Proposed Registration Decision PRD2026-01

Cold pressed orange oil and Appeal

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Overview

Proposed Registration Decision for Cold pressed orange oil

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 ORO Orange Oil and Appeal, belonging to ORO Agri Inc., containing the active ingredient cold pressed orange oil, to manage fungal diseases and insect pests on various crops in the greenhouse and field.

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 cold pressed orange oil and Appeal.

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 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'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. 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's PMRA 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 cold pressed orange oil and Appeal, Health Canada's PMRA will consider any written comments received from the public directly related to the proposed decision in this consultation document.[3]

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."

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

Health Canada will then publish a Registration Decision[4] on cold pressed orange oil and Appeal, 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 cold pressed orange oil?

Cold pressed orange oil is a new non-conventional active ingredient for disease and insect pest management in Canada. It has a physical mode of action on both fungi and arthropod pests. Cold pressed orange oil kills target pests either by suffocation or desiccation from damage to protective external tissues.

Health considerations

Can approved uses of cold pressed orange oil affect human health?

Cold pressed orange oil is unlikely to affect human health when it is used according to label directions.

Potential exposure to cold pressed orange oil may occur through the diet (food and water) and when handling 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 levels used to assess risks are established 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 where no effects are observed.

In laboratory animals, cold pressed orange oil was of low acute toxicity by the oral and inhalation routes, minimally irritating to the eyes, non-irritating to the skin, and not a dermal sensitizer.

Rationales to waive testing for short-term toxicity and prenatal developmental toxicity were accepted based on the results of published animal studies conducted with d-limonene, the major component of ORO Orange Oil. Administration of repeated high doses of d-limonene resulted in reductions in body weight, and male rat-specific kidney effects, which were determined to not be relevant to humans. Administration to pregnant animals indicated that the young were not more sensitive than the adult animal. Results from testing indicate that ORO Orange Oil is not genotoxic or mutagenic.

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

In laboratory animals, the end-use product, Appeal, was considered to be of low acute toxicity by the oral, dermal and inhalation routes, moderately irritating to the eye, slightly irritating to the skin, and not a dermal sensitizer. The end-use product label requires a sulfite allergen warning statement.

Residues in food and drinking water

Dietary risks from food and water are acceptable.

Dietary exposure to cold pressed orange oil may occur through consumption of treated crops; however, cold pressed orange oil is not expected to pose a health risk when the end-use product is applied as directed by the label. The likelihood of cold pressed orange oil residues in drinking water will be low. Consequently, health risks from dietary exposure are acceptable for all segments of the population, including infants, children, adults and seniors.

Occupational risks from handling Appeal

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

Workers handling Appeal can come into direct contact with cold pressed orange oil through inhalation and contact with skin during mixing, loading, application, clean-up and repair. Eye exposure is also possible, but expected to be minimal.

To protect workers from exposure to Appeal, the label will require workers to wear personal protective equipment (PPE) during mixing, loading, application, clean-up and repair.

The Appeal label requires a restricted-entry interval (REI) of four (4) hours, or until sprays have dried, for all uses, and includes a spray advisory statement to minimize spray drift.

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

Risks in residential and other non-occupational environments

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

There are no residential uses proposed for Appeal. The product is proposed for use as a commercial insecticide/fungicide in greenhouse food and ornamental crops, outdoor ornamentals, and field grown food crops, such as fruit, field, feed, and vegetable crops.

The label for Appeal will include measures to prevent bystander and residential exposure, such as reducing spray drift, and restricting access to the treated area until sprays have dried. For the general population involved in pick-your-own activities, health risks are not of concern.

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

Environmental considerations

What happens when cold pressed orange oil is introduced into the environment?

When used according to label directions, environmental risks associated with cold pressed orange oil and its end-use product, Appeal, are acceptable.

Cold pressed orange oil enters the environment when its end-use product is applied as a fungicide and insecticide, using field and airblast sprayers, to various terrestrial feed and food crops, greenhouse food and non-food crops, and outdoor ornamentals. The major component of cold pressed orange oil is d-limonene. In the environment, it rapidly volatilizes from both dry and moist soil to the atmosphere and if it reaches water, it is not expected to mix with water but may remain on the surface of water bodies, or will stick to plant matter, until it is broken down by bacteria. As such, it is not expected to move downward in soil to groundwater or be persistent in water or soil.

Ecotoxicity studies were conducted using d-limonene. d-Limonene is a natural product and is used as both an active and an inert ingredient in pesticide products, and as an ingredient in food products, soaps, and perfumes. As a formulant, it is used as a solvent or fragrance in many consumer products. d-Limonene has low toxicity to non-target organisms. The environmental risks from the proposed uses of cold pressed orange oil are acceptable when its end-use product is used according to the label directions.

Value considerations

What is the value of Appeal?

The registration of Appeal will provide Canadian growers with a new mode of action fungicide/insecticide to manage economically important fungal diseases and arthropod pests on the greenhouse and field-grown crops specified on the product label.

Appeal contains cold pressed orange oil as its sole active ingredient. Appeal, applied as foliar spray applications, is effective against important oomycete diseases and certain arthropod pests on multiple crops and/or crop groups.

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 ORO Orange Oil and Appeal to address the potential risks identified in this assessment are as follows.

Key risk-reduction measures

Human health

The hazard signal words “WARNING – EYE IRRITANT” and “Warning, contains the allergen sulfites” are required on the principal display panel of the Appeal label. Standard precautionary statements are also required on the label to inform users that the end-use product causes eye irritation and to avoid contact with eyes.

Workers are required to wear personal protective equipment (PPE) during mixing, loading, application, clean-up and repair. The PPE required depends on the activity and method of application.

Workers are required to wear long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes, and protective eyewear (goggles or face-shield) during handling, mixing, loading, clean-up and repair, and during open-cab airblast applications. Additionally, hand-held airblast/mistblower application requires chemical-resistant coveralls with a chemical-resistant hood, chemical resistant footwear, and a respirator with NIOSH-approved organic-vapour-removing cartridge with a prefilter approved for pesticides or a NIOSH-approved canister approved for pesticides. When applying above waist height using hand-held equipment, eye, head, and respiratory protection are also required.

For Appeal, there will be a restricted-entry interval of four (4) hours, or until sprays have dried.

To limit bystander exposure, the end-use product label requires standard drift statements.

Environment

Label statement prohibiting the discharge of greenhouse releases, effluent or runoff to water is required.

Next steps

Before making a final registration decision on cold pressed orange oil and Appeal, 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 30 days from the date of publication (by 25 February 2026) of this document. If more time is required to provide comments, a request for an extension of up to an additional 15 days can be made before the end of the original 30-day consultation period. Please forward all comments to PMRA 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's PMRA makes its registration decision, it will publish a Registration Decision on cold pressed orange oil and Appeal (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

Cold pressed orange oil and Appeal

1.0 The active ingredient, its properties and uses

1.1 Identity of the active ingredient

Active substance **Common name:**	Cold pressed orange oil
Function	Fungicide and Insecticide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	Not applicable
2. Chemical Abstracts Service (CAS)	
CAS number	Not applicable
Molecular formula	Not applicable
Molecular weight	Not applicable
Structural formula	Not applicable
Purity of the active ingredient	100%

1.2 Physical and chemical properties of the active ingredient and end-use product

Technical product—ORO Orange Oil

Property	Result	
Colour and physical state	Transparent orange liquid	
Odour	Strong citrus odour	
Melting range	The technical grade active ingredient is a liquid	
Boiling point	178°C	
Density	0.842–0.846 g/mL at 20°C	
Vapour pressure at 20°C	Flow rate (mL/min)	Vapor pressure (mPa)
	20	9880
	25	18440
	30	18030
Ultraviolet (UV)-visible spectrum	λ_{max} = 330 nm	
Solubility in water at 20°C	Insoluble in water	

Property	Result
Solubility in organic solvents at 20°C	Solvent — Solubility (g/L) n-heptane — 750 p-xylene — 750 1,2-dichloroethane — 750 Acetone — 750 Ethyl acetate — 750 Methanol — 286.9
n-Octanol-water partition coefficient (K_{ow})	log K_{ow} = 5.4
Dissociation constant (pK_a)	The active ingredient is not a salt and does not contain acid or base functionality.
Stability (temperature, metal)	The active ingredient was stable when stored in glass and epoxy-lined containers at 54°C for 14 days.

End-use product—Appeal

Property	Result
Colour	Transparent green
Odour	Citrus
Physical state	Liquid
Formulation type	Emulsion
Label concentration	Cold pressed orange oil at 6.0%
Container material and description	Plastic jug, drum and tote (1–1000 L)
Density	1.01–1.02 g/mL at 20°C
pH of 1% dispersion in water	6.8–7.8
Oxidizing or reducing action	The end-use product exhibits reducing properties
Storage stability	The end-use product is stable for 14 days when stored at 54°C
Corrosion characteristics	Not corrosive to polyethylene containers
Explodability	Not explosive

1.3 Directions for use

For the fungicide use of Appeal, the product may be applied for control of powdery mildew on roses, ornamentals (excluding roses), ornamental trees and shrubs, fruiting vegetables (Crop Group 8-09), cucurbit vegetables (Crop Group 9), caneberries (Crop Subgroup 13-07A), bushberries (Crop Subgroup 13-07B), strawberries, grapes, and herbs (Crop Group 25); for suppression of powdery mildew on pome fruits (Crop Group 11-09) and stone fruits (Crop Group 12-09); for suppression of downy mildew on roses, ornamentals (excluding roses) and cucurbit vegetables (Crop Group 9); for suppression of rust on roses, and ornamental trees and shrubs; for suppression of black spot on roses; and for suppression of late blight and early blight on potato and fruiting vegetables (Crop Group 8-09), at certain concentrations with specified spray volumes as listed in Appendix I, Table 1 in accordance with label directions.

