Proposed Registration Decision PRD2026-10

Canola Oil, Garlic Oil, Capsaicin, Related Capsaicinoids, and Captiva Prime

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Overview

Proposed Registration Decision for Canola Oil, Garlic Oil, Capsaicin, Related Capsaicinoids, and Captiva Prime

Health Canada, pursuant to subsection 28(1) of the *Pest Control Products Act*, is proposing registration for the sale and use of Captiva Prime Technical Insecticide and Captiva Prime, containing the active ingredients canola oil, garlic oil, capsaicin, and related capsaicinoids, for suppression of twospotted spider mite (*Tetranychus urticae*) and thrips on terrestrial food crops, greenhouse food crops, greenhouse non-food crops, and outdoor ornamentals.

Capsaicin and related capsaicinoids are essential oil extracts from peppers and are always co-formulated. They are currently registered as animal repellents. See the Re-evaluation Decision RVD2023-10 *Capsaicin and Related Capsaicinoids and Its Associated End-use Products* and the Proposed Re-evaluation Decision PRVD2022-14, *Capsaicin and Related Capsaicinoids and their Associated End-use Products.*

Canola oil is currently registered to control a variety of insect and mite pests, as well as to suppress powdery mildew on ornamental, vegetable, fruit, and nut crops both in the field and greenhouse, as well as on indoor cannabis. For details, see Proposed Registration Decision PRD2016-24, *Canola oil*, and Registration Decision RD2016-35, *Canola oil*. It is also registered as an attractant for rodent traps, see PRD2022-03, *Canola Oil, Goodnature Rat & Mouse Lure, and Goodnature Rat & Mouse Pre-Feed Lure* and RD2022-06, *Canola Oil, Goodnature Rat & Mouse Lure, and Goodnature Rat & Mouse Pre-Feed Lure.*

Garlic oil is registered to repel mosquitoes; for details see PRD2010-07, *Garlic oil* and RD2010-16, *Garlic oil*. It is also registered as an animal repellent, see PRD2012-33, *Whole Egg Solids, Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil, Meat Meal Mixture, Capsaicin and Related Capsaicinoids* and RD2013-18 *Dried Eggs, Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil, Meat Meal Mixture, Capsaicin and Related Capsaicinoids)*. In addition, the related active ingredient, garlic powder, is registered for use on food crops and ornamentals, see PRD2012-22, *Garlic Powder,* RD2013-02, *Garlic Powder,* PRD2013-06*, Garlic Powder* and RD2013-20, *Garlic Powder*.

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.

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 canola oil, garlic oil, capsaicin, related capsaicinoids and Captiva Prime.

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 acceptable[1] if there is reasonable certainty that no harm to human health, future

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

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 the label directions. Conditions of registration may include precautionary measures on the product label to further reduce risk.

To reach its decisions, Health Canada 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. 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 canola oil, garlic oil, capsaicin, related capsaicinoids and Captiva Prime, Health Canada 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 Decision[4] on canola oil, garlic oil, capsaicin, related capsaicinoids and Captiva Prime, 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 canola oil, garlic oil, capsaicin, and related capsaicinoids?

Canola oil, garlic oil, capsaicin, and related capsaicinoids are non-conventional insecticides and miticides derived from plants that are the active ingredients in the product, Captiva Prime, which is for use on a wide variety of field and greenhouse crops and ornamental plants. While the mode of action of garlic oil, capsaicin, and related capsaicinoids on insects and mites is not certain, canola oil acts mainly through physical control by suffocation when the target pest is directly coated with canola oil.

[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."

[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*.

Health considerations

Can approved uses of canola oil, garlic oil, capsaicin and related capsaicinoids affect human health?

Canola oil, garlic oil, and capsaicin and related capsaicinoids are unlikely to affect human health when they are used according to label directions.

Potential exposure to canola oil, garlic oil, and capsaicin and related capsaicinoids may occur through the diet (food and water), when handling and applying the end-use product or when coming into contact with treated plants.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. 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 levels used to assess risks are established to protect the most sensitive human populations (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.

In laboratory animals, the end-use product, Captiva Prime, was of low acute toxicity by the oral and dermal routes, slight acute toxicity by the inhalation route, non-irritating to the eye, moderately irritating to the skin, and a dermal sensitizer. The toxicological profile of the technical grade active ingredient (active blend of canola oil, garlic oil, capsaicin, and related capsaicinoids) is considered equivalent to that of the end-use product.

Rationales to waive testing for short-term toxicity and prenatal developmental toxicity were accepted based on the results of published animal studies conducted with capsaicin and related capsaicinoids, garlic oil, and canola oil.

Repeat high doses of capsaicin or capsicum extract resulted in reductions in body weight and changes in food consumption, and kidney effects in male rats only. There was no indication that the young were more sensitive than the adult animal.

Repeat high doses of garlic oil or canola oil were not associated with any toxic adverse effects in animal studies. Garlic oil and canola oil are not expected to have any developmental effects given regular consumption in a typical Canadian diet.

Results from testing indicate that the blend of canola oil, garlic oil, capsaicin, and related capsaicinoids present in the technical grade active ingredient and end-use product is not genotoxic or mutagenic.

Residues in food and drinking water

Dietary risks from food and drinking water are acceptable.

Dietary exposure to canola oil, garlic oil, capsaicin, and related capsaicinoids may occur through consumption of treated crops. However, the sources of these active ingredients are food grade edible and there is a history of dietary consumption in a typical diet. Captiva Prime was also of low acute oral toxicity, and based on the dilution rates and low application rates, residues of canola oil, garlic oil, capsaicin, and related capsaicinoids are expected to be low. Overall, canola oil, garlic oil and capsaicin, and related capsaicinoids are not expected to pose a health risk when the end-use product is applied as directed by the label.

Similarly, the likelihood of canola oil, garlic oil, capsaicin and related capsaicinoid residues in drinking water will also be low.

Consequently, health risks from dietary exposure are acceptable for all segments of the population, including infants, children, adults and seniors.

Risks in residential and other non-occupational environments

Estimated risk for residential and other non-occupational exposure is acceptable.

The label for Captiva Prime will include measures to prevent bystander and residential exposure, such as statements to reduce spray drift, and to prevent people and pets from entering treated areas until sprays have dried. Additionally, the Captiva Prime is diluted before application and applied at low rates.

Residential and non-occupational exposure to Captiva Prime is expected to be low when label directions are observed. Consequently, the health risk to residents and the general public is acceptable.

Occupational risks from handling Captiva Prime

Occupational risks are acceptable when Captiva Prime is used according to the label directions, which include protective measures.

Workers handling Captiva Prime can come into direct contact with canola oil, garlic oil, and capsaicin and related capsaicinoids through inhalation and contact with skin during mixing, loading, application, clean-up and repair. To protect workers from exposure to Captiva Prime, the label will require workers to wear personal protective equipment (PPE).

The Captiva Prime label requires a restricted-entry interval (REI) of four (4) hours, or until sprays have dried, and includes a spray advisory statement to minimize spray drift. If early entry is necessary during the restricted-entry interval, workers must wear the appropriate PPE as outlined in the key risk-reduction measures section.

The occupational risks are acceptable when the precautionary statements on the label are observed.

Environmental considerations

What happens when canola oil, garlic oil, and capsaicin and related capsaicinoids are introduced into the environment?

Canola oil, garlic oil, and capsaicin and related capsaicinoids are derived from plants and are expected to break down quickly in the environment through natural biological, physical, and chemical processes. When Captiva Prime is used according to label directions, canola oil, garlic oil, and capsaicin and related capsaicinoids pose acceptable risk to the environment.

Value considerations

What is the value of Captiva Prime?

Captiva Prime has value in suppressing thrips and twospotted spider mite on a wide variety of crops and ornamental plants, grown both outdoors and in greenhouses. Captiva Prime will provide a new product for organic growers to manage these pests.

