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Proposed Registration Decision

PRD2025-17

Nealta Miticide, containing Cyflumetofen

(publié aussi en français)

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Overview

Proposed Registration Decision for Cyflumetofen

Health Canada's Pest Management Regulatory Agency (PMRA), pursuant to subsection 28(1) of the *Pest Control Products Act*, is proposing registration for the sale and use of Nealta Miticide, containing the technical grade active ingredient cyflumetofen, to control spider mites on greenhouse ornamentals. This evaluation was completed under the User Requested Minor Use Label Expansion program, which is a cooperative program between Agriculture and Agri-Food Canada and Health Canada's Pest Management Regulatory Agency and includes participation by sponsors groups, manufacturers, and both provincial and federal governments.

Nealta Miticide is currently registered to control certain spider mites on a variety of agricultural crops under use-site category numbers 4, 5, 13, 14 and 27. For details, refer to the Proposed Registration Decisions PRD2014-10 *Cyflumetofen*, PRD2024-07 *Nealta Miticide, containing Cyflumetofen* and Registration Decisions RD2014-24 *Cyflumetofen*, and RD2024-13 *Nealta Miticide, containing cyflumetofen*.

An evaluation of available scientific information found that, under the approved conditions of use, the health and environmental risks and the value of the pest control product are acceptable.

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 Nealta Miticide, containing cyflumetofen.

What does Health Canada consider when making a registration decision?

The primary objective of the *Pest Control Products Act* is to prevent unacceptable risks to individuals and the environment from the use of pest control products. Health or environmental risk is considered acceptable¹ 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 value² when used according to the label directions. Conditions of registration may include precautionary measures on the product label to further reduce risk.

To reach its decisions, Health Canada's PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children). They also consider the unique characteristics of organisms in the environment.

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."

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 Health Canada regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and pest management portion of Canada.ca.

Before making a final registration decision on Nealta Miticide, containing cyflumetofen, Health Canada's PMRA will consider any written comments received from the public directly related to the proposed decision in this consultation document.³ Health Canada will then publish a Registration Decision⁴ on Nealta Miticide, containing cyflumetofen, which will include the decision, the reasons for it, a summary of comments received on the proposed registration decision and Health Canada's response to these comments.

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

What is cyflumetofen?

Cyflumetofen is a *beta*-ketonitrile derivative. It interferes with energy production within cells and acts as an acaricide on contact with spider mites. Foliar application of cyflumetofen formulated as Nealta Miticide provides control of spider mites on greenhouse ornamentals.

Health considerations

Can approved uses of cyflumetofen affect human health?

Nealta Miticide, containing cyflumetofen, is unlikely to affect your health when used according to label directions.

Potential exposure to cyflumetofen may occur when handling and applying the end-use product or when entering an area that has been treated with the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are selected to protect the most sensitive human population (for example, children and nursing mothers). As such, sex and gender are taken into account in the risk assessment. 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 level at which no effects are observed. The health effects noted in animals occur at dose levels more than 100-times higher (and often much higher) than levels to which humans are normally exposed when pesticide products are used according to label directions.

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*.

In laboratory animals, the technical grade active ingredient cyflumetofen was of low acute toxicity by the oral, dermal, and inhalation routes of exposure. It was minimally irritating to the eyes and non-irritating to the skin. Cyflumetofen caused an allergic skin reaction; consequently, the hazard statement “POTENTIAL SKIN SENSITIZER” is required on the label.

The end-use product, Nealta Miticide, containing cyflumetofen, was of low acute toxicity via the oral, dermal and inhalation routes of exposure. Nealta Miticide was non-irritating to the eyes, minimally irritating to the skin and did not cause an allergic skin reaction.

Prior to the initial registration of cyflumetofen, registrant-supplied short- and long-term (lifetime) animal toxicity tests, as well as information from the published scientific literature, were assessed for the potential of cyflumetofen to cause neurotoxicity, immunotoxicity, chronic toxicity, cancer, reproductive and developmental toxicity, and various other effects. The most sensitive endpoints for risk assessment were effects on the adrenal glands. There was no evidence that cyflumetofen damaged genetic material; however, it did cause testicular tumours and thyroid tumours in male rats. There was no evidence of increased sensitivity of the young compared to adult animals, although a serious endpoint (a birth defect) was noted in rabbit fetuses at a dose level that was also toxic to the mothers. The risk assessment protects against the effects noted above and other potential effects by ensuring that the level of exposure to humans is well below the lowest dose level at which these effects occurred in animal tests.