Appeal may be applied to greenhouse and field-grown crops as indicated on the product label. Appeal can be applied by ground application equipment only.

For the insecticide use of Appeal, the product may be applied for suppression of spider mites on roses, ornamentals (excluding roses), potato, fruiting vegetables (Crop Group 8-09), cucurbits (Crop Group 9), pome fruits (Crop Group 11-09), stone fruits (Crop Group 12-09), tree nuts (Crop Group 14-11), caneberries (Crop Subgroup 13-07A), bushberries (Crop Subgroup 13-07B), strawberries, herbs (Crop Group 25), Asian water spinach, globe artichokes and hops; for suppression of aphids on roses, ornamentals (excluding roses), ornamental trees and shrubs, leafy vegetables (Crop Group 4-13), brassica head and stem vegetables (Crop Group 5-13), stalk, stem, leaf petiole vegetables (Crop Group 22), tree nuts (Crop Group 14-11), caneberries (Crop Subgroup 13-07A), bushberries (Crop Subgroup 13-07B), strawberries, cereal grains (including English grain aphid, Crop Group 15-21), oilseeds, herbs (Crop Group 25), Asian water spinach and globe artichokes; to reduce numbers of woolly apple aphid on apples; for suppression of scales and mealybugs on ornamental trees and shrubs; for suppression of box tree moth larvae on boxwood; to reduce numbers of pear psylla on pear; and to reduce number of whiteflies on roses, ornamentals (excluding roses), leafy vegetables (Crop Group 4-13), fruiting vegetables (Crop Group 8-09), cucurbits (Crop Group 9), caneberries (Crop Group 13-07A), bushberries (Crop Group 13-07B), strawberries, herbs (Crop Group 25) and Asian water spinach, at the concentrations with specified spray volumes in accordance with label directions. Appeal can be applied by ground application equipment only.

1.4 Mode of action

Cold pressed orange oil is a new non-conventional active ingredient for disease and insect pest management in Canada. It acts as a contact fungicide and insecticide. Cold pressed orange oil has a physical mode of action on both fungi and arthropod pests. Cold pressed orange oil causes disruption of protective outer layers of fungi, leading to exposure and desiccation. Further, it affects soft-bodied insects and mites, entering tracheae and affecting respiration and causing degradation of the cuticle, leading to loss of fluids and death. Cold pressed orange oil is not classified by either the Insecticide Resistance Action Committee (IRAC) or the Fungicide Resistance Action Committee (FRAC) at this time.

2.0 Methods of analysis

2.1 Methods for analysis of the active ingredient

The methods provided for the analysis of the active ingredient and impurities in the technical product have been validated and assessed to be acceptable.

2.2 Method for formulation analysis

The method provided for the analysis of the active ingredient in the formulation has been validated and assessed to be acceptable for use as an enforcement analytical method.

2.3 Methods for residue analysis

Not required.

3.0 Impact on human and animal health

3.1 Toxicology summary

A detailed review of toxicology information was conducted in support of ORO Orange Oil and Appeal and the database was found to be acceptable (Appendix I, Tables 2 and 3) to assess the toxic effects that may result from exposure to cold pressed orange oil.

The data package for ORO Orange Oil consisted of acute toxicity (via oral and inhalation routes), eye and skin irritation, dermal sensitization, in vitro bacterial gene mutation, in vitro mammalian gene mutation, and in vivo mammalian bone marrow cytogenetics studies conducted with cold pressed orange oil, as well as waiver rationales to address short-term toxicity and prenatal developmental toxicity.

ORO Orange Oil is considered to be of low acute toxicity by the oral and inhalation routes, minimally irritating to the eyes, non-irritating to the skin, and is not a dermal sensitizer.

In lieu of submitting a short-term toxicity study with ORO Orange Oil, a published report by the National Toxicology Program (NTP) was provided which included 16-day, 91-day, and 2-year repeat dose studies conducted with d-limonene in F344/N rats and B6C3F1 mice. d-Limonene is the principal chemical constituent in cold pressed orange oil (>90%) and as such, was considered appropriate to characterize the toxicology of ORO Orange Oil.

In the 16-day study, F344/N rats (5/sex/dose) were administered d-limonene at 0, 413, 825, 1650, 3300 or 6600 mg/kg bw/d and B6C3F1 mice were administered d-limonene at doses of 0, 413, 825, 1650, 3300 or 6600 mg/kg bw/d. All animals were dosed by gavage in corn oil once a day for 5 days/week.

All rats (5/5) exposed to the 6600 mg/kg bw/d and 5/5 male rats and 3/5 female rats that received 3300 mg/kg bw/d died within the first two days of the study. Reductions in body weight gain (8-10%) were seen in rats at the middle doses (1650 mg/kg bw/d and 3300 mg/kg bw/d). There were no compound-related clinical signs observed in rats that received lower than 1650 mg d-limonene/kg bw and they survived until the study termination.

All mice (5/5) exposed to 6600 mg/kg bw/d, 4/5 males and 5/5 females exposed to 3300 mg/kg bw/d, and 1/5 males and 1/5 females exposed to 1650 mg/kg bw/d died before study termination. In mice that received 1650 mg d-limonene/kg bw/d and survived, there were no compound-related clinical or histopathological findings.

In the 91-day study, F344/N rats (10/sex/dose) were administered d-limonene at 0, 150, 300, 600, 1200, or 2400 mg/kg bw/d, and B6C3F1 mice (10/sex/dose) were administered d-limonene at 0, 125, 250, 500, 1000, or 2000 mg/kg bw/d. All animals were dosed by gavage in corn oil once a day for 5 days/week.

In rats, deaths occurred in the high dose group males (5/10) and females (1/10) during Week 1. Dose-dependent α2μ-globulin-induced nephropathy was observed in male rats. Reduction in body weight gain was also observed in male rats at the two highest doses, and in female rats at the highest dose. No treatment-related nephropathy or histopathologic lesions were observed in female rats.

In mice, deaths occurred in a non-dose-dependent manner and some deaths were caused by gavage error. A reduction in body weight gain was observed in male mice in the two highest dose groups. No other adverse effects were observed in mice of either sex.

In the 2-year study, 50 animals/species/sex/dose were administered 0, 75, or 150 mg/kg bw/d (male rats); 0, 300, or 600 mg/kg bw/d (female rats); 0, 250, or 500 mg/kg bw/d (male mice); or 0, 500, or 1000 mg/kg bw/d (female mice) d-limonene by gavage in corn oil once a day for 5 days/week. Male rats dosed at 150 mg/kg bw/d had slightly decreased body weight and developed α2μ-globulin-induced nephropathy and renal adenoma/adenocarcinoma. Female rats showed no effects at 300 mg/kg bw/d, but at 600 mg/kg bw/d had slightly decreased body weight and increased mortality.

d-Limonene is reported to have produced hyaline droplet nephropathy and caused renal tubular tumours only in adult male rats through an α2μ-globulin-associated response. Male rats are unique in that they exhibit a background of spontaneous protein droplets in the proximal tubule, particularly within the cells of the P2 segment. d-Limonene increases the formation of these droplets, and it was shown by two-dimensional gel electrophoresis that the only protein accumulating was α2μ-globulin. Alpha 2μ-globulin is synthesized in the liver of adult male rats, secreted into the general circulation and reabsorbed by the renal proximal tubule cells. The critical role of this protein in renal effects of d-limonene is demonstrated by the absence of histopathological changes in female rats and in species that do not synthesize α2μ-globulin. Therefore, d-limonene did not show renal toxicity in female rats.

Nephrotoxicity was induced in the male rats but was not considered to be a relevant endpoint for human health risk assessment purposes. Binding of d-limonene, and particularly the 1,2-epoxide, to α2μ-globulin is the requisite step in the development of α2μ-globulin nephropathy. However, the protein content of human urine is very different from that of rat urine, since humans excrete very little protein (about 1% of the concentration found in urine of male rats). Also, human urinary protein is predominantly a species of high molecular mass, and there is no protein in human plasma or urine identical to α2μ-globulin. As such, the information suggests that the renal tumours caused by d-limonene in male rats are not relevant to humans.

In mice, females from the high dose group (1000 mg/kg bw/d) had decreased body weight. No treatment-related nephropathy or renal adenomas/carcinomas were observed in either sex in mice.

An acceptable rationale to waive the required prenatal developmental toxicity study for ORO Orange Oil was based on published prenatal developmental toxicity studies conducted with d-limonene in rodent (rat, mice) and non-rodent (rabbit) species.

In a rat study, 15 pregnant rats per group were administered 0, 591, or 2869 mg/kg bw/d d-limonene by gavage on gestation days 9-15. In high-dose animals, maternal toxicity (significant reduction in body weight) and mortality (8/20) was observed, as was developmental toxicity presenting as skeletal abnormalities (delayed ossification in the paws) and decreased organ weights (thymus, spleen, ovaries) in fetuses. At the low dose, no maternal toxicity and no fetal effects were noted. This study is limited because of the small sample size, limited number of dose levels, and because dosing did not cover the entire period of organogenesis.

In a mouse study, 15 pregnant mice per group were administered 0, 591, or 2363 mg/kg bw/d d-limonene by gavage on gestation days 7-12. In high-dose animals, maternal toxicity (significant reduction in body weight) and developmental toxicity presenting as skeletal abnormalities (lumbar ribs, fused ribs, and delayed ossification of several bones in the paws) were observed. At the low dose, no maternal or fetal effects were noticed. This study is also limited because of the small sample size, limited number of dose levels, and as dosing did not cover the entire period of organogenesis.