Thrips and twospotted spider mite feed on a wide variety of plants and are important pests in many crops grown outdoors and in greenhouses. Captiva Prime is active against all life stages, including adults, nymphs and eggs. As Captiva Prime has a physical mode of action, the development of resistance to this product is not expected. As a result, Captiva Prime has value as a new tool to support resistance management of thrips and twospotted spider mite.

Measures to minimize risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human health and the environment. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Captiva Prime Technical Insecticide and Captiva Prime to address the potential risks identified in this assessment are as follows.

Key risk-reduction measures

Human health

The hazard signal words “WARNING”, “POISON”, “SKIN IRRITANT” and “POTENTIAL SKIN SENSITIZER” are required on the principal display panels of the Captiva Prime Technical Insecticide and Captiva Prime labels. Standard precautionary statements are also required on the labels to inform users that the product is harmful if inhaled, causes skin irritation and that it is a potential skin sensitizer.

Workers are required to wear personal protective equipment (PPE) when handling the product. The PPE required depends on the activity and method of application.

During handling, mixing, loading, clean-up and repair, workers are required to wear coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, socks and chemical-resistant footwear. The same PPE is also required to be worn by applicators when Captiva Prime is applied using open-cab groundboom, or handheld (including high-pressure hand wand but excluding handheld airblast) equipment, and when applied by aerial applications with an open-cockpit. In addition, for above the waist (including overhead spraying) application using any handheld equipment (except by airblast), workers are also required to wear chemical-resistant headgear, protective eyewear (goggles or face shield), 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.

During open-cab airblast and open-cab overhead sprayer applications, workers are required to wear coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, socks, chemical-resistant footwear and headgear.

If applications are made using a closed-cockpit/closed-cab (by aerial, or airblast and/or groundboom equipment), workers are required to wear a long-sleeved shirt, long pants, socks and shoes.

During handheld airblast/mistblower application workers are required to 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.

For Captiva Prime, there will be a restricted-entry interval of four (4) hours, or until sprays have dried. If early entry is required, workers must wear appropriate PPE as follows:

- For early entry into treated areas when aerial, airblast (except handheld airblast) and open-cab overhead sprayer application was made, workers are required to wear coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, socks, chemical-resistant footwear and headgear.
- For early entry into treated areas when groundboom application was made, workers are required to wear coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, socks and chemical-resistant footwear.
- For early entry into treated areas for all other methods of applications, workers are required to wear PPE specific for the method of application.

To limit bystander and residential exposure, the end-use product label requires a standard drift statement and a statement to prevent people and pets from entering the treated area until sprays have dried.

Environment

Best management practice label statements are required to reduce runoff entering aquatic habitats.

A label statement is required prohibiting the discharge of greenhouse releases, effluent or runoff containing the pesticide to water.

Next steps

Before making a final registration decision on canola oil, garlic oil, capsaicin, related capsaicinoids and Captiva Prime, Health Canada 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 30 days from the date of publication (9 June 2026) of this document. If more time is required to provide comments, a request for an extension of an additional 15 days can be made. Your request must be submitted in writing to the Pesticides Regulatory Directorate's Publications Section (pmra.publications-arla@hc-sc.gc.ca) within the 30-day consultation period.

Please forward all comments to Pesticides Regulatory Directorate Publications, through the Public Engagement Portal (Public Engagement Portal 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

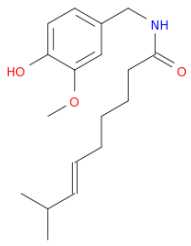
When Health Canada makes its registration decision, it will publish a Registration Decision on canola oil, garlic oil, capsaicin, related capsaicinoids and Captiva Prime (based on the Science evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the Pesticides Regulatory Directorate's Reading Room. For more information or if you have questions, please contact the Pesticides Information Service.

Science evaluation

Canola oil, garlic oil, capsaicin, related capsaicinoids and Captiva Prime

1.0 The Active Ingredients, Their Properties and Uses

1.1 Identity of the Active Ingredients

Active substance 1	Capsaicin
Function	Acaricide, Insecticide and Insect Repellent
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	(6E)-N-[(4-hydroxy-3-methoxyphenyl)methyl]-8-methylnon-6-enamide
2. Chemical Abstracts Service (CAS)	6-Nonenamide, N-[(4-hydroxy-3-methoxyphenyl)methyl]-8-methyl-, (6E)-
CAS number	404-86-4
Molecular formula	$C_{18}H_{27}NO_3$
Molecular weight	305.4 g/mol
Structural formula	
Purity of the active ingredient in Technical Material	0.134%
Active substance 2	Related capsaicinoids (Dihydrocapsaicin* and Nordihydrocapsaicin**)
Function	Acaricide, Insecticide and Insect Repellent
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	Not applicable

2. Chemical Abstracts Service (CAS)	Not applicable
CAS number	Not applicable
Molecular formula	Not applicable
Molecular weight	Not applicable
Structural formula	Not applicable
Purity of the active ingredient in Technical Material	0.175%
Active substance	Dihydrocapsaicin*
Function	Acaricide, Insecticide and Insect Repellent
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	*N*-[(4-hydroxy-3-methoxyphenyl)methyl]-8-methylnonanamide
2. Chemical Abstracts Service (CAS)	Not applicable
CAS number	19408-84-5
Molecular formula	$C_{18}H_{29}NO_3$
Molecular weight	307.4 g/mol
Structural formula	
Purity of the active ingredient	N/A
Active substance	Nordihydrocapsaicin**
Function	Acaricide, Insecticide and Insect Repellent
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	N-[(4-hydroxy-3-methoxyphenyl)methyl]-7-methyloctanamide
2. Chemical Abstracts Service (CAS)	Not applicable
CAS number	28789-35-7
Molecular formula	$C_{17}H_{27}NO_3$

Molecular weight	293.4 g/mol
Structural formula	
Purity of the active ingredient	N/A
Active substance 3	Garlic oil
Function	Acaricide, Insecticide and Insect Repellent
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	Not applicable
2. Chemical Abstracts Service (CAS)	Not applicable
CAS number	8000-78-0
Molecular formula	Not applicable
Molecular weight	Not applicable
Structural formula	Not applicable
Purity of the active ingredient in Technical Material	27.21%
Active substance 4	Canola oil
Function	Acaricide, Insecticide and Insect Repellent
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	Not applicable
2. Chemical Abstracts Service (CAS)	Not applicable
CAS number	120962-03-0
Molecular formula	Not applicable
Molecular weight	Not applicable
Structural formula	Not applicable
Purity of the active ingredient in Technical Material	63.95%

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

Technical Product — Captiva Prime Technical Insecticide

Property	Result
Colour and physical state	Reddish brown liquid
Odour	Distinctive garlic odour
Melting range	The product is a liquid.
Boiling point or range	The technical grade active ingredient is a mixture of complex components. As a result, this requirement is waived.
Density	0.943 g/mL at 20°C
Vapour pressure at 20°C	The technical grade active ingredient is a mixture of complex components. As a result, this requirement is waived.
Ultraviolet (UV)-visible spectrum	The technical grade active ingredient is a mixture of complex components. As a result, this requirement is waived.
Solubility in water at 20°C	Slightly soluble in water
Solubility in organic solvents at 20°C	Immiscible with corn oil
n-Octanol-water partition coefficient (K_{ow})	The technical grade active ingredient is a mixture of complex components. As a result, this requirement is waived.
Dissociation constant (pK_a)	The technical grade active ingredient is a mixture of complex components. As a result, this requirement is waived.
Stability (temperature, metal)	The technical grade active ingredient is a mixture of complex components. As a result, this requirement is waived.