Occupational risks from handling Nealta Miticide

Occupational risks are not of health concern when Nealta Miticide is used according to the proposed label directions, which include protective measures.

Workers mixing, loading or applying Nealta Miticide, and workers entering recently treated fields, nurseries, and greenhouses can be exposed to cyflumetofen residues through direct skin contact or through inhalation. Therefore, the label specifies that anyone mixing, loading and applying Nealta Miticide must wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes. In addition, the label specifies that for application of Nealta Miticide using handheld airblast/mistblower equipment, workers must wear chemical-resistant coveralls with a chemical-resistant hood over long-sleeved shirt, long pants, chemical-resistant gloves, socks, chemical-resistant footwear and a respirator with a NIOSH-approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH-approved canister approved for pesticides. Eye, head and respiratory protective equipment are required when applying Nealta Miticide above waist height using handheld equipment. The label also requires that workers do not enter or be allowed into treated areas during the restricted-entry interval (REI) of 12 hours. Taking into consideration the label statements, the number of applications and the duration of exposure for handlers and postapplication workers, the risks to these individuals from exposure to Nealta Miticide are not of health concern when the end-use product is used according to the proposed label directions.

Health risks in residential and other non-occupational environments

Non-occupational risks are not of concern when used according to label directions.

There are no risks in residential and other non-occupational environments as Nealta Miticide will only be applied in commercial greenhouses. Furthermore, exposure to treated ornamental plants that are subsequently purchased at retail locations is considered negligible.

Environmental considerations

What happens when cyflumetofen is introduced into the environment?

When used according to label directions, the environmental risks associated with the major new use of cyflumetofen on greenhouse ornamentals is acceptable.

The proposed major new use of cyflumetofen in greenhouse non-food crops (ornamentals) poses a negligible risk to terrestrial or aquatic organisms. When cyflumetofen is used according to the label, the environmental risks are considered acceptable.

Value considerations

What is the value of Nealta Miticide?

Nevalta Miticide contains the active ingredient cyflumetofen and controls spider mites on greenhouse ornamentals.

The use of Nealta Miticide to control spider mites on greenhouse ornamentals is new. The product is applied to the foliage of these crops. Nealta Miticide represents a new mode of action against spider mites on greenhouse ornamentals. Therefore, it may aid in resistance management of these pests on these crops.

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 Nealta Miticide to address the potential risks identified in this assessment are as follows.

Key risk-reduction measures

Human health

To reduce the potential exposure of workers to cyflumetofen through direct skin contact or through inhalation, workers mixing, loading and applying Nealta Miticide and performing cleaning and repair activities must wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes. In addition, the label specifies that for application of Nealta Miticide

using handheld airblast/mistblower equipment, workers must wear chemical-resistant coveralls with a chemical-resistant hood over long-sleeved shirt, long pants, chemical-resistant gloves, socks, chemical-resistant footwear and a respirator with a NIOSH-approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH-approved canister approved for pesticides. The label also requires that workers do not enter or be allowed entry into treated areas during the REI of 12 hours. Furthermore, a standard label statement to prohibit the use of this product in residential areas is present on the label.

Additional mitigation label statements are required on the label of Nealta Miticide. Eye, head and respiratory protective equipment are required when applying Nealta Miticide above waist height using handheld equipment and the statement to prohibit the use of this product in residential areas must be revised.

Environment

No additional mitigation label statements are required on the label of Nealta Miticide.

Next steps

Before making a final registration decision on Nealta Miticide, containing cyflumetofen, Health Canada's PMRA will consider any written comments received from the public that are directly related to this proposed decision, such as comments directed to the science evaluation, in response to this consultation document up to 45 days from the date of publication (by 22 January 2026) of this document. Please forward all comments to PMRA Publications, through the Public Engagement Portal (Public Engagement Forms – Consultation Comment). Health Canada will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed decision and Health Canada's response to these comments.

Other information

When Health Canada makes its registration decision, it will publish a Registration Decision on Nealta Miticide, containing cyflumetofen (based on the Science evaluation of 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. For more information or if you have questions, please contact the PMRA's Pest Management Information Service.