In a rabbit study, groups of 10-21 pregnant Japanese white rabbits were dosed with 0, 250, 500, or 1000 mg/kg bw/d d-limonene by gavage on days 6-18 of gestation. Maternal toxicity and significant reductions in food consumption and body weight occurred at 500 and 1000 mg/kg bw/d, and mortality occurred at the highest dose tested (6/21). Developmental toxicity was not observed at any dose. This study is limited by the small sample size.

Developmental effects seen in the studies in rats and mice (variations in skeletal formation and decrease in body weight) were secondary to maternal toxicity and were not accompanied by other effects; therefore, there is no evidence of increased sensitivity in young animals relative to adult animals.

ORO Orange Oil was not mutagenic in a reverse gene mutation assay in bacteria, nor in an in vitro mammalian cell gene mutation assay in V79 Chinese hamster cells. Additionally, it was not genotoxic in an in vivo mammalian erythrocyte micronucleus test in bone marrow of mice.

To address the data requirements for the end-use product, acute toxicity studies were conducted with OR-030 A, a liquid formulation containing 6% orange oil which was acceptable to evaluate the toxicology profile of the end-use product Appeal (containing 6% w/w cold pressed orange oil). The results of these studies indicate that Appeal is of low acute toxicity by the oral, dermal and inhalation routes, moderately irritating to the eye, slightly irritating to the skin, and is not a dermal sensitizer.

3.2 Occupational, residential and bystander exposure and risk assessment

3.2.1 Use description

Appeal is proposed for registration as a commercial insecticide/fungicide end-use product, and there are no residential uses proposed. The product is proposed for use on greenhouse food and ornamental crops, outdoor ornamentals, and field-grown food crops, such as various vegetables, orchard crops, berries, grapes, and potato.

Appeal is a liquid formulation that is mixed with water at concentrations of 0.4–0.8% v/v in spray volumes of 200–1500 L/ha and applied as a foliar spray using conventional ground equipment (such as boom sprayers, high- and low-volume sprayers, ultra-low-volume sprays, airblast), or by chemigation. Re-applications can be made every 7–14 days until harvest.

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 Appeal is characterized as short- and intermediate-term in duration and is expected to occur primarily by the inhalation and dermal routes during handling, mixing, loading, and application. During clean-up and repair, occupational exposure will be primarily by the dermal route. Ocular exposure is expected to be minimal.

Workers are required to wear personal protective equipment (PPE) during mixing, loading, application, clean-up and repair. The PPE required depends on the activity and method of application.

Workers are required to wear long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes, and protective eyewear (goggles or face-shield) during handling, mixing, loading, clean-up and repair, and during open-cab airblast applications. Additionally, hand-held airblast/mistblower application requires chemical-resistant coveralls with a chemical-resistant hood, chemical resistant footwear, and a respirator with NIOSH-approved organic-vapour-removing cartridge with a prefilter approved for pesticides or a NIOSH-approved canister approved for pesticides. When applying above waist height using hand-held equipment, eye, head, and respiratory protection are also required. Eye protection is not required during closed cab, open cab groundboom, or all other handheld equipment applications. Gloves are not required during application within a closed cab.

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.

Methyleugenol is a genotoxic carcinogen that is naturally occurring in some spices, herbs, fruit, and essential oils, including in cold pressed orange oil. Existing mitigative label statements are expected to be sufficient to minimize any unnecessary risk due to occupational exposure to methyleugenol. Additionally, the level present in the end-use product is less than the concentration permitted in leave-on personal care products and personal insect repellents (2 ppm). Therefore, the risk from worker exposure to the level of methyleugenol in Appeal is considered acceptable.

3.2.2.2 Postapplication exposure and risk assessment

There is a potential for postapplication exposure to workers entering areas treated with Appeal. 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 4 hours, or until sprays have dried.

Precautionary statements on the end-use product label, 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 assessment

Appeal is a commercial-class product. Given that pome fruit, stone fruit, and berry crops can be treated with Appeal, there is potential for exposure during pick-your-own activities; however, since Appeal has a low toxicity profile, is only slightly irritating to the skin, and is diluted before application at low rates, risks to the general population are acceptable.

While the commercial use of Appeal may result in residential and bystander exposure due to drift, this will be mitigated by the inclusion of a spray drift statement on the label advising against application to areas of human habitation unless consideration has been given to the wind speed, wind direction, temperature inversions, application equipment, and sprayer settings. Also, access to the treated area will be restricted until sprays have dried.

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

3.3 Dietary exposure and risk assessment

3.3.1 Food

While dietary exposure to cold pressed orange oil may occur through consumption of crops treated with Appeal, residues are expected to be low, based on the low concentration of the active ingredient in the diluted end-use product solution, and the low application rates. In addition, cold pressed orange oil has a low toxicity profile, and humans are already exposed to 'sweet orange oil' in the diet, as a flavouring agent, and in various consumer products.

Conservative residue estimates on crops following treatment with Appeal were calculated using maximum use rates and lowest crop yield values. These calculations showed that there is no expectation of quantifiable residues of methyleugenol (<0.01 ppm) on crops. Using the conservative residue estimates, a dietary exposure assessment was also conducted which concluded that dietary exposure to methyleugenol from the use of Appeal was not of concern.

Consequently, 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.

3.3.2 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 cold pressed orange oil. Health risks from residues of cold pressed orange oil in drinking water are acceptable due to the low toxicity profile and limited exposure following application of Appeal.

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 assessment

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.

Cold pressed orange oil is considered to be of low toxicity by the oral, dermal, and inhalation routes, and the end-use product label has the necessary mitigative measures to limit contamination of drinking water. Furthermore, when used as directed on the label, non-occupational exposure to Appeal will be low.

Therefore, when the end-use product is used as labelled, there is reasonable certainty that no harm will result from aggregate exposure of residues of cold pressed orange oil. 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 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 potential common mechanism of toxicity with other pesticides was undertaken.

While constituents of cold pressed orange oil may share structural similarities to components found in other essential oil-based pest control products, it is difficult to determine which constituents may share a common mechanism of action as it is often not possible to fully identify and characterize the constituent(s) responsible for toxicity.

However, methyleugenol is a natural component of cold pressed orange oil and certain other essential oils (for example, tea tree oil, lemon eucalyptus oil, clove leaf oil) and other active ingredients (cis-jasmone) which are registered for use as agricultural pesticides with food uses and as personal insect repellents (PIRs).

In terms of dietary exposure, the active ingredients Clove Leaf Oil Technical and Tea Tree Oil both meet the Food Chemicals Codex (FCC) requirements, and both essential oils are already consumed in food and as flavouring agents. Based on calculations which consider levels in the end-use product, dilutions and use rates, dietary exposure to methyleugenol from the food uses for both clove leaf oil and tea tree oil are expected to be below existing dietary background levels of methyleugenol.

The use of cis-jasmone is limited to use as a seed treatment, and based on batch data and the relative level in the end-use product, dietary exposure to methyleugenol from this active ingredient would be below existing dietary background levels, by several orders of magnitude.

While ORO Orange Oil does not meet the FCC requirements, orange oil is present in various food items and is used as a flavoring agent; and it is therefore already part of the diet. Dietary exposure to methyleugenol that considered worst-case residue levels based on highest levels in the end-use product, lowest dilutions and use rates, was determined to be well below the level which would be a health risk of concern.

Given the label instructions regarding procedures for avoiding the contamination of water, and the moderate to high volatility of components of essential oils, including methyleugenol, the contamination of surface or groundwater sources of drinking water with methyleugenol from the registered and proposed uses would be negligible.

In addition to existing background dietary exposure, exposure to methyleugenol occurs from other consumer products containing essential oils (such as cosmetics, natural health products, cleaning products), which includes PIRs. The PMRA has established an allowable limit for methyleugenol in PIRs at 0.0002%. Further non-occupational and residential exposure to methyleugenol from pesticidal uses is not expected to occur under the proposed conditions of use as commercial agricultural products.

Considering the available information, as required under section 7(7)(b)(i) of the *Pest Control Products Act*, the PMRA has determined that the non-occupational exposure (dietary and residential) of methyleugenol in cold pressed orange oil for the proposed uses would have little impact on the overall cumulative health risk. Based on the qualitative approach, the cumulative risks from potential co-exposure to methyleugenol from pesticidal uses are 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 ORO Orange Oil is acceptable, given the low toxicity profile of ORO Orange Oil, as well as the low application rates for Appeal. Furthermore, sweet orange oil has a history of use as a flavouring agent and in spices, and is naturally occurring in certain foods.

Consequently, the specification of an MRL, under the *Pest Control Products Act*, will not be required for cold pressed orange oil.

3.7 Health incident reports

As of 29 July 2025, no human or domestic animal incidents involving the active ingredient orange oil have been submitted to the PMRA.

4.0 Impact on the environment

4.1 Fate and behaviour in the environment

Information on the major component of cold pressed orange oil, d-limonene, was used to inform the fate and behaviour of cold pressed orange oil. The environmental fate and behaviour of d-limonene was previously assessed. Refer to the Proposed Registration Decision PRD2010-21, *d-Limonene* and the Registration Decision RD2015-23, *d-Limonene* for more information.