End-Use Product — Captiva Prime

Property	Result
Colour	Reddish brown
Odour	Distinctive garlic odour
Physical state	Liquid
Formulation type	Solution
Label concentration	Capsaicin at 0.115% Related capsaicinoids at 0.151% Garlic oil at 23.40% Canola oil at 55.0%
Container material and description	HDPE bottle, jug, pail, bag, drum and tote (3.5 L to bulk)
Density	0.943 g/mL at 20°C
pH of 1% dispersion in water	3.80
Oxidizing or reducing action	The end-use product exhibits reducing properties.

Property	Result
Storage stability	The end-use product is stable when stored for a year at ambient temperature.
Corrosion characteristics	Not corrosive to high density polyethylene containers
Explodability	The product is not explosive in nature.

1.3 Directions for use

Captiva Prime is a commercial-class product which is applied at a rate of 1.2–2.4 L of product per ha to suppress thrips and twospotted spider mite on a wide variety of agricultural and ornamental crops, including berries, bulb vegetables, cucurbit vegetables, fruiting vegetables, herbs, spices, legume vegetables, leafy vegetables, brassica leafy vegetables, stalk, stem and leaf petioles, pome fruits, root and tuber vegetables, stone fruit, tree nuts, greenhouse vegetables and transplant production, and ornamental shrubs, plants, and trees. Captiva Prime is applied by ground application equipment in a minimum spray volume of 100 L per ha for field crops. For greenhouse crops and ornamentals, Captiva Prime is applied in a spray volume of 378 L per ha. Captiva Prime may also be applied by aerial application in a spray volume of 20–150 L per ha. Captiva Prime may be re-applied every 4–7 days.

1.4 Mode of action

Captiva Prime contains botanically-derived active ingredients: canola oil, garlic oil, capsaicin and related capsaicinoids. The main insecticidal/miticidal mode of action of canola oil is physical. The oil coats the insect or mite and floods their spiracles (breathing pores). This results in the rapid asphyxiation and suffocation of the organism. Canola oil is active against multiple life stages of the insect or mite, including eggs. The mode of action of garlic oil, capsaicin, and related capsaicinoids against thrips and twospotted spider mite has not been determined. These active ingredients are not classified by the Insecticide Resistance Action Committees.

2.0 Methods of analysis

2.1 Methods for analysis of the active ingredient

The requirement of a validated analytical method has been waived for garlic oil and canola oil as they are complex in nature and are food grade edible. The validated analytical method provided for the determination of capsaicin and related capsaicinoids in the end-use product has been extended to the technical grade active ingredient.

2.2 Method for formulation analysis

The method provided for the analysis of both capsaicin and related capsaicinoids in the formulation has been validated and assessed to be acceptable for use as an enforcement analytical method. The requirement of a validated analytical method for the determination of garlic oil and canola oil has been waived as they are complex in nature and are of food grade.

3.0 Impact on human and animal health

3.1 Toxicology summary

A detailed review of toxicology information was conducted in support of the technical grade active ingredient, Captiva Prime Technical Insecticide, and the associated end-use product, Captiva Prime, and the database was found to be acceptable (Appendix I, Table 1) to assess the toxic effects that may result from exposure to the actives capsaicin and related capsaicinoids, garlic oil, and canola oil.

The data package consisted of unpublished Organisation for Economic Co-operation and Development (OECD) guideline studies with Captiva Prime as the test material (acute oral, dermal, and inhalation toxicity, eye and skin irritation, skin sensitization, and genotoxicity), and waiver requests to address short-term oral toxicity and prenatal developmental toxicity. The technical grade active ingredient and end-use product are considered to have an equivalent toxicological profile.

Captiva Prime Technical Insecticide and Captiva Prime are considered to be of low acute toxicity by the oral and dermal routes of exposure, slight acute toxicity by the inhalation route of exposure, non-irritating to the eye, and moderately irritating to the skin, and sensitizing to the skin.

In lieu of submitting a short-term oral toxicity study for the active blend, published literature studies for capsaicin/capsaicinoids/capsicum extract, garlic oil, and canola oil were cited.

Capsaicin/Capsaicinoids

In a published, non-guideline short term oral (gavage) toxicity study in rats, receiving 50 mg/kg bw/day capsaicin or 500 mg/kg bw/day capsicum fruit extract, there were statistically significant reductions in body weight gain and slight increases in food consumption. Slight hyperemia without hemorrhage in the liver, and reddening of the gastric mucosa with increased mucus, were found in both treatment groups at day 60. The lowest observed adverse effect level (LOAEL) for capsaicin was 50 mg/kg bw/day based on decreased body weight gain. The study was considered acceptable with limitations (only a single dose level; not conducted under good laboratory practice procedures (non-GLP); limited study reporting and design).

In a published 13-week repeated-dose range-finding oral toxicity study, B6C3F1 mice were given a capsaicinoid mixture in the diet, with reviewer-calculated male/female test doses ranging from 71.91/95.07 to 1171.97/1296.61 mg/kg bw/day. Mice showed significant decreases in mean body weights and food consumption, and increases in liver/body weight ratios. Kidney focal tubular dilatation was observed in male mice at the highest dose tested. Based on reductions in body weight and food consumption, the LOAEL was 71.91 mg/kg bw/day in males and 95.07 mg/kg bw/day in females. The study was considered acceptable with limitations (limited study reporting; unclear similarity of the test substance to the technical grade active ingredient).

Garlic oil

In an OECD guideline 28-day repeated dose oral toxicity study, Institute of Cancer Research (ICR) mice were orally administered 0, 15, 25, or 50 mg/kg bw/day garlic essential oil. There were no treatment-related adverse findings. The NOAEL for garlic essential oil was determined to be > 50 mg/kg bw/day.

Canola oil

In a published OECD guideline 90-day repeated dose oral (diet) toxicity rat study comparing the toxicological effects of genetically modified (GMO) canola compared to non-GMO canola (control), there were no adverse toxicological effects under the conditions tested.

In lieu of submitting a prenatal developmental toxicity study for the active blend, published literature studies for capsaicin were submitted, and an acceptable rationale based on the history of consumption in food for garlic oil and canola oil was provided. The capsaicin studies are both considered acceptable with limitations, because they were non-guideline, raw data were not available, the test material was administered dermally rather than via the oral route of exposure, and the doses were expressed in µl/cm^2 instead of mg/kg bw/day.

Capsaicin

In a developmental rat study, pregnant rats were exposed to 16, 24, and 32 mg capsaicin/rat via a dermal patch on gestation days (GD) 7 through 17. Systemic absorption was confirmed. At the highest dose tested (HDT), dams demonstrated clinical signs of toxicity, and there was delayed ossification in fetuses. The maternal LOAEL was 16 mg capsaicin/rat based on clinical signs at all tested doses. The developmental NOAEL was 24 mg capsaicin/rat based on delayed ossification.

In a developmental rabbit study, pregnant rabbits were exposed to 0, 60, 130, or 260 mg capsaicin/rabbit via a dermal patch on GD 7 through 18. Rabbits exhibited only localized dermal effects (erythema, flaking, wrinkling), and no signs of systemic toxicity. The maternal and developmental NOAELs were both 260 mg trans-capsaicin/rabbit (HDT). In both the rat and rabbit studies, the young were not more sensitive than the adult animal.

Additionally, capsaicin is the primary ingredient in spicy foods and has an extensive history of dietary consumption and capsicum extracts have a long history of safe exposure, as natural health products, and topical analgesics. Furthermore, capsaicin and related capsaicinoids in Captiva Prime are food grade edible (FGE). Consequently, considering available information, capsaicin and related capsaicinoids are not expected to be developmental toxicants.

Garlic oil and canola oil

Prenatal developmental toxicity studies were not available for garlic oil or canola oil. Garlic oil has a long history of exposure worldwide through the consumption of garlic in food, as well as in dietary supplements. Canola oil is one of the most commonly consumed vegetable oils in food in Canada. The garlic oil and canola oil active ingredients in Captiva Prime are FGE. Neither garlic oil nor canola oil are expected to have developmental effects given their extensive consumption in food.