Science evaluation

Cyflumetofen, Nealta Miticide

1.0 The Active Ingredient, Its Properties and Uses

1.1 Directions for use

Greenhouse ornamentals			
Crop(s)	Pest(s)	Amount of product per application (L/1000 L)	Pre-harvest interval (days)
Greenhouse Ornamentals (container, bench, flat, plug, in-ground bed)	Spruce spider mite European red mite Two-spotted spider mite McDaniel spider mite	1.0	N/A
<ul style="list-style-type: none">• Maximum of 2 applications per crop cycle for indoor ornamentals.• Allow a minimum of 14 days between applications. Monitor pest population and reapply if necessary once thresholds are reached.• Apply in a maximum spray volume of 1000 L/ha to ensure thorough coverage.• DO NOT exceed a maximum of 2 L of product per crop cycle for indoor ornamentals.• Do not water crops within 1 hour of application.• Foliar Spray application only.• Do not apply through any type of irrigation system. <p>DO NOT use in residential areas. Residential areas are defined as any use site where bystanders or the public, including children, could be exposed during or after application. This includes areas in and around homes, schools, public buildings or any other areas where they could be exposed.</p> <p>Nealta Miticide is not systemic or translaminar. Thorough and uniform coverage of the leaf surface and/or direct contact of the spray mixture with the target pest is required for satisfactory control. Because Nealta Miticide is not systemic, complete coverage is necessary for effective control.</p>			

1.2 Mode of action

Cyflumetofen is a mitochondrial complex II electron transport inhibitor (IRAC Mode of Action Group 25) and thus interferes with cellular energy metabolism. It acts through direct contact with the target pests and has no systemic activity in plants but is active against all life stages of spider mites (Tetranychidae), including eggs.

2.0 Impact on human and animal health

2.1 Hazard assessment

A detailed review of the toxicology database for cyflumetofen was conducted previously and is summarized in the Proposed Registration Decision, PRD2014-10. Additionally, a literature search was conducted and no published scientific studies relevant to the human health hazard assessment were identified as of 3 July 2025.

A scan of the literature and international regulatory decisions released subsequent to the previous detailed assessment was conducted and did not yield any information that impacted the previous assessment. An extensive toxicology database is available for the assessment of human health risks of cyflumetofen and is considered adequate to characterize the potential health hazards associated with cyflumetofen.

2.2 Toxicology reference values

Toxicology reference values for use in the human health risk assessment were established previously and are reported in PRD2014-10. A summary is presented in Appendix I, Table 1.

2.3 Route and duration of exposure

For mixers, loaders and applicators, occupational exposure to Nealta Miticide is characterized as short-term in duration and is predominantly by the dermal and inhalation routes. For postapplication workers, occupational exposure to cyflumetofen is characterized as long-term in duration for greenhouse uses, and is predominantly by the dermal route.

2.4 Dermal absorption

A rat in vivo dermal absorption study was previously reviewed. Based on the data presented in the study, a dermal absorption value of 11% was selected for the risk assessment of cyflumetofen. Refer to PRD2014-10 for further details regarding the dermal absorption of cyflumetofen.

2.5 Occupational and residential risk assessment

2.5.1 Acute hazards of Nealta Miticide product and mitigation measures

The results of acute toxicity studies conducted with the end-use product Nealta Miticide are summarized in Table 2 of PRD2014-10. Nealta Miticide was of low acute toxicity via the oral, dermal, and inhalation routes of exposure in rats. It was non-irritating to the eyes and minimally irritating to the skin of rabbits, and was negative for dermal sensitization when tested using the local lymph node assay in mice. Based on these acute hazards, a long-sleeved shirt, long pants, socks, shoes and chemical-resistant gloves are required for workers during mixing, loading, application, clean-up and repair.

2.5.2 Occupational exposure and risk assessment

2.5.2.1 Mixer, loader and applicator exposure and risk

Individuals have potential for exposure to cyflumetofen during mixing, loading, application, clean-up and repair. Dermal and inhalation exposure estimates were generated from the Pesticide Handlers Database (PHED, v1.1), data from the Agricultural Handlers Exposure Task Force (AHETF), and data from the Non-Dietary Exposure Task Force (NDETF) for mixers, loaders and applicators applying Nealta Miticide to greenhouse grown ornamentals using conventional handheld application equipment and handheld airblast/mistblower application equipment. The unit exposure values in the risk assessment for mixer/loaders and applicators using conventional

handheld equipment are based on workers wearing a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes (Appendix I, Table 2). The unit exposure values in the risk assessment for applicators using handheld airblast/mistblower equipment are based on workers wearing chemical-resistant coveralls with a chemical-resistant hood over long-sleeved shirt, long pants, chemical-resistant gloves, socks, chemical-resistant footwear and a respirator with a NIOSH-approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH-approved canister approved for pesticides (Appendix I, Table 2).