4.2 Environmental risk characterization

Cold pressed orange oil was evaluated in accordance with PMRA Guidance Document, *Guidance for the Registration of Non-Conventional Pest Control Products.* Where data was available, an environmental risk assessment was conducted as described in the PMRA Guidance Document, Health Canada's Approach to Environmental Risk Assessment for Pest Control Products to estimate the potential for adverse effects on non-target species. Environmental exposure and ecotoxicology information were integrated by comparing estimated environmental concentrations (EECs) to effects-based values used to assess risk (effects metrics). EECs were estimated using standard models that consider application rate(s) and chemical and environmental fate properties, including pesticide dissipation between applications. The EECs used in this risk assessment are presented in Appendix I, Table 4.

Acute and chronic ecotoxicological data based on d-limonene, the major component of cold pressed orange oil, are summarized in Appendix I, Table 5. In the risk assessment, toxicity endpoints were adjusted via an uncertainty factor (UF) to calculate the effects metrics. The effects metrics account for potential differences in species sensitivity as well as varying protection goals (in other words, protection at the community, population or individual level).

Initially, a screening-level risk assessment was performed using simple methods, conservative exposure scenarios and sensitive effects metrics. A risk quotient (RQ) was calculated by dividing the EEC by the effects metric and was then compared to the level of concern (LOC). When the screening level RQ was below the LOC, the risk was considered to be acceptable, and no further risk characterization was necessary. When the screening level RQ was equal to or greater than the LOC, a refined risk assessment was performed to further characterize the risk.

The refined risk assessment considered additional effects metrics as well as more realistic exposure scenarios, including spray drift. Refinements to the risk assessment continued until the risk was adequately characterized or the available data did not permit further refinements.

4.2.1 Risks to terrestrial organisms

When used according to the proposed label directions, risks to terrestrial organisms are acceptable.

Pollinators

During foliar application, pollinators may be exposed to cold pressed orange oil by contact with spray droplets during flight or spray residues on plant foliage. Pollinators can also be exposed orally by feeding on pollen and nectar after spray droplets were deposited on open flowers or from systemic movement of cold pressed orange oil residues to pollen and nectar following application.

Cold pressed orange oil is relatively non-toxic to honeybees based on acute oral and contact exposure. An acute and chronic foliar application screening-level risk assessment for honeybees was conducted using the single maximum seasonal application rate of 0.548 kg a.i./ha. The LOC was not exceeded at the screening level for adult honeybees from contact and oral exposures (Appendix I, Table 6). Therefore, the risks to honeybees from the application of cold pressed orange oil to various terrestrial feed and food crops, greenhouse food and non-food crops, and outdoor ornamental crops are acceptable when used according to label directions.

Birds and small wild mammals

The potential exposure of birds and small wild mammals to cold pressed orange oil was assessed based on screening-level estimated daily exposure values (EDEs) from food items sprayed with the maximum seasonal rate for the proposed use on potato crops with 10 applications of 487.20 g a.i./ha followed by 5 applications of 365.40 g a.i./ha with a 7-day re-application interval and a default foliar half-life of 10 days.

The major route of exposure for birds and small wild mammals is through ingestion of residues on food sources following application. Based on acute oral toxicity, cold pressed orange oil is slightly toxic to Japanese quail (*Coturnix coturnix japonica*) with a 7-day LD_{50} of greater than 1107 mg a.i./kg bw; however, the screening-level risk assessment did not exceed the LOC for birds (Appendix I, Table 7).

A 14-day acute oral chronic exposure of cold pressed orange oil to mammals was investigated and it was found to be practically non-toxic to mammals. The screening-level risk assessment did not exceed the LOC for small wild mammals (Appendix I, Table 7).

Overall, the risks to birds and small wild mammals from the application of cold pressed orange oil to various terrestrial feed and food crops, greenhouse food and non-food crops, and outdoor ornamental crops are acceptable when used according to label directions.

Non-target terrestrial vascular plants

Non-target terrestrial vascular plants can be exposed to spray drift during the application of cold pressed orange oil to crops. The toxicity of cold pressed orange oil on vegetative vigour of several monocotyledonous and dicotyledonous plants was evaluated with an ER_{25} >1181 g a.i./ha based on shoot dry weight. The screening-level risk assessment exceeded the LOC for non-target terrestrial vascular plants (Appendix I, Table 8).

As such, a refined assessment, assuming 74% spray drift at 1 m off-field from early season airblast application resulted in the LOC not being exceeded (Appendix I, Table 8). Thus, the risks to non-target terrestrial vascular plants from the application of cold pressed orange oil to various terrestrial feed and food crops, greenhouse food and non-food crops, and outdoor ornamental crops are acceptable when used according to label directions.

4.2.2 Risks to aquatic organisms

When used according to the proposed label directions, risks to aquatic organisms are acceptable.

Cold pressed orange oil is moderately toxic to water flea *(Daphnia magna)* based on 48-h acute toxicity with an EC_{50} of 4.68 mg a.i./L and slightly toxic to zebrafish (*Danio rerio*) based on 96-h acute toxicity with a 96-h LC_{50} of 50 mg a.i./L. The screening-level risk assessment indicated that the LOCs were not exceeded for acute exposure to *Daphnia magna* and fish (Appendix I, Table 9).

4.3 Environmental Incident Reports

As of 29 July 2025, no environmental incident reports involving cold pressed orange oil have been submitted to the PMRA.

5.0 Value

Cold pressed orange oil is a new non-conventional active ingredient for insect pest and disease management in Canada. Appeal is a non-conventional pesticide that has a low-risk for resistance development and contributes to resistance management. Appeal showed similar efficacy compared to similar registered oil-based products against fungal and insect pests. Cold pressed orange oil is not expected to affect plant respiration via obstruction of stomata due to its high volatility.

Scientific rationales and efficacy results from field and greenhouse trials on rose, lisianthus, spiked speedwell, petunia, oak, potato, tomato, pepper, eggplant, tomatillo, cucumber, zucchini, pumpkin, melon, apple, strawberry, grapes and sage conducted in Austria, Czech Republic, France, Germany, Greece, Hungary, Italy, Poland, Portugal, Romania, Spain, the Netherlands and the United Kingdom demonstrated that Appeal was effective against targeted diseases when applied by foliar spray applications in accordance with label directions. Appeal has demonstrated an acceptable level of disease control or suppression as compared to the non-treated control in the efficacy trials. The use of Appeal for the listed disease/crop combinations is accepted from a value perspective.

Scientific rationales and efficacy results from field and greenhouse trials on apple, barley, bell pepper, boxwood, chrysanthemum, citrus, eggplant, hibiscus, ivy, lettuce, pear, pumpkin, rose, strawberry, tomato, watermelon, wheat, winter melon, woody shrubs and zucchini in Austria, Belgium, Czech Republic, France, Germany, Greece, Hungary, Italy, the Netherlands, Poland, Portugal, Romania, Spain and the United Kingdom demonstrated that Appeal was effective against targeted insects and mites when applied by foliar spray applications in accordance with label directions.

Appeal has demonstrated an acceptable level of suppression or reducing number of insects as compared to the non-treated control in the efficacy trials. The use of Appeal for the listed pest/crop combinations is accepted from a value perspective.

No phytotoxicity or other injury to the crops was observed in the trial studies. When used according to label directions, application of Appeal is not expected to result in any non-safety adverse effects to the labelled crops. However, as it is not possible to verify the tolerance of all types of plants within the diverse ornamentals and herbs groups, a requirement to test Appeal on a small sample of the plants to be treated will appear on the label.

6.0 Pest Control Product Policy considerations

6.1 Toxic Substances Management Policy considerations

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 pest control product.

During the review process, cold pressed orange oil was assessed in accordance with the PMRA Regulatory Directive DIR99-03[2] and evaluated against the Track 1 criteria. Health Canada has reached the conclusion that cold pressed orange oil does not meet all of the TSMP Track 1 criteria. Cold pressed orange oil is made from natural materials, is not expected to bioaccumulate (in accordance with PMRA *Guidance for the Registration of Non-Conventional Pest Control Products* (2023)) and is not expected to form any transformation products that meet all of the TSMP Track 1 criteria.

6.2 Formulants and contaminants of health or environmental concern

During the review process, contaminants in the active ingredient as well as formulants and contaminants in the end-use products 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 the *Formulants Policy*,[7] and taking into consideration the *Ozone-depleting Substances and Halocarbon Alternatives Regulations* under the *Canadian Environmental Protection Act* (substances designated under the *Montreal Protocol*).

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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 PMRA's Science 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*

Health Canada has reached the conclusion that cold pressed orange oil and its end-use product, Appeal, do not contain any formulants or contaminants identified in Parts 1 or 3 in the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.

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's PMRA, pursuant to subsection 28(1) of the *Pest Control Products Act*, is proposing registration for the sale and use of ORO Orange Oil and Appeal, containing the active ingredient cold pressed orange oil, to manage fungal diseases and insect pests on various crops in the greenhouse and field.