Captiva Prime was not mutagenic in a reverse gene mutation assay in bacteria, in the presence and absence of metabolic activation. The results of an in vitro mammalian cell micronucleus assay were equivocal, on the basis of a non-statistically significant concentration-dependent increase in micronucleated cells. Captiva Prime was not genotoxic in an in vivo micronucleus study in rats. Consequently, based on weight of evidence, Captiva Prime and Captiva Prime Technical Insecticide are not considered to be genotoxic or mutagenic.

3.2 Occupational, residential and bystander exposure and risk assessment

3.2.1 Use description

Captiva Prime is proposed for use as a commercial-class insecticide/miticide for the suppression of mites and thrips on a variety of food crops (field and greenhouse crops), as well as ornamental plants (shrubs, trees, plants) grown both outdoors and in nurseries/greenhouses. Consequently, there are potential commercial uses (outdoor ornamental shrubs, trees, and plants) in residential areas proposed for Captiva Prime.

Captiva Prime is a liquid formulation that is diluted in water and applied as a foliar application using conventional spraying equipment including airblast, groundboom sprayers, handheld sprayers (including high-pressure hand wand) and handheld airblast/mistblowers. The end-use product should be diluted in a water volume of 378 L per ha for greenhouse crops and ornamentals, in a minimum of 100 L of total spray volume per ha for field crops and 20–150 L per ha for aerial application. This is equal to 1.2–2.4% spray dilutions for ground applications, while aerial application has a wider range of spray dilutions, ranging from 0.8–12.0%. For all uses, re-application is permitted every 4–7 days, as required.

3.2.2 Occupational exposure and risk assessment

3.2.2.1 Mixer, loader, and applicator exposure and risk assessment

When used according to label directions, occupational exposure to Captiva Prime is characterized as short- and intermediate-term in duration and is expected to occur primarily by the inhalation and dermal routes of exposure during mixing, loading, application, clean-up and repair.

Workers are required to wear personal protective equipment (PPE) during handling as outlined in the key risk-reduction measures section. The PPE required depends on the activity and method of application.

Precautionary statements on the end-use product label, such as the wearing of PPE, aimed at mitigating exposure, are adequate to protect individuals from any risk due to occupational exposure. Overall, occupational risks to workers are acceptable when the precautionary statements on the label are followed, which include PPE.

3.2.2.2 Postapplication exposure and risk

There is a potential for postapplication exposure to workers entering areas treated with Captiva Prime. Given the nature of the postapplication activities typically performed (for example, scouting, harvesting, thinning and pruning) dermal contact with treated plants is possible.

Workers must remain out of the treated area for four (4) hours, or until sprays have dried. If early entry is necessary during the restricted-entry interval, workers must wear the appropriate PPE as outlined in the Key risk-reduction measures section.

Precautionary statements on the end-use product labels, aimed at mitigating exposure, are adequate to protect workers from risk due to postapplication exposure. Consequently, the risks to workers due to postapplication exposure are acceptable.

3.2.3 Residential and bystander exposure and risk

There is potential for residential exposure from the uses proposed for Captiva Prime (outdoor ornamental shrubs, trees, and plants). The label for Captiva Prime will include measures to prevent bystander and residential exposure such as a statement to prevent people or pets from entering treated areas until sprays have dried, as well as a drift statement to only apply the product when the potential for drift beyond the area to be treated is minimal, and to take into consideration wind speed, wind direction, temperature inversions, application equipment, and sprayer settings.

Given that pome fruit, stone fruit, and berry crops can be treated with Captiva Prime, there is potential for dermal exposure during pick-your-own activities. Although Captiva Prime is moderately irritating to the skin and a potential skin sensitizer, it is of low acute toxicity via the dermal route of exposure. Additionally, considering that the end-use product is diluted before application and applied at low rates, risks to the general population from pick-your-own scenarios are acceptable.

Overall, residential and bystander exposure to Captiva Prime is expected to be low when label directions are observed.

Consequently, the health risks to bystanders and individuals in residential areas from the use of Captiva Prime are considered acceptable.

3.3 Dietary exposure and risk assessment

3.3.1 Food

Dietary exposure to canola oil, garlic oil, capsaicin and related capsaicinoids may occur through consumption of treated crops. Captiva Prime was found to be of low acute oral toxicity, and the sources of these active ingredients are food grade edible.

Residues of canola oil, garlic oil, capsaicin and related capsaicinoids on treated crops are expected to be very low based on the levels of the actives in the end-use product, the dilution rates (maximum 2.4% spray solution for ground applications; maximum 12.0% for aerial applications) and low application rates (max 2.4 L of product/ha).

There is a history of dietary consumption of canola oil (through cooking oil) and garlic oil (through the high consumption of garlic) as well as of capsaicinoids (in spicy food) in the typical diet.

For capsaicin and related capsaicinoids, limited information was available on short-term toxicity and the effects observed were related to palatability issues with the test substance consistent with its spicy/irritating nature. Taking into account the various lines of evidence including the existing dietary exposure of capsaicin and related capsaicinoids; the long history of food consumption; that the source of the active ingredient is FGE; and the anticipated low residues of capsaicin and related capsaicinoids on food, risk from dietary exposure to capsaicin and related capsaicinoids is acceptable.

Consequently, when the end-use products are applied as directed by the label, the health risk is acceptable for the general population, including infants and children.

3.3.2 Drinking water

Dietary exposure from drinking water is expected to be low as the label has the necessary mitigative measures to limit contamination of drinking water from the proposed uses of canola oil, garlic oil, capsaicin and related capsaicinoids.

The end-use product label will instruct users not to contaminate irrigation or drinking water supplies or aquatic habitats through equipment cleaning or waste disposal. The label will also include a statement to limit runoff into aquatic habitats.

In addition, the standard greenhouse effluent statement will appear on the label to instruct workers not to allow releases, effluent or runoff from greenhouses containing this product to enter lakes, streams, ponds or other waters.

Health risks from residues of canola oil, garlic oil, capsaicin and related capsaicinoids in drinking water are acceptable.

3.3.3 Acute and chronic dietary risks for sensitive subpopulations

As noted above, when the end-use product is applied as directed by the label, the health risk is acceptable for the general population, including infants and children.

3.4 Aggregate exposure and risk

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).

In an aggregate risk assessment, the combined potential risk associated with food, drinking water and various residential exposure pathways (including pick-your-own) is assessed. A major consideration is the likelihood of co-occurrence of exposures. Additionally, only exposures from routes that share common toxicological endpoints can be aggregated.

Captiva Prime Technical Insecticide is of low acute toxicity by the oral and dermal routes and of slight acute toxicity via the inhalation route of exposure. The end-use product is diluted prior to application and applied at low rates, and the end-use product label has the necessary mitigative measures to limit contamination of drinking water.

When the end-use product is used as labelled, there is reasonable certainty that no harm will result from aggregate exposure of residues of canola oil, garlic oil, capsaicin, and related capsaicinoids. This includes all anticipated dietary (food and drinking water) exposures and all other non-occupational exposures (dermal and inhalation) for which there is reliable information.

3.5 Cumulative assessment

The *Pest Control Products Act* requires that Health Canada 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, assessments of potential common mechanisms of toxicity with other pesticides were undertaken.

While canola oil may share constituents with other fatty acid-based active ingredients, the potential health risks from cumulative exposure to canola oil and other fatty acid-based pest control products are acceptable given the inherent low toxicity profile of canola oil. Also, canola oil is a common food ingredient and part of the average Canadian diet. The source of canola oil used in Captiva Prime is food grade edible. Overall, the potential health risks from cumulative exposure to canola oil and other fatty acid-based pest control products are acceptable.