Dermal exposure was estimated by coupling the unit exposure values with the amount of product handled per day with a dermal absorption value of 11%. Inhalation exposure was estimated by coupling the unit exposure values with the amount of product handled per day with 100% inhalation absorption. Exposure was normalized to mg/kg bw/day by using 80 kg adult body weight.

Exposure estimates were compared to the selected toxicology reference value to obtain the margin of exposure (MOE); the target MOE is 300 for short-term dermal exposure and 100 for all durations of inhalation exposure. Dermal and inhalation MOEs were not combined, since the dermal and inhalation reference values are based on different toxicological effects. Calculated MOEs are greater than the target MOEs for all chemical handler scenarios for greenhouse grown ornamentals and are therefore not of health concern (Appendix I, Table 3).

Taking into account both the acute toxicity of the end-use product and the risk assessment of cyflumetofen, workers are required to wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes.

2.5.2.2 Exposure and risk assessment for workers entering treated areas

There is potential for exposure to workers entering areas treated with Nealta Miticide to complete tasks such as harvesting and pruning. Given the nature of activities performed, exposure should be primarily via the dermal route based on contact with treated foliage. Inhalation exposure is not expected as cyflumetofen is considered non-volatile with a vapour pressure of $<5.9 \times 10^{-9}$ kPa (25°C), which is less than the North American Free Trade Agreement (NAFTA) criterion for non-volatile products for indoor scenarios [1×10^{-4} kPa (7.5×10^{-4} mm Hg) at 20–30°C]. As such, a quantitative postapplication inhalation risk assessment is not required. Inhalation risk is not of health concern for postapplication workers as cyflumetofen is considered to be non-volatile and the restricted-entry interval of 12 hours will allow residues to dry, suspended particles to settle and vapours to dissipate.

Dermal exposure to workers entering treated areas is estimated using dislodgeable foliar residue (DFR) values with activity-specific transfer coefficients (TCs). Activity TCs are based on data from the Agricultural Re-entry Task Force (ARTF). As chemical-specific DFR data were not submitted for greenhouse crops, a standard DFR value of 25% of the application rate coupled with 2% daily dissipation of residues were used in the exposure assessment.

Exposure estimates were compared to the toxicology reference value to obtain the margin of exposure (MOE); the target MOE is 100. Only exposures and risks to the activities with the highest TCs are presented as MOEs for these activities exceed the target MOE of 100, and are thus, not of health concern (Appendix I, Table 4). The REI of 12 hours is adequate to protect workers entering treated greenhouses to conduct postapplication activities.

2.5.3 Residential exposure and risk assessment

2.5.3.1 Handler exposure and risk

Nealta Miticide is not a domestic class product and is not permitted for use in residential settings; therefore, a residential handler exposure assessment is not required.

2.5.3.2 Postapplication exposure and risk

Nealta Miticide is not a domestic class product and is not permitted for use in residential settings. Furthermore, residential exposure to Nealta Miticide from treated ornamental plants that are subsequently purchased at retail locations is considered negligible. Residues are anticipated to decline from the time of application to the time of consumer purchase. In addition, the postapplication occupational exposure risk mitigation measures would also protect the consumer purchasing treated retail plants from dermal exposure. Therefore, a quantitative residential postapplication exposure assessment is not required.

2.5.3.3 Bystander exposure and risk

Bystander exposure is considered negligible as application is limited to within greenhouses only.

2.6 Aggregate exposure and risk assessment

For cyflumetofen, the aggregate assessment consisted of combining food and drinking water exposure only, since residential exposure is expected to be negligible as a result of the proposed new uses assessed herein. As the application is to be made to ornamental plants in the greenhouse, no increase in exposure to cyflumetofen in food or drinking water is expected and the combined exposure to cyflumetofen from food and drinking water is covered by the dietary exposure assessments previously conducted for the registered uses (see PRD2024-07). Therefore, aggregate exposure to cyflumetofen from food and drinking water is considered acceptable and not of health concern.