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
λ	wavelength
µg	microgram(s)
°C	degrees centigrade(s)
a.i.	active ingredient
bw	body weight
CAS	Chemical Abstracts Service
cm	centimetre(s)
d	day(s)
EC_{50}	effective concentration on 50% of the population
EDE	estimated daily exposure
EEC	estimated environmental concentration
ER_{25}	effective rate for 25% of the population
FIR	Food Ingestion Rate
FRAC	Fungicide Resistance Action Committee
FCC	Food Chemicals Codex
g	gram(s)
hr	hour(s)
ha	hectare(s)
IUPAC	International Union of Pure and Applied Chemistry
IRAC	Insecticide Resistance Action Committee
kg	kilogram(s)
K_{ow}	*n*–octanol-water partition coefficient
L	litre(s)
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
LOC	level of concern
m	metre(s)
MAS	maximum average score
MIS	maximum irritation score
mg	milligram(s)
mL	millilitre(s)
min	minute(s)
mPa	milliPascal(s)
MRL	maximum residue limit
N/A	not applicable
NIOSH	National Institute for Occupational Safety and Health
nm	nanometre(s)
NTP	National Toxicology Program
PIR	personal insect repellent
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
ppm	parts per million
REI	restricted-entry interval
RQ	risk quotient

TSMP	*Toxic Substances Management Policy*
UF	uncertainty factor
USEPA	United States Environmental Protection Agency
UV	ultraviolet
v/v	volume per volume dilution
w/w	weight per weight

Appendix I Tables and figures

Table 1 List of supported uses

Supported use claims
Crop: Roses (Greenhouse and field)
Fungicide claims: Control of powdery mildew (*Podosphaera pannosa*), and suppression of black spot (*Diplocarpon rosae*), downy mildew (*Peronospora sparsa*) and rust (*Phragmidium mucronatum*) **Rate:** 600 mL/100 L water **Maximum number of applications per year:** 3 times **Re-application interval:** 7 days **Spray volume**: 500-1000 L/ha. **Insecticide claims:** Suppression of aphids and spider mites, and reduces numbers of whiteflies **Rate:** 400-600 mL/100 L water **Maximum number of applications per year:** 5 times **Re-application interval:** 7 days **Spray volume:** 400-1000 L/ha.
Crop: Ornamentals, excluding roses (Greenhouse and field)
Fungicide claims: Control of powdery mildew (*Erysiphe* spp.), and suppression of downy mildew (*Peronospora* spp.) **Rate:** 600 mL/100 L water **Maximum number of applications per year:** 3-5 times **Re-application interval:** 7 days **Spray volume**: 400-1000 L/ha. **Insecticide claims:** Suppression of aphids and spider mites, and reduces numbers of whiteflies **Rate:** 400-600 mL/100 L water **Maximum number of applications per year:** 3-5 times **Re-application interval:** 7 days **Spray volume:** 400-1000 L/ha.
Crop: Ornamental trees and shrubs (Greenhouse and field)
Fungicide claims: Control of powdery mildew (*Erysiphe* spp.), and suppression of rust (*Melampsora* spp.) **Rate:** 600 mL/100 L water **Maximum number of applications per year:** 3 times **Re-application interval:** 7 days **Spray volume**: 500-1000 L/ha. **Insecticide claim:** Suppression of aphids **Rate:** 400-600 mL/100 L water **Maximum number of applications per year:** 3 times **Re-application interval:** 7 days **Spray volume:** 400-1000 L/ha. **Insecticide claims:** Suppression of scales, mealybugs and box tree moth larvae **Rate:** 600 mL/100 L water **Maximum number of applications per year:** 3 times **Re-application interval:** 7 days **Spray volume:** 500-1,000 L/ha.

Supported use claims
Crop: Potato
Fungicide claims: Suppression of early blight (*Alternaria solani*) and late blight (*Phytophthora infestans*) **Rate:** 600-800 mL/100 L water **Maximum number of applications per year:** 10 times **Re-application interval:** 7 days **Spray volume**: 400-1000 L/ha. **Insecticide claims:** Suppression of spider mites **Rate:** 400-600 mL/100 L water **Maximum number of applications per year:** 5 times **Re-application interval:** 7 days **Spray volume:** 400-1000 L/ha.
Crop: Crop Group 4-13: Leafy vegetables (Greenhouse and field)
Insecticide claims: Suppression of lettuce aphids and aphids, reduces numbers of whiteflies **Rate:** 400-600 mL/100 L water **Maximum number of applications per year:** 3-5 times **Re-application interval:** 7 days **Spray volume:** 300-600 L/ha.
Crop: Crop Group 5-13: Brassica head and stem vegetables and Crop Group 22: Stalk, stem, leaf petiole vegetables (Greenhouse and field)
Insecticide claims: Suppression of aphids **Rate:** 400-600 mL/100 L water **Maximum number of applications per year:** 3 times **Re-application interval:** 7 days **Spray volume:** 300-600 L/ha.
Crop: Crop Group 8-09: Fruiting vegetables (Greenhouse and field)
Fungicide claims: Control of powdery mildew (*Oidium neolycopersici*; *Leveillula taurica*) **Rate:** 400-600 mL/100 L water **Maximum number of applications per year:** 8 times **Re-application interval:** 7 days **Spray volume**: 400-1000 L/ha. **Fungicide claims:** Suppression of early blight (*Alternaria solani*) **Rate:** 600-800 mL/100 L water **Maximum number of applications per year:** 10 times **Re-application interval:** 7 days **Spray volume**: 400-1000 L/ha. **Fungicide claims:** Suppression of late blight (*Phytophthora infestans*) **Rate:** 600-800 mL/100 L water **Maximum number of applications per year:** 8 times **Re-application interval:** 7 days **Spray volume**: 400-1000 L/ha. **Insecticide claims:** Suppression of spider mites and reduces numbers of whiteflies **Rate:** 400-600 mL/100 L water **Maximum number of applications per year:** 5 times **Re-application interval:** 7 days **Spray volume:** 400-1000 L/ha.

Supported use claims
Crop: Crop group 9: Cucurbit vegetables (Greenhouse and field)
Fungicide claims: Control of powdery mildew (*Golovinomyces* spp.; syn: *Erysiphe* spp.*; Podosphaera xanthii*; *Sphaerotheca fuliginea*), and suppression of downy mildew (*Pseudoperonospora cubensis*) **Rate:** 400-600 mL/100 L water **Maximum number of applications per year:** 8 times **Re-application interval:** 7 days **Spray volume**: 400-1000 L/ha. **Insecticide claims:** Suppression of spider mites and reduces numbers of whiteflies **Rate:** 400-600 mL/100 L water **Maximum number of applications per year:** 5 times **Re-application interval:** 7 days **Spray volume:** 400-1000 L/ha.
Crop: Crop group 11-09: Pome fruit
Fungicide claim: Suppression of powdery mildew (*Podosphaera leucotricha*) **Rate:** 400-600 mL/100 L water **Maximum number of applications per year:** 6 times **Re-application interval:** 7 days **Spray volume**: 500-1000 L/ha. **Insecticide claim:** Suppression of spider mites **Rate:** 400-600 mL/100 L water **Maximum number of applications per year:** 3 times **Re-application interval:** 7-14 days **Spray volume:** 500-1000 L/ha. **Insecticide claims:** Reduces numbers of woolly apple aphid and pear psylla **Rate:** 600 mL/100 L water **Maximum number of applications per year:** 3 times **Re-application interval:** 7 days **Spray volume:** 500-1000 L/ha.
Crop: Crop group 12-09: Stone fruit
Fungicide claim: Suppression of powdery mildew (*Podosphaera* spp.) **Rate:** 400-600 mL/100 L water **Maximum number of applications per year:** 6 times **Re-application interval:** 7 days **Spray volume**: 500-1000 L/ha. **Insecticide claim:** Suppression of spider mites **Rate:** 400-600 mL/100 L water **Maximum number of applications per year:** 3 times **Re-application interval:** 7-14 days **Spray volume:** 500-1000 L/ha
Crop: Crop subgroups 13-07A: Caneberries and 13-07B: Bushberries (Greenhouse and field)
Fungicide claim: Control of powdery mildew (*Podosphaera* spp.) **Rate:** 400-600 mL/100 L water **Maximum number of applications per year:** 6 times **Re-application interval:** 7 days **Spray volume**: 300-1000 L/ha. **Insecticide claim:** Suppression of spider mites **Rate:** 400 mL/100 L water

Supported use claims
Insecticide claims: Suppression of aphids, and reduces numbers of whiteflies **Rate:** 400-600 mL/100 L water **Maximum number of applications per year:** 3-5 times **Re-application interval:** 7-14 days **Spray volume:** 300-1000 L/ha.
Crop: Crop group 14-11: Tree nuts
Insecticide claims: Suppression of spider mites and aphids **Rate:** 400-600 mL/100 L water **Maximum number of applications per year:** 3 times **Re-application interval:** 7-14 days **Spray volume:** 500-1500 L/ha.
Crop: Crop group 15-21: Cereal grains
Insecticide claims: Suppression of aphids (including English grain aphid) **Rate:** 1.8 L/ha (0.6% v/v) **Maximum number of applications per year:** 2 times **Re-application interval:** 7 days **Spray volume:** 200-400 L/ha.
Crop: Oilseeds
Insecticide claim: Suppression of aphids **Rate:** 1.8 L/ha (0.6% v/v) **Maximum number of applications per year:** 2 times **Re-application interval:** 7 days **Spray volume:** 200-400 L/ha.
Crop: Strawberries
Fungicide claim: Control of powdery mildew (*Podosphaera aphanis*) **Rate:** 400-600 mL/100 L water **Maximum number of applications per year:** 6 times **Re-application interval:** 7 days **Spray volume**: 300-1000 L/ha. **Insecticide claim:** Suppression of spider mites **Rate:** 400 mL/100 L water **Insecticide claims:** Suppression of aphids, and reduces numbers of whiteflies **Rate:** 400-600 mL/100 L water **Maximum number of applications per year:** 3-5 times **Re-application interval:** 7 days **Spray volume:** 300-1000 L/ha.
Crop: Grapes
Fungicide claim: Control of powdery mildew (*Uncinula necator* syn: *Erysiphe necator*) **Rate:** 400-600 mL/100 L water **Maximum number of applications per year:** 7 times **Re-application interval:** 7 days **Spray volume**: 300-1000 L/ha.
Crop: Crop group 25: Herbs (Greenhouse and field)
Fungicide claim: Control of powdery mildew (*Erysiphe* spp.) **Rate:** 400-600 mL/100 L water **Maximum number of applications per year:** 3 times **Re-application interval:** 7 days **Spray volume**: 200-1000 L/ha. **Insecticide claims:** Suppression of aphids and spider mites, and reduces numbers of whiteflies **Rate:** 400-600 mL/100 L water

Supported use claims
Maximum number of applications per year: 3-5 times **Re-application interval:** 7 days **Spray volume:** 200-1000 L/ha.
Crop: Asian Water Spinach (Greenhouse and field)
Insecticide claims: Suppression of aphids and spider mites, and reduces numbers of whiteflies **Rate:** 400-600 mL/100 L water **Maximum number of applications per year:** 3-5 times **Re-application interval:** 7 days **Spray volume:** 400-1000 L/ha.
Crop: Globe Artichokes (Greenhouse and field)
Insecticide claims: Suppression of aphids and spider mites **Rate:** 400-600 mL/100 L water **Maximum number of applications per year:** 3-5 times **Re-application interval:** 7 days **Spray volume:** 400-1000 L/ha.
Crop: Hops
Insecticide claim: Suppression of spider mites **Rate:** 400-600 mL/100 L water **Maximum number of applications per year:** 3-5 times **Re-application interval:** 7-14 days **Spray volume:** 400-1000 L/ha.