While garlic oil shares constituents with other garlic-based active ingredients, the potential health risks from cumulative exposure to garlic oil and other garlic-based pest control products are acceptable given the low toxicity profile of Captiva Prime Technical. In addition, Captiva Prime is diluted before use and applied at low rates. The sulphur compounds present in garlic oil are also routinely consumed in the diet through garlic, and the source of garlic oil used in Captiva Prime is food grade edible. Consequently, under the proposed conditions of use, the anticipated dietary and residential exposure and risk from garlic oil in Captiva Prime is considered acceptable, and cumulative risks are therefore acceptable.

The potential health risks from cumulative exposure to capsaicin and related capsaicinoids-based pest control products are considered acceptable given the inherently low acute oral toxicity of capsaicin and related capsaicinoids. While capsaicin and related capsaicinoids may share structural similarities with components found in essential oil-based pest control products, it is difficult to determine which constituents share a common mechanism of action as it is often not possible to fully identify and characterize the constituent(s) responsible for toxicity.

The use of Captiva Prime represents the first food use as a pesticide for the active ingredients capsaicin and related capsaicinoids. However, dietary exposure from the use of Captiva Prime is expected to be low based on the dilution and applications rates. Capsaicin and related capsaicinoids have a long history of safe consumption worldwide in spicy foods, and the source is food grade edible. Consequently, under the proposed conditions of use, the anticipated dietary and residential exposure and risk from capsaicin and related capsaicinoids in Captiva Prime is considered acceptable, and cumulative risks are therefore, acceptable.

3.6 Maximum residue limits

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine whether dietary risks are acceptable from the consumption of foods treated with the pesticide when used according to the supported label directions. If acceptable, this means food

containing that amount of residue is safe to eat, and maximum residue limits (MRLs) may be proposed. MRLs are the maximum amount of pesticide residue legally permitted to remain in/on food sold in Canada and are specified under the *Pest Control Products Act* for the purposes of the adulteration provision of the *Food and Drugs Act.*

Dietary risk from the proposed use of Captiva Prime is acceptable, given the low toxicity profile of Captiva Prime Technical Insecticide, and the low application rates.

In addition, the sources of each of the components in the technical grade active ingredient (canola oil, garlic oil, capsaicin and related capsaicinoids) are certified as food grade edible. There is also a long history of consumption worldwide for garlic and canola oil in the average diet. Capsaicin and related capsaicinoids are also consumed in the diet in spicy food worldwide.

Consequently, the specification of MRLs, under the *Pest Control Products Act*, will not be required for garlic oil, canola oil, capsaicin or related capsaicinoids.

3.7 Health incident reports

As of 29 December 2025, two minor human incident reports involving canola oil, one minor human incident report (involving six people) involving capsaicin, and one minor domestic animal incident involving garlic oil have been submitted to Health Canada.

Two of the human incident reports were considered to be at least possibly related to the reported exposure. In one incident, a woman spraying an outdoor spray product containing pyrethrins and canola oil reported getting too close to the product mist. She experienced a sensation of her nostrils burning for an hour. However, the effect is likely attributed to the exposure to pyrethrins, as dermal and respiratory irritation are consistent with short exposures to pyrethrins. In the second incident, a bear deterrent spray containing capsaicin went off in a car with six occupants. The car was filled with the product and two of the occupants got spray in their eyes, nose and mouth. All six occupants experienced minor eye, nose and lung irritation.

One domestic animal incident involving garlic oil was determined to be unlikely related to the reported exposure to garlic oil, due to the unspecific nature of the reported adverse effects.

Based on the low number of incidents involving canola oil, garlic oil, capsaicin and related capsaicinoids, no health concerns were identified.

4.0 Impact on the environment

4.1 Fate and behaviour in the environment

The environmental fate of canola oil, garlic extracts such as garlic oil, and capsaicin and related capsaicinoids are described in PRD2016-24, *Canola Oil*, PRD2012-22, *Garlic Powder*, and PRD2012-33, *Whole Egg Solids, Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil, Meat Meal Mixture, Capsaicin and Related Capsaicinoids*. In general, canola oil, garlic oil, and capsaicin and related capsaicinoids are plant-derived substances, and rapid degradation in the environment is expected to occur through normal biological, physical, and chemical processes.

4.2 Environmental risk characterization

4.2.1 Canola oil and garlic oil

The environmental risk posed by the canola oil and garlic oil components of Captiva Prime is captured by the environmental risk assessments for field and greenhouse uses of canola oil and garlic powder described in PRD2016-24, *Canola Oil* and PRD2012-22, *Garlic Powder*, respectively. On the basis of these reports, the environmental risks of canola oil and garlic oil from use of Captiva Prime were determined to be acceptable. The spray buffer zones (up to 2 m for field sprayer) and precautionary statements for aquatic organisms and beneficial arthropods, implemented in PRD2016-24 to address risk from canola oil, are not relevant for Captiva Prime given the relatively low single application rate compared to that considered in PRD2016-24 (36.1 kg canola oil/ha, versus a maximum of 1.2 kg canola oil/ha for Captiva Prime).

4.2.2 Capsaicin and related capsaicinoids

Available mammalian toxicology data indicates that capsaicin and related capsaicinoids are expected to be non-toxic to terrestrial wildlife. The relatively rapid transformation of capsaicin and related capsaicinoids under environmental conditions (half-life of two to eight days) is expected to limit potential exposure and risks. Furthermore, these compounds are registered as animal repellents in Canada and thus terrestrial organisms, including birds and mammals, may avoid exposure. Therefore, the risk to terrestrial organisms is acceptable when the end-use product is used according to label directions.

Compared to terrestrial organisms, aquatic organisms are less able to avoid chemicals that have been dispersed in their environment. In addition, the available acute aquatic toxicity information for capsaicin suggest it is “moderately toxic”, according to USEPA ecotoxicity classifications. To address potential risks to aquatic organisms (fish, algae, and amphibians), a screening-level risk assessment was conducted using available information (Appendix I, Table 3). The screening-level assessment considers simple methods, conservative exposure scenarios and sensitive effects metrics. As all screening-level risk quotients were below the level of concern, the risks are acceptable and no further risk characterization was necessary.

4.3 Environmental incident reports

As of 29 December 2025, no environmental incident reports involving canola oil or garlic oil had been submitted to Health Canada.

As of 29 December 2025, one environmental incident report involving capsaicin and related capsaicinoids had been submitted to Health Canada. This incident was minor and unlikely to be caused by capsaicin and related capsaicinoids and thus was not considered further in the risk assessment for Captiva Prime.

5.0 Value

Health Canada’s value approach for pest control products considers efficacy, effects on host crops or use sites, social and economic impact and health, safety and environmental benefits. This approach is characterized by flexibility in the type of information that can be provided by applicants and uses a weight of evidence approach to consider all information provided to

support the value assessment. Value information may include use history, results of research trials, scientific rationales or published information, as appropriate. The intent is to assess the overall value of the product or new use by considering product performance as well as the benefits it provides to users. A combination of some or all of these types of information may be used to support the value of a pest control product. A list of supported uses for Captiva Prime can be found under Appendix I, Table 4.

5.1 Effectiveness against pests

Value information submitted in support of the efficacy of Captiva Prime included 22 trials on twospotted spider mite and 36 trials on thrips, conducted on a wide variety of different field and greenhouse crops, including ornamental plants. Efficacy trials were submitted to support a claim that applications of 1.2–2.4 L of Captiva Prime per hectare will suppress thrips and twospotted spider mite. Trials included both the proposed formulation of Captiva Prime and an earlier formulation. An acceptable scientific rationale was also provided to bridge from trials conducted on an earlier formulation to Captiva Prime. The submitted trials which did not test rates of 1.2–2.4 L of Captiva Prime per ha were also considered as additional supporting information and to support crop tolerance. The submitted value information demonstrated that Captiva Prime provided suppression of twospotted spider mite and thrips at an application rate of 1.2–2.4 L of product per ha on a wide variety of crops. In some trials, more than one application was required to achieve sufficient suppression of the target pests. The submitted value information also supported a re-application interval of 4–7 days.

