelling standards (Appendices II, III).

The use of nucleopolyhedrovirus for Douglas-fir tussock moth in forested areas may result in bystander exposure of individuals present for recreational purposes. The risk to bystanders is acceptable given the low toxicity and lack of infectivity associated with this MPCA. Although nucleopolyhedrovirus for Douglas-fir tussock moth products are used in tree nurseries, in seed

orchards, and in areas that are less than half a hectare with high-value trees or ornamental trees, non-occupational exposure is not expected as the end-use products are restricted class products and spray drift statements are present on labels to mitigate residential exposure. However, label statements are proposed to be updated to reflect current standards (Appendix II).

The *Neodiprion abietis* nucleopolyhedrovirus end-use product is applied to field-grown conifers, including Christmas trees, but due to the timing of the applications (early to late spring), consumer exposure to residues on treated Christmas trees is not expected to be above levels found naturally occurring in the environment (Canada, 2013). It is proposed that a spray drift statement be added to the *Neodiprion abietis* nucleopolyhedrovirus end-use product label (Appendix III).

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal and inhalation). Dietary (food and drinking water) exposure and residential exposure are not anticipated under current conditions of use. Products are not registered for use on food or feed crops and drinking water contamination is considered unlikely. The only anticipated non-occupational exposure is to individuals present in forested areas for recreational purposes during applications of nucleopolyhedrovirus for Douglas-fir tussock moth. On this basis, the potential aggregate risk is considered acceptable when products are used according to proposed label directions.

The *Pest Control Products Act* requires that the Health Canada consider the cumulative exposure to pest control products with a common mechanism of toxicity. For the current re-evaluation, Health Canada has determined that nucleopolyhedrovirus for Douglas-fir tussock moth and *Neodiprion abietis* nucleopolyhedrovirus share a common mechanism of toxicity with the MPCAs *Cydia pomonella* granulovirus isolate V-22, nuclear polyhedrosis virus of red-headed pine sawfly, *Cydia pomonella* granulosis virus (strain CMGv4), *Cydia pomonella* granulovirus (strain M), *Autographa californica* nucleopolyhedrovirus FV11 and *Helicoverpa armigera* nucleopolyhedrovirus BV-0003, all of which are baculoviruses. The potential health risks from cumulative exposure of nucleopolyhedrovirus of Douglas-fir tussock moth and *Neodiprion abietis* nucleopolyhedrovirus and these other MPCAs are acceptable when used as labelled given their low toxicity and pathogenicity.

2.0 Environment assessment

Nucleopolyhedrovirus for Douglas-fir tussock moth and *Neodiprion abietis* nucleopolyhedrovirus are biological organisms which occur naturally, and the use of these actives as pest control agents is not expected to result in sustained increases of these viruses beyond natural background levels.

These viruses are host-specific (the nucleopolyhedrovirus for Douglas-fir tussock moth infects only forest insects in the lymantriinae family, and *Neodiprion abietis* nucleopolyhedrovirus infects only insects in the hymenopteran order). Additionally, known insect host range and scientific literature on honeybee mortality demonstrate that nucleopolyhedrovirus for Douglas-fir tussock moth and other baculoviruses do not have adverse effects on honey bees (USEPA, 1996).

Non-target insect testing with *Neodiprion abietis* nucleopolyhedrovirus indicates that species closely related to the target pest, *N. abietis*, in the hymenopteran order may be at risk. However, this is mitigated by limiting the use of this active to forestry. Spray applications of the *Neodiprion abietis* nucleopolyhedrovirus end-use product introduce relatively little virus into the environment compared to natural baculovirus epizootics. Therefore, background levels of the virus will not be increased significantly in the environment. (Canada, 2006). The potential risks to non-target organisms are acceptable when these products are used according to label directions.

Nucleopolyhedrovirus for Douglas-fir tussock moth and *Neodiprion abietis* nucleopolyhedrovirus are not Track 1 substances as they do not meet all Track 1 criteria as per the Toxic Substances Management Policy.

Potential risk to the environment (terrestrial and aquatic) from the current use of these nucleopolyhedroviruses (Nucleopolyhedrovirus for Douglas-fir tussock moth and *Neodiprion abietis* nucleopolyhedrovirus) is considered acceptable under the current conditions of use.

3.0 Incident reports

As of 16 May 2022, no human, domestic animal or environmental incidents involving nucleopolyhedrovirus for Douglas-fir tussock moth or *Neodiprion abietis* nucleopolyhedrovirus have been reported to Health Canada.

4.0 Value assessment

Nucleopolyhedrovirus for Douglas-fir tussock moth and *Neodiprion abietis* nucleopolyhedrovirus are naturally occurring baculoviruses used as microbial pest control agents for the management of Douglas-fir tussock moth, white marked tussock moth, and balsam fir sawfly larvae. Due to their narrow spectrums of activity, they have value as pest management compatible (species-specific) pest control products for use in forest trees, woodlands, along rights-of-way, in tree nurseries, in seed orchards, on high value trees or ornamental trees, and on field-grown conifers including Christmas trees.

Appendix I Registered products containing Nucleopolyhedrovirus for Douglas-Fir Tussock Moth or *Neodiprion abietis* nucleopolyhedrovirus.

Table 1 Registered Products Containing Nucleopolyhedrovirus for Douglas-Fir Tussock Moth in Canada as of 15 August 2022[3]

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 Orgyia pseudotsugata nucleopolyhedrovirus per gram)
19293	R	Natural Resources Canada (FPM)	Tm Biocontrol-1 Nucleopolyhedrovirus Biological Insecticide for Douglas-Fir Tussock Moth Wettable Powder	wettable granules	7.05×10^{9} PIBs of Douglas-fir tussock moth nucleopolyhedrovirus per gram
20290	T	Natural Resources Canada (FPM)	Tm Biocontrol-1 Nuclear Polyhedrosis Virus Biological Insecticide for Douglas-Fir Tussock Moth	wettable powder	3.5% (Contains at least 70 million activity units per gram)
29106	T	Natural Resources Canada (FPM)	Virtuss Technical Active Nucleopolyhedrovirus Biological Insecticide	wettable powder	2.5% (Contains at least 1×10^{10} PIBs of Orgyia pseudotsugata nucleopolyhedrovirus per gram)

Table 2 Registered Products Containing *Neodiprion abietis* nucleopolyhedrovirus in Canada as of 15 August 2022[3]

Registration number	Marketing class	Registrant	Product name	Formulation type	Guarantee
28303	T	Natural Resources Canada (CDQ)	Abietiv Technical	suspension	4×10^{9} PIBs per millilitre
28304	R	Natural Resources Canada (CDQ)	Abietiv Flowable Biological Insecticide	suspension	4×10^{9} PIBs per millilitre

T= technical
R= restricted

[3] As of 15 August 2022, excluding discontinued products or products with a submission for discontinuation.

Appendix II Proposed label updates 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 Proposed label updates 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 mouth-to-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."

References

PMRA#	Reference
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