Table 2 Toxicity Profile of ORO Orange Oil (100.0% w/w cold pressed orange oil)[1]

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

Study Type/Animal/PMRA No.	Study results
Acute toxicity studies	
Acute oral toxicity Rat, Wistar (♀) PMRA No. 3255185	LD_{50} > 2000 mg/kg bw Low acute toxicity
Acute inhalation toxicity (Nose-only exposure) Rat, Wistar (♂ and ♀) PMRA No. 3255187	LC_{50} (combined) > 3.149 mg/L air Epistaxis, muscular tremors, prostration, ataxia, dyspnea and lethargy resolved by Day 2 or earlier, except for one male (persisted until death, Day 6) Low acute toxicity
Eye irritation Rabbit, New Zealand (♀) PMRA No. 3255188	MAS = 0.44/110 (at 24, 48 and 72 hrs) MIS = 2.0/110 (1 hr) All signs of irritation resolved by 48 hours. Minimally irritating
Skin Irritation Rabbit, New Zealand (♂) PMRA No. 3255189	MAS = 0/8 (at 24, 48 and 72 hrs) MIS = 0/8 (1 hr) No signs of irritation. Non-irritating
Dermal sensitization Guinea pig – Hartley PMRA No. 3255190	Negative Not a dermal sensitizer

Study Type/Animal/PMRA No.	Study results
Genotoxicity studies	
Bacterial Reverse Mutation Assay *S. typhimurium* (TA97a, TA98, TA100, TA102 and TA1535) PMRA No. 3255193	Negative ± metabolic activation
Mammalian Cell Gene Mutation Assay Chinese hamster ovary V79 cells PMRA No. 3497990	Negative ± metabolic activation
Mammalian Bone Marrow Cytogenetics Swiss Albino Mice PMRA No. 3255195	No signs of genotoxicity

[1] Toxicity testing was conducted with cold pressed orange oil containing d-limonene at 95.87%, which was considered suitable to address toxicity for ORO Orange Oil (containing 90.56-92.12% d-limonene).

Table 3 Toxicity profile of Appeal (6% ORO Orange Oil)[1]

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

Study Type/Animal/PMRA No.	Study results
Acute Oral Toxicity Rat, Wistar (♀) PMRA No. 3255462	LD_{50} > 2000 mg/kg bw Low acute toxicity
Acute Dermal Toxicity Rat, Wistar (♂ and ♀) PMRA No. 3255463	LD_{50} > 2000 mg/kg bw Low acute toxicity
Acute Inhalation Toxicity (Nose-only exposure) Rat, Sprague-Dawley PMRA No. 3566617	LC_{50} (combined) > 2.13 mg/L air ↓ mean bw, red crust around muzzles, gasping resolved by Day 2. Low acute toxicity
Eye Irritation Rabbit, New Zealand (♀) PMRA No. 3255465	MAS = 31.78/110 (at 24, 48 and 72 hrs, 7 days, 14 days) MIS = 35/110 (1 hr) All signs of irritation resolved by Day 7 (two animals) and Day 14 (one animal). Moderately irritating
Skin Irritation Rabbit, New Zealand (♂) PMRA No. 3255466	MAS = 1/8 (at 24, 48 and 72 hrs) MIS = 1/8 (1 hr) All signs of irritation resolved by Day 7. Slightly irritating
Dermal Sensitization (Method of Maximization) Guinea pigs, Dunken-Hartley (♂) PMRA No. 3255467	Negative. Not a dermal sensitizer

[1] Toxicity testing was conducted with OR-030 A (6% w/w d-limonene) which is considered to be toxicologically equivalent to the proposed formulations.

Table 4 Estimated environmental concentrations (EECs) for cold pressed orange oil in the environment (excluding birds and mammals)

Substance	EEC		Method of calculation	Notes
Soil: screening level risk assessment				
Orange oil	3.0		The maximum cumulative application rate to soil based on 6699.0 g a.i./ha and stable in soil. The EEC in soil was calculated based on the maximum cumulative application rate to soil, assuming a soil bulk density of 1.5 g/cm^3 and a soil depth of 15 cm.	EECs in g a.i./ha were used to evaluate risks to non-target terrestrial plants (seedling emergence).
Water: screening level risk assessment				
Water depth:	**15 cm**	**80 cm**	The maximum cumulative application rate to water was calculated based on 10 applications of 487.20 g a.i./ha followed by 5 applications of 365.40 g a.i./ha with a 7-day re-application interval and stable in water. The EECs in surface water were calculated considering a direct overspray of the maximum cumulative application rate to a 1 ha wetland with depths of 15 and 80 cm.	EECs in surface water at 15-cm depth were used to determine risk to amphibians, and the 80-cm depth EECs were used to evaluate risks to all other aquatic organisms.
Orange oil	4.47	0.84		
Plant surfaces: screening level and refined risk assessments				
Orange oil	1241.92		The EEC was refined using a 74% drift deposition factor for early-season airblast based on 8 applications of 487.20 g a.i./ha followed by 5 applications of 365.40 g a.i./ha with a 7-day re-application interval using a foliar half-life of 10 days.	Used to evaluate on-field and off-field risks to non-target terrestrial plants (vegetative vigour).
Bee matrices				
Orange oil	(adult)		Oral exposure estimate for bees (where the toxicity endpoints are in µg a.i./bee): • For foliar applications: maximum single application rate (0.548 kg a.i./ha) × 98 µg a.i./g (default tall grass residues) × 0.292 g/bee/day * The consumption rate is 0.292 g/bee/day for adult bees and 0.124 g/bee/day for larvae. Note: Where the toxicity endpoint is a concentration (mg a.i./kg diet), the level of exposure should also be estimated as the concentration in the same units. Empirical residue data can be used to refine the risk assessment, ideally as residues measured from plant pollen and nectar.	Used to evaluate risks to pollinators (bees).
	(adult, contact)		Estimated contact exposure (µg a.i./bee) = 2.4 µg a.i./bee per kg a.i./ha × maximum single application rate (0.548 kg a.i./ha)	

Table 5 Toxicity to non-target organisms

Organism	Exposure (observation)	Test substance	Endpoint value	Degree of toxicity[1] and/or comments	PMRA No.
Invertebrates					
Honeybees (*Apis mellifera*)	Adult acute oral (48-h)	Technical grade active ingredient (d-limonene at 95.87%)	48-h LD_{50}: >110 µg active ingredient/bee	Relatively non-toxic	3255201
	Adult acute contact (48-h)	Technical grade active ingredient (d-limonene at 95.87%)	48-h LD_{50}: >100 µg active ingredient/bee	Relatively non-toxic	3255202
Birds					
Japanese quail (*Coturnix coturnix japonica*)	Acute oral (7-d)	Technical grade active ingredient (d-limonene at 92%)	7-d LD_{50}: > 1107 mg a.i./kg bw	Slightly toxic	3497992
	Dietary (8-d)	Technical grade active ingredient (d-limonene at 92%)	8-d LC_{50}: > 2000 mg a.i./kg feed	Slightly toxic	3497994
Mammals					
Rats (*Rattus norvegicus*)	Acute oral (14-d)	Technical grade active ingredient (d-limonene at 95.87%)	14-d LD_{50}: >2000 mg a.i./kg bw	Practically non-toxic	3255185
Vascular plants					
All species tested	21-d Vegetative vigour	End-use product (6%)	ER_{25}: >1181 g a.i./ha	N/A	3497995
Freshwater species					
Water flea *(Daphnia magna)*	48-h Acute	Technical grade active ingredient (d-limonene at 95.87%)	48-h EC_{50}: = 4.68 mg a.i./L	Moderately toxic	3255203
Zebrafish (*Danio rerio*)	96-h Acute	Technical grade active ingredient (d-limonene at 95.87%)	96-h LC_{50}: = 50 mg a.i./L	Slightly toxic	3255204

[1] USEPA classification, where applicable.