5.2 Impact on host crop/site

Submitted trials were conducted on a wide variety of different field crops, ornamental plants, and greenhouse crops. Trials against twospotted spider mite were conducted on greenhouse butterfly bush, greenhouse rose, greenhouse grown pansy, chrysanthemum, marigold, greenhouse grown cotton, sweet almond, sugar beet, field strawberries, field blackberries, papaya, corn, against thrips on onions, chrysanthemum, greenhouse marigold, snapdragon, greenhouse grown pansy, impatiens, greenhouse rose, pepper, tomato, lettuce, peach, and grape. No adverse effects were reported in these trials on any of the tested crops, therefore no unacceptable phytotoxic effects are expected to the crops listed on the Captiva Prime label.

5.3 Consideration of benefits

5.3.1 Survey of alternatives

Thrips and twospotted spider mite are common polyphagous pests, therefore many different pest control products with various modes of action are registered for this use. Canola oil is currently registered for control of mites on a wide variety of greenhouse, field, and ornamental crops. Non-pesticide alternatives for management of thrips and twospotted spider mite can include biological control using natural predators and cultural control to reduce pest pressure (for example, sanitation, crop rotation, management of humidity and temperature, and installing screening in greenhouse production).

5.3.2 Compatibility with current management practices including integrated pest management

Captiva Prime uses standard application equipment and is expected to be compatible with current management practices, including Integrated Pest Management (IPM), and is also intended for use in organic production. Captiva Prime can be tank mixed with fertilizers or registered pest control products whose labels also allow tank mixing, provided the entirety of both labels are followed for each product.

5.3.3 Resistance management

Captiva Prime contains new active ingredients (garlic oil, capsaicin and related capsaicinoids) for use against twospotted spider mite, and four new active ingredients (garlic oil, canola oil, capsaicin and related capsaicinoids) for use against thrips. Based on the physical mode of action of Captiva Prime, resistance to this product is not expected. As Captiva Prime provides new active ingredients for suppression of thrips and twospotted spider mite and as resistance is not expected, Captiva Prime may aid in resistance management of these pests.

5.3.4 Social and economic impacts

Thrips and twospotted spider mite are common pests of many different crops and can cause significant crop damage and economic losses if not controlled. In addition, as a product intended for organic production, Captiva Prime will provide an additional tool to support Canadian organic production and help meet the increasing consumer demand for organically grown crops.

5.3.5 Contribution to risk reduction and health, safety and environmental benefits

Captiva Prime is a non-conventional pest control product which is formulated with plant-derived active ingredients, canola oil, garlic oil, capsaicin and related capsaicinoids. Captiva Prime provides an alternative to conventional chemical pest control products for management of thrips and twospotted spider mite in a wide variety of field and greenhouse crops and ornamentals.

5.4 Value of Captiva Prime

Captiva Prime has value in suppression of twospotted spider mite and thrips on a wide variety of field and greenhouse crops, outdoor and greenhouse woody and herbaceous ornamentals, berries, stone and pome fruit trees, and nut trees, and provides a new product for use in organic production. As Captiva Prime provides new active ingredients for suppression of these pests and the development of resistance is not expected based on the physical mode of action, Captiva Prime has value as a new tool to support resistance management of thrips and twospotted spider mite in field and greenhouse production.

The submitted value information was sufficient to support the use of Captiva Prime for suppression of twospotted spider mite and thrips in listed field and greenhouse crops and ornamentals at an application rate of 1.2–2.4 L Captiva Prime per ha, re-applied every 4–7 days, as required. When pest pressure is heavier or canopy is dense, the higher application rate or shorter re-application interval should be used.

Captiva Prime may be applied with ground application equipment in a minimum of 100 L total spray volume per ha or by air in a spray volume of 20–150 L per ha. For greenhouse crops and ornamentals, Captiva Prime is applied in a water volume of 378 L per ha.

6.0 Pest Control Product Policy considerations

6.1 Toxic Substances Management Policy

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances, in other words, those that meet all four criteria outlined in the policy: persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*. The *Pest Control Products Act* requires that the TSMP be given effect in evaluating the risks of a product.

Health Canada has previously reached the conclusion that canola oil, garlic oil, and capsaicin and related capsaicinoids are not considered to be Track 1 substances as they do not meet all of the TSMP Track 1 criteria, nor will they form any transformation products that meet all of the TSMP Track 1 criteria. Please refer to PRD2016-24, *Canola Oil,* for further information on the TSMP assessment for canola oil and the evaluation report, ERC2012-03, *Whole Egg Solids, Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil, Meat Meal Mixture, Capsaicin and Related Capsaicinoids*, for further information on the TSMP assessments for garlic oil and capsaicin and related capsaicinoids.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the active ingredients as well as formulants and contaminants in the end-use product are compared against Parts 1 and 3 of the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.[5] The list is used as described in the Science Policy Note SPN2020-01[6] and is based on existing policies and regulations, including the *Toxic Substance Management Policy* and *Formulants Policy*,[7] and taking into consideration the *Ozone-depleting Substances and Halocarbon Alternatives Regulations* under the *Canadian Environmental Protection Act, 1999*, (substances designated under the *Montreal Protocol*).

Health Canada has reached the conclusion that Captiva Prime Technical Insecticide and its end-use product, Captiva Prime, do not contain any formulants or contaminants identified on Parts 1 or 3 of the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.

[5] SI/2005-114, last amended on June 24, 2020. See Justice Laws website, Consolidated Regulations, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern.*

[6] PScience Policy Note SPN2020-01, *Policy on the List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under paragraph 43(5)(b) of the Pest Control Products Act*

[7] DIR2006-02, *Formulants Policy and Implementation Guidance Document*

The use of formulants in registered pest control products is assessed on an ongoing basis through Health Canada formulant initiatives and Regulatory Directive DIR2006-02.

7.0 Proposed regulatory decision

Health Canada, pursuant to subsection 28(1) of the *Pest Control Products Act*, is proposing registration for the sale and use of Captiva Prime Technical Insecticide and Captiva Prime, containing the active ingredients canola oil, garlic oil, capsaicin, and related capsaicinoids, for suppression of twospotted spider mite (*Tetranychus urticae*) and thrips on terrestrial food crops, greenhouse food crops, greenhouse non-food crops, and outdoor 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

♀	female
♂	male
µl	microlitre
°C	degrees centigrade
a.i.	active ingredient
bw	body weight
CAS	Chemical Abstracts Service
cm	centimetres
DIR	Regulatory Directive
EEC	estimated environmental concentration
ERC	Evaluation Report
FGE	food grade edible
g	gram
GD	gestation days
GLP	good laboratory practice
GMO	genetically modified
ha	hectare
HDPE	high density polyethylene
HDT	highest dose tested
hr	hour
ICR	Institute of Cancer Research
IPM	integrated pest management
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
K_{ow}	octanol-water partition coefficient
L	litre
LC_{50}	lethal concentration on 50% of the population
LD_{50}	lethal dose 50%
LLNA	local lymph node assay
LOAEL	lowest observed adverse effect level
LOC	level of concern
m	metre
MAS	maximum average score
mg	milligram
min	minutes
MIS	maximum irritation score
mL	millilitre
mol	mole
MRL	maximum residue limit
NIOSH	National Institute for Occupational Safety and Health
NOAEL	no observed adverse effect level
N/A	not applicable
OECD	Organisation for Economic Co-operation and Development
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment

PRD	Proposed Registration Decision
RED	Reregistration Eligibility Decision
REI	restricted entry interval
RD	Registration Decision
RQ	risk quotient
SPN	Science Policy Note
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
UV	ultraviolet
w/w	weight for weight
WP	wettable powder

Appendix I Tables and figures

Table 1 Acute toxicity and genotoxicity of Captiva Prime Technical Insecticide and Captiva Prime (86% active ingredients)[1]

(Effects are known or presumed to occur in both sexes unless otherwise noted.)