2.7 Cumulative assessment

The *Pest Control Products Act* requires that the PMRA consider the cumulative non-occupational exposure to pesticides with a common mechanism of toxicity, based on the likelihood that people may be exposed to more than one of these pesticides at the same time.

Accordingly, an assessment of a potential common mechanism of toxicity with other pesticides was undertaken for cyflumetofen. Cyflumetofen belongs to a group of acaricides that act to control mites via mitochondrial complex II electron transport inhibition. Specifically, cyflumetofen interferes with energy production within cells by disrupting steroid metabolism resulting in knockdown and residual control of mites.

There are two other pesticides in this pesticidal mode of action (MOA): pyflubumide, which has an established U.S. tolerance on imported tea based on registration in Japan, and cyenopyrafen. Cyenopyrafen is not registered in Canada or the United States and has no established U.S. tolerances nor Codex maximum residue limits (MRLs), and therefore is not included in the Canadian cumulative risk assessment.

Under the Proposed Registration Decision PRD2024-07, Nealta Miticide, containing Cyflumetofen, it was determined that based on the available information, while cyflumetofen and pyflubumide are known to share a common pesticidal MOA, it is unclear if they have the same MOA for mammalian toxicity. Nevertheless, the two pesticides were considered at this time to form a common mechanism group (CMG) and a qualitative cumulative risk assessment was undertaken. Taking into account the dietary exposure to cyflumetofen through food (including imported citrus fruits and tree nuts) and drinking water, and to pyflubumide through imported tea, as well as residential dermal exposure to cyflumetofen from picking fruit, it was concluded that the cumulative risks from potential co-exposure to cyflumetofen and pyflubumide are acceptable.

Additionally, the proposed expansion of use for cyflumetofen is for the control of spider mites on greenhouse ornamentals. No food or drinking water exposure is expected, and residential exposure is expected to be negligible from the proposed use. Therefore, the contribution of exposure to cumulative risk of this CMG will not be impacted from the new use of cyflumetofen.

3.0 Impact on the environment

3.1 Fate and behaviour in the environment

The fate and environmental behaviour of cyflumetofen have been previously assessed for use on agricultural crops. For further details, see the PMRA Proposed Registration Document for Cyflumetofen (PRD2014-10) and the Registration Decision for Cyflumetofen (RD2014-24).

Cyflumetofen is proposed as a foliar spray to control mites on greenhouse ornamentals. When used in this manner, potential environmental exposure of cyflumetofen may occur via residues that are released from the greenhouse in effluent or runoff water.

3.2 Environmental risk characterization

The maximum total rate of application for greenhouse ornamental uses is 400 g a.i./ha per crop cycle (based on a maximum spray volume of 1000 L/ha). This is the same as that currently registered for greenhouse crops. For various terrestrial crops registered on the Nealta label, the maximum total rate of application is 400 g a.i./ha per year. The environmental risk characterisation of cyflumetofen has been previously assessed for applications to agricultural

crops where potential risks to non-target terrestrial plants and amphibians were identified. It was concluded that the risks to the environment were acceptable when label directions were followed. For further details, see the PMRA Proposed Registration Document for Cyflumetofen (PRD2014-10) and the Registration Decision for Cyflumetofen (RD2014-24).

Potential environmental exposure to cyflumetofen from greenhouse uses may occur via residues released in effluent or runoff water, resulting in exposure to aquatic organisms in surface waters. The Nealta Miticide product label specifies that effluent or runoff from greenhouses containing this product must not be allowed to enter lakes, streams, ponds or other waters.

4.0 Incident reports

Health incident reports

As of 28 May 2025, no human or domestic animal incidents involving cyflumetofen have been submitted to the PMRA.

Environment incident reports

As of 28 May 2025, no environmental incident reports involving cyflumetofen have been submitted to the PMRA.

5.0 Value

Extrapolation from registered uses, use history describing an efficacy trial, and efficacy data from two additional field trials supported claims for control of spruce spider mite, European red mite, twospotted spider mite and McDaniel spider mite on greenhouse ornamentals at the rate of 1 L product/1000 L. Nealta Miticide provides a new active ingredient with a new mode of action for these pests on greenhouse ornamentals, which may aid in resistance management.

6.0 Pest Control Product Policy considerations

6.1 Toxic Substances Management Policy considerations

As described in the PMRA Proposed Registration Document for Cyflumetofen (PRD2014-10) and the Registration Decision for Cyflumetofen (RD2014-24), cyflumetofen and associated transformation products do not meet all Track 1 criteria and are not considered Track 1 substances.