Table 6 Risk assessment for pollinators

Organism	Test substance	Exposure type	EEC	Endpoint value	UF	Effects metric	RQ	LOC	LOC exceeded?
Invertebrates									
Honeybees (*Apis mellifera*)	Technical grade active ingredient (d-limonene at 95.87%)	Adult acute oral (48-h)	1.315	LD_{50}: > 112.0 kg a.i./ha	1	LD_{50}: > 112 .0 kg a.i./ha	<0.011	0.4	No
		Adult acute contact (48-h)	15.684	LD_{50}: > 123.2 kg a.i./ha	1	LD_{50}: > 123.2 kg a.i./ha	<0.1	0.4	No

Table 7 Screening level risk assessment for birds and mammals

Organism	Effects metric[1] (mg a.i./kg bw/d)	Feeding guild (food item)	EDE[2] (mg a.i./kg bw)	RQ	LOC	LOC exceeded?
Small bird (0.02 kg)						
Acute oral	>110.7	Insectivore	102	<0.92	1	No
Medium-sized bird (0.1 kg)						
Acute oral	>110.7	Insectivore	80.1	<0.72	1	No
Large-sized bird (1 kg)						
Acute oral	>110.7	Herbivore (short grass)	51.6	<0.47	1	No
Small mammal (0.015 kg)						
Acute oral	>200	Insectivore	58.3	<0.29	1	No
Medium-sized mammal (0.035 kg)						
Acute oral	>200	Herbivore (short grass)	111	<0.55	1	No
Large-sized mammal (1 kg)						
Acute oral	>200	Herbivore (short grass)	61	<0.31	1	No

[1] Uncertainty factors of 10 and 1 were applied to the acute oral (or acute dietary) and reproduction endpoints, respectively.

[2] EDE = Estimated dietary exposure. EDEs were calculated using the following formula: (FIR/body weight) × EEC, where:

FIR: Food Ingestion Rate (Nagy, 1987). For generic birds with body weight less than or equal to 200 g, the "passerine" equation was used; for generic birds with body weight greater than 200 g, the "all birds" equation was used:

Passerine Equation (body weight < or =200 g): FIR (g dry weight/day) = 0.398 (body weight in g) $^{0.850}$

All birds Equation (body weight > 200 g): FIR (g dry weight/day) = 0.648 (body weight in g) $^{0.651}$

For mammals, the "all mammals" equation was used: FIR (g dry weight/day) = 0.235 (body weight in g) $^{0.822}$

EEC: Concentration of pesticide on food item based on Hoerger and Kenaga (1972) and Kenaga (1973) and modified according to Fletcher et al. (1994). At the screening level, relevant food items representing the most conservative EEC for each feeding guild are used. The EECs for birds and mammals were calculated based on 10 applications of 487.20 g a.i./ha followed by 5 applications of 365.40 g a.i./ha with a 7-day re-application interval and a default foliar half-life of 10 days.

Table 8 Risk assessment for non-target terrestrial vascular plants

Organism	Test substance	Exposure type	EEC	Endpoint value	UF	Effects metric	RQ	LOC	LOC exceeded?	Drift EEC	Drift RQ	Drift LOC Exceeded?
Vascular plants												
All plants tested	End-use product (6%)	21-d Vegetative vigour	1241.92	ER_{25} > 1181 g a.i./ha	1	ER_{25} > 1181 g a.i./ha	<1.1	1	Yes	918.68	< 0.78	No

Table 9 Risk assessment for aquatic organisms

Organism	Exposure	Test substance	EEC (mg a.i./L)	Endpoint value (mg a.i./L)	UF	Effects metric	RQ	LOC of 1 exceeded?
Freshwater species								
Water flea (*Daphnia magna*)	48-h Acute	Technical grade active ingredient (d-limonene at 95.87%)	0.84	EC_{50} = 4.68	2	2.34	= 0.36	No
Zebrafish (*Danio rerio*)	96-h Acute	Technical grade active ingredient (d-limonene at 95.87%)	0.84	LC_{50} = 50	10	5	= 0.17	No
Zebrafish (*Danio rerio*) – as surrogate for amphibian	96-h Acute	Technical grade active ingredient (d-limonene at 95.87%)	4.47	LC_{50} = 50	10	5	= 0.89	No

References

A. List of studies/Information submitted by registrant

1.0 Chemistry

PMRA Document Number	Reference
Sub. No. 2023-4584: ORO Orange Oil	
3255177	2021, Manufacturing process, DACO: 2.11.1,2.11.2,2.11.3 CBI
3255180	2015, Final report for physical and chemical characteristics of cold pressed orange oil, DACO: 2.14, 2.14.1, 2.14.10, 2.14.11, 2.14.13, 2.14.14, 2.14.15, 2.14.2, 2.14.3, 2.14.4, 2.14.5, 2.14.6, 2.14.7, 2.14.9 CBI
3255181	2013, Determination of the solubility of Orange Oil Technical in organic solvents, DACO: 2.14.8 CBI
3255182	2013, UV-Visible analysis and molar absorption coefficient determination on Orange Oil Technical, DACO: 2.14.12 CBI
3497986	2023, Confidential attachment Sweet orange oil preliminary analysis of a test substance (5 Batch Analysis), DACO: 2.13.1, 2.13.2, 2.13.3 CBI
3497987	2023, Sweet orange oil preliminary analysis of a test substance (5 Batch Analysis), DACO: 2.13.1, 2.13.2, 2.13.3 CBI
3497989	2021, Certificate of Analysis, DACO: 2.13.4 CBI
3662575	2024, ORO Orange Oil, DACO: 2.13.3 CBI
3695028	2025, [CBI Removed] in Sweet orange oil enforcement analytical method, DACO: 2.13.1 CBI
Sub. No. 2023-4586: Appeal	
3255450	2018, Manufacturing Process, DACO: 3.2.1,3.2.2 CBI
3255451	2015, Purity of OR-030 A and analytical method validation for content of active ingredient d-Limonene, DACO: 3.4.1 CBI
3255452	2014, Validation of the analytical method for the determination of d-limonene in PREV-AM BATCH 7463/02 02/11, DACO: 3.4.1 CBI
3255453	2014, Final Report for: Physical and chemical characteristics of OR-030-A, DACO: 3.5.1, 3.5.2, 3.5.3, 3.5.4, 3.5.5, 3.5.6, 3.5.8, 3.5.9 CBI
3255455	2014, Physico-chemical tests and chemical stability after a storage procedure for 2 years at 20 ± 2 °C on [CBI Removed], DACO: 3.5.10 CBI
3255456	2015, Flash point of OR-030 A, DACO: 3.5.11 CBI
3255457	2015, Miscibility in water and organic solvents of OR-030 A, DACO: 3.5.13 CBI
3255458	2015, Corrosiveness of OR-030A, DACO: 3.5.14 CBI
3662581	2024, Manufacturing procedure, DACO: 3.2.2 CBI

2.0 Human and animal health

PMRA Document Number	Reference
3255468	2020, Use Description, DACO: 5.2
3255185	2018, Study of Acute Oral Toxicity in Rats (Rattus norvegicus) with the test substance Oleo essencial de laranja, DACO: 4.2.1
3255186	2018, Acute Dermal Toxicity with the Test Substance Cold pressed Orange oil in Rats (Rattus norvegicus), DACO: 4.2.2

PMRA Document Number	Reference
3255187	2018, Acute Inhalation Toxicity Test with Cold pressed Orange oil in Rats (Rattus novegicus), DACO: 4.2.3
3255188	2018, Acute Eye Irritation/Corrosion in Rabbits (Oryctolagus cuniculus) with the Test Substance Oleo essencial de laranja, DACO: 4.2.4
3255189	2018, Acute Dermal Irritation/Corrosion study in Rabbits (Oryctolagus cuniculus) with the Test Substance Oleo essencial de laranja, DACO: 4.2.5
3255190	2018, Study of Skin Sensitization test In Guinea Pigs (Cavia porcellus) with the test item Oleo essencial de laranja (Buehler Test Method), DACO: 4.2.6
3255191	U.S. Department of Health and Human Services, 1990, Toxicology And Carcinogenesis Studies Of d-Limonene (CAS No. 5989-27-5) In F344/N Rats And B6C3Fi Mice (Gavage Studies), DACO: 4.3.1
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3577956	Ryuhei Kodama, Atsushi Okubo, Eiki Araki, Kanji Noda, Hiroyuki Ide and Takayoshi Ikeda, 1976, Studies on d-Limonene as a Gallstone Solubilizer (VII) Effects on Development of Mouse Fetuses and Offsprings, *Applied Pharmacology*, 13 (6) 863-873, DACO: 4.5.2
3255193	2018, Evaluation of the mutagenic potential of the test substance Cold pressed orange oil by reverse mutation assay in Salmonella enterica serovar Typhimurium (Ames Test), DACO: 4.5.4
3497990	2015, In vitro mammalian cell gene mutation test of 92% d-limonene, DACO: 4.5.5
3255195	2018, Evaluation of the genotoxic potential of the test item Cold pressed Orange oil by micronucleus assay in bone marrow of mice, DACO: 4.5.7
3255462	2015, Study of Acute Oral Toxicity in Rats (Rattus norvegicus) with the test substance OR-030 A, DACO: 4.6.1
3255463	2015, Study of Acute Oral Toxicity in Rats (Rattus norvegicus) with the test substance OR-030 A, DACO: 4.6.2
3566617	2014, OR030-A Acute inhalation toxicity in rats, DACO: 4.6.3
3255465	2015, Acute Eye Irritation/Corrosion in Rabbits (Oryctolagus cuniculus) with the Test Substance OR-030 A, DACO: 4.6.4
3255466	2015, Acute Dermal Irritation/Corrosion study in Rabbits (Oryctolagus cuniculus) with the Test Substance OR- 030 A, DACO: 4.6.5
3255467	2015, Evaluation of the Skin Sensitization Potential of OR - 030 A in the Guinea Pig Maximization Test (Magnusson & Kligman Test Method), DACO: 4.6.6