Study type/Animal/PMRA No.	Study results
Acute toxicity studies	
Acute oral toxicity[2] Rat, Wistar (♀) PMRA No. 3358434	LD_{50} > 2000 mg/kg bw **Low acute toxicity**
Acute dermal toxicity[2] Rat, Wistar (♀) PMRA No. 3358435	LD_{50} > 2000 mg/kg bw **Low acute toxicity**
Acute inhalation toxicity[2] (Nose-only exposure) Rat, Wistar (♂/♀) PMRA No. 3358436	LC_{50} (combined) > 1.417 mg/L air Clinical signs of toxicity included mild prostration and diarrhea, resolved by Day 3. **Slight acute toxicity**
Eye irritation[3] Rabbit, New Zealand White (♀) PMRA No. 3234022	MAS = 0/110 (at 24, 48 and 72 hrs) MIS = 6/110 (at 1 hr) One hour after instillation, all treated eyes exhibited minimal conjunctivitis, resolved by 24 hrs. **Non-irritating to the eye**
Eye irritation (in vitro)[2] Bovine Corneas PMRA No. 3358437	In Vitro Irritation Score (IVIS) = 2.5051 (composite score including corneal opacity and permeability) **Non-irritating to the eye**
Skin irritation[3] Rabbit, New Zealand White (♂/♀) PMRA No. 3234023	MAS = 4.67/8 (at 24, 48 and 72 hrs) MIS = 5.67/8 (at 1 hr) Well-defined to moderate/severe erythema and slight to severe edema within 24 hrs, resolved by Day 10. Desquamation, shiny skin and/or hyperkeratosis between 72 hours and Day 10. **Moderately irritating to the skin**

Study type/Animal/PMRA No.	Study results
Skin irritation (in vitro)[2] Reconstructed Human Epidermis (SkinEthic™) PMRA No. 3358438	Cell viability = 98.75% Tissue viability in the presence of test substance was comparable to the negative control. **Non-irritating to the skin**
Dermal sensitization (LLNA)[2] Mice, CBA/J (♀) PMRA No. 3358439	Positive **Dermal sensitizer**
Genotoxicity studies	
Bacterial reverse mutation assay[2] *S.* Typhimurium (TA97a, TA98, TA100, TA102 and TA1535) PMRA No. 3442409	**Negative ± metabolic activation**
In vitro mammalian cell micronucleus assay[2] Chinese hamster ovary (CHO) cells PMRA No. 3442410	**Equivocal ± metabolic activation**
In vivo mammalian bone marrow erythrocyte micronucleus test[2] Rats, Wistar PMRA No. 3678501	**No evidence of genotoxicity**

[1] Based on the content of active ingredients, the technical grade active ingredient and end-use product are considered to have an equivalent toxicological profile.

[2] Toxicity testing was conducted with the end-use product Captiva Prime.

[3] Toxicity testing was conducted with a test material that was very similar to the end-use product formulation, containing 7.6% oleoresin capsicum extract, 23.4% garlic oil, and 55% soybean oil (Note: Oleoresin capsicum extract is the source of capsaicin and related capsaicinoids).

Table 2 Repeat dose and prenatal developmental studies available for actives of Captiva Prime Technical Insecticide

Study type/Animal/PMRA No.	Study results
Short-term oral	
90-day oral toxicity (diet), non-guideline B6C3F1 mice PMRA No. 3387283	Capsaicinoid mixture (64.5% capsaicin, 32.6% dihydrocapsaicin, 2.9% other capsaicinoids)[1] **NOAEL: < 0.0625% or 71.91 / 95.07 mg/kg bw/day (♂/♀)** ≥ 0.0625% or 71.91 / 95.07 mg/kg bw/day (♂/♀): ↓ body weight (bw), ↓ food consumption (fc), ↑ relative liver weight (♂/♀) 1.0% or (1171.97 / 1296.61 mg/kg bw/day (♂/♀): focal tubular dilation of kidney (♂) Limitations: limited study reporting; unclear similarity of the test substance to the technical grade active ingredient
60-day oral toxicity (gavage), non-guideline Rats (strain, sex unspecified) PMRA No. 3773294	Capsaicin and capsicum fruit extract **NOAEL: < 50 mg/kg bw/day (capsaicin)** 50 mg/kg bw/day capsaicin and 500 mg/kg bw/day capsicum fruit extract: ↓ body weight gain, ↑ food consumption, ↓ clinical chemistry parameters (phospholipids, triglycerides, total cholesterol, free fatty acids), slight hyperemia (no hemorrhage) in liver, reddening of the gastric mucosa with increased mucus Limitations: only a single dose level; non-GLP; limited study reporting and design
28-day oral toxicity (gavage) ICR mice PMRA No. 3521229	Garlic oil **NOAEL: > 50 mg/kg bw/day**
90-day oral toxicity (diet) Sprague-Dawley rats PMRA No. 3773298	Incidence of mortality: 1 ♂/ treatment group (GM, control and reference canola diets No adverse effects from treatment groups (GM, control or reference canola)

Study type/Animal/PMRA No.	Study results
Prenatal developmental	
Developmental toxicity (dermal), non-guideline. Sprague-Dawley rats PMRA No. 3387287	Capsaicin **Maternal** **NOAEL: < 25 cm^2 dermal patch or 16 mg capsaicin/rat** ≥ 25 cm^2 dermal patch or 16 mg/rat: erythema and ungroomed coats ≥ 37.5 cm^2 dermal patch or 24 mg/rat; ↑ lacrimation, urine-stained abdominal fur 50 cm^2 dermal patch or 32 mg/rat: ↑ coldness to the touch **Developmental** **NOAEL: 37.5 cm^2 dermal patch or 24 mg trans-capsaicin/rat** 50 cm^2 dermal patch or 32 mg/rat: ↑ incidence of incompletely ossified 1st sternebra, ↓ ossification in forelimb phalanges and hindlimb metatarsals and phalanges **No evidence of treatment-related malformations** **Preferred test species for this data requirement.** Limitations: Route of administration was dermal, not oral. Test doses were not reported in mg/kg bw/day. Raw data was not available.
Developmental toxicity (dermal), non-guideline New Zealand white rabbits PMRA No. 3387287	**Maternal** **NOAEL: 13 µl/cm^2 or 260 mg capsaicin/rabbit (HDT)** Mortalities (20%, 0, 5%, 5%) ≥ 6.5µl/cm^2 or 60 mg/rabbit: Local dermal lesions: erythema, flaking, wrinkling **Developmental** **NOAEL: 13 µl/cm^2 or 260 mg *trans*-capsaicin/rabbit (HDT)** **No evidence of treatment-related malformations** Limitations:

Study type/Animal/PMRA No.	Study results
	Route of administration was dermal, not oral. Test doses were not reported in mg/kg bw/day. Raw data was not available. Not the preferred test species for this data requirement.

[1] While the capsaicinoid mixture contained higher levels of the active ingredient capsaicin (64.5%), than in the technical grade active ingredient (0.134% (w/w) capsaicin) it was still considered relevant to the toxicity profile of the technical grade active ingredient/end-use product.

Table 3 Screening-level aquatic risk assessment for capsaicin and related capsaicinoids

Organism	Exposure	Effect metric[1]	EEC[2]	RQ	LOC[3] Exceeded?
Zebrafish	96-h acute	0.598 mg a.i./L	0.007 mg a.i./L	0.012	No
Amphibians	Acute[4]	0.598 mg a.i./L	0.037 mg a.i./L	0.061	No
Green alga	72-h acute	2.56 mg a.i./L	0.007 mg a.i./L	0.003	No

[1] Effect metric = endpoint (from PMRA No. 3805886) divided by an uncertainty factor of 10 for fish (*Brachydanio rerio*) and amphibians, and 2 for algae (*Selenastrum capricornutum*).