6.2 Formulants and contaminants of environmental concern

As described in the PMRA Proposed Registration Document for Cyflumetofen (PRD2014-10) and the Registration Decision for Cyflumetofen (RD2014-24), technical grade cyflumetofen and the associated end-use product, Nealta Miticide, do not contain any formulants or contaminants of environmental concern.

7.0 Proposed Regulatory Decision

Health Canada's PMRA, pursuant to subsection 28(1) of the *Pest Control Products Act*, is proposing registration for the sale and use of Nealta Miticide, containing the technical grade active ingredient cyflumetofen, to control spider mites on greenhouse ornamentals.

An evaluation of available scientific information found that, under the approved conditions of use, the health and environmental risks and the value of the pest control products are acceptable.

List of abbreviations

µg	microgram
ADI	acceptable daily intake
a.i.	active ingredient
AHETF	Agricultural Handler Exposure Task Force
ARfD	acute reference dose
ARTF	Agricultural Re-entry Task Force
ATPD	area treated per day
bw	body weight
CAF	composite assessment factor
cm	centimeter
CR	chemical-Resistant
d	day
DFR	dislodgeable foliar residue
g	gram(s)
h	hour
ha	hectare(s)
hr	hour
IRAC	Insecticide Resistance Action Committee
kg	kilogram(s)
kPa	kilopascal
L	litre(s)
M/L	mixer/loader
M/L/A	mixer/loader/applicator
mg	milligram(s)
mL	milliliter(s)
MOA	mode of action
MOE	margin of exposure
NAFTA	North American Free Trade Agreement
NOAEL	no observed adverse effects levels
PCPA	<i>Pest Control Products Act</i>
PHED	Pesticide Handler Exposure Database
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
ppm	parts per million
PRD	proposed registration decision
REI	restricted-entry interval
TC	transfer coefficient
USEPA	United States Environmental Protection Agency

Appendix I Tables

Table 1 Toxicology reference values for use in health risk assessment for cyflumetofen

Exposure scenario	Study	Point of departure and Endpoint	CAF ¹ or Target MOE
Acute dietary general population	Not required as no endpoint of concern attributable to a single exposure was identified.		
Acute dietary females 13–49 years of age	Rabbit developmental toxicity study	250 mg/kg bw/day: malformations (paws bent downward) at 1000 mg/kg bw/day	300
	ARfD = 0.8 mg/kg bw		
Repeated dietary	2-year rat oncogenicity and 90-day rat oral toxicity studies (co-critical)	16.5 mg/kg bw/day: adrenal toxicity	100
	ADI = 0.2 mg/kg bw/day		
Short-term dermal ²	Rabbit developmental toxicity study	250 mg/kg bw/day: malformations (paws bent downward) at 1000 mg/kg bw/day	300
Intermediate-, and long-term dermal ²	2-year rat oncogenicity and 90-day rat oral toxicity studies (co-critical)	16.5 mg/kg bw/day: adrenal toxicity	100
Inhalation – all durations ³	2-year rat oncogenicity and 90-day rat oral toxicity studies (co-critical)	16.5 mg/kg bw/day: adrenal toxicity	100
Aggregate (pick-your-own) – general population	Not required. A relevant endpoint of concern was not identified in the database.		
Aggregate (pick-your-own) – females 13–49 years of age	Rabbit developmental toxicity study	250 mg/kg bw/day: malformations (paws bent downward) at 1000 mg/kg bw/day	300
Cancer	Testicular interstitial cell tumours and thyroid c-cell tumours observed in male rats; a threshold approach to cancer risk assessment was necessary due to limitations in the available data.		

¹ CAF (composite assessment factor) refers to a total of uncertainty and PCPA factors for dietary assessments; MOE (margin of exposure) refers to a target MOE for occupational and residential assessments.

² Since an oral NOAEL was selected, a dermal absorption factor of 11% was used in route-to-route extrapolation.

³ Since an oral NOAEL was selected, an inhalation absorption factor of 100% (default value) was used in route-to-route extrapolation.