[2] Estimated Environmental Concentration, based on an application pattern of 6.0 g a.i./ha × 20 at 4-day intervals, and the following assumptions: all of the capsaicin and related capsaicinoids in the applied Captiva Prime is capsaicin, a water half-life of 28 days (conservative estimate extrapolated from ready biodegradability experiment in PMRA No. 3805886) and a depth of 15 cm for amphibians and 80 cm for other aquatic organisms.

[3] Level of Concern = 1

[4] 96-h acute fish data used as surrogate

Table 4 List of supported uses

- For suppression of twospotted spider mite (*Tetranychus urticae*) and thrips in listed crops, apply Captiva Prime at an application rate of 1.2–2.4 L product per ha.
- Apply with ground application equipment in a minimum of 100 L total spray volume per ha or by air in a spray volume of 20–150 L per ha.
- For greenhouse crops and ornamentals, apply in a total spray volume of 378 L per ha.
- Re-apply every 4–7 days, as required.
- When pest pressure is heavier or canopy is dense, use the higher rate or shorter re-application interval.

Agriculture (Field)

Groups	Crops
Berries	Blackberry, Blueberry, Currant, Elderberry, Gooseberry, Huckleberry, Loganberry, Raspberry (black and red), Strawberries
Bulb vegetables	Garlic, Leek, Onion (dry bulb, green and Welsh), Shallot
Cucurbit vegetables	Chayote, Chinese wax gourd, Citron melon, Cucumber, Gherkin, Gourd (edible), Muskmelon, Pumpkin, Squash (summer and winter), Watermelon
Fruiting vegetables	Eggplant, Groundcherry, Pepino, Pepper (including bell pepper, chili pepper, cooking pepper, pimento, sweet pepper), Tomatillo, Tomato

Groups	Crops
Herbs group	Angelica, Balm (lemon balm), Basil, Borage, Burnet, Chamomile, Caraway, Catnip, Chervil (dried), Chive, Chinese chive, Clary, Coriander/Cilantro/Chinese Parsley (leaf), Costmary, Curry (leaf), Dill (Dillweed), Fennel (Florence), Fenugreek, Horehound, Hyssop, Lavender, Lemongrass, Lovage (leaf), Marigold, Marjoram, Nasturtium, Parsley (dried), Pennyroyal,, Rosemary, Sage, Savory (summer and winter), Sweet Bay (bay leaf), Tansy, Tarragon, Thyme, Wintergreen, Woodruff, Wormwood
Spices group	Caper buds, Caraway (black), Celery seed, Cumin, Dill (seed), Fennel (common), Juniper berry, Lovage (seed), Mustard (seed), Poppy (seed), Rue, Saffron
Legume vegetables	Bean, Broad bean, Chickpea, Guar, Jackbean, Lablab bean, Lentil, Pea, Pigeon pea, Soybean, Sword bean
Leafy vegetables (EXCEPT brassica vegetables)	Amaranth, Arugula, Broccoli, Broccoli raab (rapini), Cabbage, Chinese cabbage (bok choy, Napa), Chinese mustard Cabbage (gai choy), Chervil, Chrysanthemum (edible-leaved, Garland), Collards, Corn salad, Cress (garden, upland), Dandelion, Dock (sorrel), Endive (escarole), Kale, Lettuce (head and leaf), Mizuna, Mustard greens, Orach, Parsley, Purslane (garden, winter), Radicchio (red chicory), Rape greens, Spinach (New Zealand, vine), Swiss Chard, Turnip Greens
Brassica leafy vegetables	Brussels sprouts, Cauliflower, Cavolo broccoli, Chinese broccoli (gai lan), Kohlrabi, Mustard spinach
Stalk, stem, and leaf petioles	Cardoon, Celery, Chinese celery, Fennel (Florence), Kohlrabi, Rhubarb, Celtuce
Pome fruits	Apple, Crabapple, Loquat, Mayhaw, Quince, Oriental Pear, or Pear
Root and tuber vegetable	Arracacha, Arrowroot, Artichoke (Jerusalem, Chinese), Beet (garden, sugar), Burdock (edible), Canna (edible), Carrot, Cassava (bitter and sweet), Celeriac (celery root), Chayote (root), Chervil, (turnip-rooted), Chicory, Chufa, Dasheen (taro), Ginger, Ginseng, Horseradish, Leren, Oriental radish (daikon), Parsley (turnip-rooted), Parsnip, Potato, Radish, Rutabaga, Salsify (oyster plant, black, Spanish), Skirret, Sweet potato, Tanier, Turmeric, Turnip, Yam bean (jicama, manioc pea), Yam (true)
Stone fruit	Apricot, Cherry (sweet and tart), Nectarine, Peach, Plum (Chickasaw, Damson, Japanese), Plumcot, Prune
Tree and nut	Almond, Beech nut, Butternut, Chestnut, Chinquapin, Filbert (hazelnut, Hickory nut, Pecan, Walnut (black and English), Pistachios

Greenhouse

Production type	Crops
Greenhouse vegetable production	Tomatoes, Cucumbers, Leaf and Bibb lettuces, Bell peppers, Eggplant, Herbs (Angelica, Balm (lemon balm), Basil, Borage, Burnet, Chamomile, Caraway, Caraway (black), Catnip, Celery seed, Chervil (dried), Chive, Chinese chive, Clary, Coriander/Cilantro/Chinese Parsley (leaf), Costmary, Curry (leaf), Dill (Dillweed), Fennel (Florence), Fenugreek, Horehound, Hyssop, Lavender, Lemongrass, Lovage (leaf), Marigold, Marjoram, Nasturtium, Parsley (dried), Pennyroyal, Rosemary, Sage, Savory (summer and winter), Sweet Bay (bay leaf), Tansy, Tarragon, Thyme, Wintergreen, Woodruff, Wormwood), and spices (Allspice, Anise (anise seed and star), Annatto (seed), Caper buds, Caraway (black), Cardamom, Cassia bark, Cassia buds, Cinnamon, Clove buds, Celery seed, Cumin, Grains of paradise, Dill (seed), Fennel (common), Juniper berry, Mace, Nutmeg, Mustard (seed), Pepper (black and white), Poppy (seed), Rue, Saffron, Vanilla)
Transplant vegetable production	Brassicas (Brussels sprouts, Cauliflower, Cavolo broccoli, Chinese broccoli (gai lan), Kohlrabi, Mustard spinach), Cucumbers, Eggplants, Melons, Onion, Peppers, Squash

Ornamentals (Herbaceous and Woody) Growing Outdoors, in Nurseries or in Greenhouses

Use sites	Representative commodities
Ornamental shrubs and plants	Amaranthus, Aster, Azalea, Ferns, Fuchsias, Caladium, Carnation, Chrysanthemum, Dahlia, Daisy, Lilies, Ivy, Ficus, Gardenia, Impatiens, Iris, Jasmine, Lilac, Marigold, Philodendron, Poinsettia, Rose, Zinnia
Ornamental trees	Ash, Birch, Dogwood, Elm, Maple, Oak

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A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

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3234016	2013, Food Grade Certificate - Oleoresin Capsicum, DACO: 2.11.2 CBI
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3254096	2021, [CBI Removed] Vegetable Oils Food Grade Status Statement, DACO: 2.11.2 CBI
3254097	2021, [CBI Removed] Canola Oil Certificate of Analysis for [CBI Removed] DACO: 2.11.2 CBI
3254098	2015, Process Flow Chart – [CBI Removed] Oleoresins and Pelletized Ground Spices, DACO: 2.11.1 CBI
3254099	2021, Certificate of Analysis Garlic Oil, [CBI Removed], DACO: 2.11.2 CBI
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3.0 Environment

PMRA Document Number	Reference

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B. Additional Information Considered

i) Published Information

1.0 Chemistry

None

2.0 Human and Animal Health

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4.0 Value

None