Table 2 AHETF/NDETF/PHED unit exposure estimates for mixers, loaders and applicators handling Nealta Miticide ($\mu\text{g}/\text{kg}$ a.i. handled)

Exposure scenario and PPE		Dermal	Dermal absorbed ¹	Inhalation ²
Mixer/loader + Applicator unit exposure estimates				
A	Liquid open pour low pressure handwand (PHED scenario 21a). PPE: single layer + CR gloves.	943.37	103.77	45.20
B	Liquid open pour backpack (PHED scenario 23a). PPE: single layer + CR gloves.	5445.85	599.04	62.1
C	Liquid open pour high pressure handwand (PHED scenario 24a). PPE: single layer + CR gloves.	5585.49	614.40	151
D	Liquid open mix/load (AHETF). PPE: single layer + CR gloves.	58.50	6.44	0.63
E	Handheld airblast/mistblower application (NDETF). PPE: CR coveralls with CR hood over single layer + CR gloves + respirator.	32561	3581.71	3940

¹ Adjusted with dermal absorption factor 11%

² Light inhalation rate (except for backpack- moderate inhalation rate)

Table 3 Mixer/Loader/Applicator risk assessment

Mixer/Loader/Applicator risk assessment – Greenhouse ornamentals					
Exposure scenario	Unit exposure ($\mu\text{g}/\text{kg}$ a.i. handled) ¹	ATPD (ha/day) ²	Rate (kg a.i./ha)	Daily exposure (mg/kg bw/day) ³	MOE ⁴
Dermal exposure					
PPE: Single layer and chemical-resistant gloves					
A	103.77	0.15	0.2	3.89E-05	6424421
B	599.04	0.15	0.2	2.25E-04	1112885
C	614.40	3.8	0.2	5.84E-03	42831
D + E	3588.15	2	0.2	1.79E-02	13935
Inhalation exposure					
PPE: Single layer and chemical-resistant gloves					
A	45.20	0.15	0.2	1.70E-05	973451
B	62.1	0.15	0.2	2.33E-05	708535
C	151	3.8	0.2	1.43E-03	11502
D + E	3940.63	2	0.2	1.97E-02	837

¹ Unit exposure based on AHETF/NDETF/PHED unit exposure estimates (see Table 2)

² Default Area Treated per Day values from USEPA Policy No. 9 and Statistics on Pesticide Use Database (SPUD) 1996-1997

³ Daily exposure = (Unit exposure \times ATPD \times Rate) / (80 kg bw \times 1000 $\mu\text{g}/\text{mg}$)

⁴ Based on NOAELs = 250 mg/kg bw/day, target MOE = 300 for dermal exposure and 16.5 mg/kg bw/day, target MOE = 100 for inhalation exposure.

Table 4 Postapplication exposure and risk estimates for cyflumetofen on day 0 after the last application

Postapplication activity	Peak DFR ($\mu\text{g}/\text{cm}^2$) ¹	Transfer coefficient (cm^2/hr) ²	Dermal exposure (mg/kg bw/day) ³	MOE ⁴	REI ⁵
Greenhouse ornamentals – cut flowers hand harvesting, hand pruning, disbudding	0.8768	4000	0.0386	428	12

¹ Calculated using the default 25% dislodgeable on the day of application and 2% dissipation per day

² Transfer coefficients obtained from PMRA Agricultural TCs Table (10.29.2024)

³ Exposure = (Peak DFR [$\mu\text{g}/\text{cm}^2$] \times TC [cm^2/hr] \times 8 hours \times 11% dermal absorption) / (80 kg bw \times 1000 $\mu\text{g}/\text{mg}$)

⁴ Based on a NOAEL of 16.5 mg/kg bw/day, target MOE = 100

⁵ Minimum REI is 12 hours to allow residues to dry suspended particles to settle and vapours to dissipate.

References

List of studies/Information submitted by Registrant

1.0 Value

PMRA

Document

Number

Reference

2731723	2017, efficacy bridging rationale, DACO: 10.2,10.6
2731724	2017, Credible Use History, DACO: 10.2,10.6
2776005	2017, Value report - Nealta Miticide (cyflumetofen) on field-, bed- and container-grown conifers including Christmas trees, DACO: 10.1
2776006	2017, Value data summary tables - Nealta Miticide (cyflumetofen) on field-, bed- and container-grown conifers including Christmas trees, DACO: 10.2.3.1
2776007	Field trial reports - Nealta Miticide (cyflumetofen) on field-, bed- and container-grown conifers including Christmas trees, DACO: 10.2.3.3