3.0 Environment

PMRA Document Number	Reference
3255201	2018, Acute contact toxicity of Oleo essencial de laranja to honeybee Apis mellifera (africanized), DACO: 9.2.4.1
3255202	2018, Acute oral toxicity of Oleo essencial de laranja to honeybee Apis me/lifera (africanized), DACO: 9.2.4.2
3497992	2014, 92% d-limonene Avian Acute Oral Toxicity Test - English, DACO: 9.6.2.3
3497994	2014, 92% d-limonene Avian Acute Dietary Toxicity Test - English, DACO: 9.6.2.6
3255185	2018, Study of Acute Oral Toxicity in Rats (Rattus norvegicus) with the test substance Oleo essencial de laranja, DACO: 4.2.1
3497995	2021, Orange oil (as a nominally 6 % w/w ME formulation): Effects on the Vegetative Vigour of Non-Target Terrestrial Plant Species under Greenhouse Conditions, DACO: 9.8.4
3255203	2018, Acute toxicity of Oleo essencial de laranja to Daphnia magna, DACO: 9.3.2
3255204	2018, Acute toxicity of Oleo essencial de laranja to fish Dania rerio, DACO: 9.5.2.3

4.0 Value

i) Studies/Information submitted in support of fungicide uses

PMRA Document Number	Reference
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3255470	2016, Efficacy of RR-030-D against powdery mildew in ornamentals - Rose, DACO: 10.2.3.3
3255471	2017, Powdery mildew in roses, DACO: 10.2.3.3
3255472	2017, Control of *Sphaerotheca* in roses with OR-030-D, France 2017, DACO: 10.2.3.3
3255473	2017, Powdery mildew on roses, DACO: 10.2.3.3
3255474	2017, Control of *Sphaerotheca* in roses with OR-030-D, DACO: 10.2.3.3
3255475	2018, Control of *Sphaerotheca* in Roses with OR-030-D, DACO: 10.2.3.3
3255476	2019, Control of powdery mildew in non-woody ornamentals with OR-030-D, DACO: 10.2.3.3
3255477	2017, Efficacy of OR-030-D against powdery mildew in oak trees, DACO: 10.2.3.3
3255478	2017, Efficacy of OR-030-D against powdery mildew in oak trees, DACO: 10.2.3.3
3255479	2019, Efficacy of OR-030-D against powdery mildew in oak trees, DACO: 10.2.3.3
3255480	2017, Efficacy of OR-030-D against powdery mildew in oak trees, DACO: 10.2.3.3
3255481	2017, Efficacy of OR-030-D against powdery mildew in oak trees, DACO: 10.2.3.3
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3255484	2018, Evaluation of the efficacy of 030-S-3 against *Podosphaera leucotricha* in applet tree, DACO: 10.2.3.3
3255485	2017, Efficacy of 030-S-3 against powdery mildew (PODOLE) in apples (MABSD), DACO: 10.2.3.3
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3255488	2018, Efficacy of 030-S-3-D against powdery mildew (*Podosphaera leucotricha*) on apple, DACO: 10.2.3.3
3255489	2018, Efficacy Evaluation of 030-S-3-D against *Podosphaera leucotricha* in apple, DACO: 10.2.3.3
3255490	2018, Efficacy Evaluation of 030-S-3-D against *Podosphaera leucotricha* in apple, DACO: 10.2.3.3
3255491	2018, Efficacy Evaluation of 030-S-3-D against Apple Powdery Mildew (*Podosphaera leucotricha*) in Hungary, DACO: 10.2.3.3
3255492	2018, Efficacy Evaluation of 030-S-3-D against Apple Powdery Mildew (*Podosphaera leucotricha*) in Hungary, DACO: 10.2.3.3
3255493	2017, Determination of Efficacy of 030-S-3-D against Apple Powdery Mildew (*Podosphaera leucotricha*) in apple, DACO: 10.2.3.3
3255494	2017, Evaluation of preventative/curative efficacy of 030-S-3-D and PREV-AM PLUS solo and in mix against powdery mildew and secondary against apple scab in Italy, DACO: 10.2.3.3
3255495	2017, Efficacy evaluation of 030-S-3-D against Apple Powdery mildew, DACO: 10.2.3.3
3255496	2017, Efficacy evaluation of 030-S-3-D against Powdery mildew (*Podosphaera leucotricha* – PODOLE) on apple, DACO: 10.2.3.3
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3255501	2018, Determination of Efficacy of 030-S-3-D Against Powdery Mildew on Strawberries under Field Conditions in One Site in Spain, DACO: 10.2.3.3
3255502	2018, Crop safety and efficacy evaluation of 030-S-3-D against powdery mildew on open field strawberry in Spain -2018, DACO: 10.2.3.3
3255503	2019, Crop safety and efficacy evaluation of 030-S-3-D against powdery mildew on protectioned strawberry in Spain -2018, DACO: 10.2.3.3
3255504	2019, Efficacy Evaluation of 030-S-3-D Against Powdery Mildew (*Podosphaera aphanis*) in Strawberry under Greenhouse, DACO: 10.2.3.3
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3255507	2018, Efficacy of 030-S-3-D against Powdery Mildew (*Podosphaera aphanis*) on Strawberry, in Open Field, DACO: 10.2.3.3
3255508	2019, Efficacy Evaluation of 030-S-3-D Against Powdery Mildew (*Podosphaera aphanis*) in Strawberry Under Greenhouse, DACO: 10.2.3.3
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3255511	2019, Evaluation of efficacy and crop selectivity of 030-S-3-D against powdery mildew in protected strawberry., DACO: 10.2.3.3
3255512	2017, The effectiveness, crop safety and minimum effective rate of 030-S-3-D against powdery mildew (*Podosphaera aphanis*) on strawberries (*Fragaria x ananassa*), under protected conditions, DACO: 10.2.3.3
3255513	2017, Efficacy of OR-030-D against powdery mildew in Solanaceae, DACO: 10.2.3.3
3255514	2017, Efficacy of OR-030-D against powdery mildew in Solanaceae, DACO: 10.2.3.3
3255515	2017, Efficacy of OR-303-D against powdery mildew in Solanaceae, DACO: 10.2.3.3
3255516	2019, Fungicide against powdery mildew in Solanaceae, DACO: 10.2.3.3
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3255519	2016, The effectiveness, crop safety and minimum effective rate of 030-S-3-D against powdery mildew on cucumbers (*Cucumis sativus*) under protected conditions, DACO: 10.2.3.3
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3255527	2017, Efficacy of ORO-030-D against powdery mildew in cucurbits, DACO: 10.2.3.3
3255529	2017, Efficacy of OR-030-D against powdery mildew in cucurbits, DACO: 10.2.3.3
3255530	2017, Efficacy of OR-030-D against powdery mildew in cucurbits, DACO: 10.2.3.3

PMRA Document Number	Reference
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3255532	2017, Downy mildew on cucumbers, DACO: 10.2.3.3
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3255546	2016, Efficacy of OR-030-D against black spot in roses, DACO: 10.2.3.3
3255547	2016, Efficacy of OR-030-D against black spot in roses, DACO: 10.2.3.3
3255548	2016, Efficacy of OR-030-D against black spot in roses, DACO: 10.2.3.3
3255551	2016, Efficacy of OR-030-D against black spot in roses, DACO: 10.2.3.3
3255552	2016, Efficacy of OR-030-D against black spot in roses, DACO: 10.2.3.3
3255553	2016, Efficacy of OR-030-D against black spot in roses, DACO: 10.2.3.3
3255554	2016, Efficacy of OR-030-D against black spot in roses, DACO: 10.2.3.3
3255555	2017, Efficacy of OR-030-D against black spot in roses, DACO: 10.2.3.3
3255556	2019, Efficacy of OR-030-D against black spot in roses, DACO: 10.2.3.3
3255557	2018, Efficacy of OR-030-D against black spot in roses (*Diplocarpon rosae*) in roses, Spain 2018, DACO: 10.2.3.3
3255558	2019, Control of black spot in roses with OR-030-D, DACO: 10.2.3.3
3255564	2016, Efficacy of OR-030-D against downy mildew in ornamentals, DACO: 10.2.3.3
3255565	2017, Downy Mildew in roses, DACO: 10.2.3.3
3255566	2017, Efficacy of OR-030-D against downy mildew in Roses, DACO: 10.2.3.3
3255567	2017, Efficacy of OR-030-D against downy mildew in Roses, DACO: 10.2.3.3

PMRA Document Number	Reference
3255568	2017, Efficacy of OR-030-D against downy mildew in Roses, DACO: 10.2.3.3
3255569	2018, Efficacy of OR-030-D against downy mildew (*Peronospora sparsa*) in Roses Spain 2018, DACO: 10.2.3.3
3255570	2017, Efficacy of OR-030-D against downy mildew in Lisianthus, France 2017, DACO: 10.2.3.3
3255571	2017, Efficacy of OR-030-D against downy mildew in Lisianthus, DACO: 10.2.3.3
3255572	2017, Efficacy of OR-030-D against downy mildew in Lisianthus, DACO: 10.2.3.3
3255573	2017, Efficacy of OR-030-D against downy mildew in Lisianthus, DACO: 10.2.3.3
3255574	2017, Efficacy of OR-030-D against downy mildew in Lisianthus, DACO: 10.2.3.3
3255575	2018, Efficacy of OR-030-D against downy mildew in Veronica, DACO: 10.2.3.3
3255576	2018, Determination of efficacy of 030-S-3-D against Late Blight (*Phytophthora infestans*) in potato in Germany, 2017, DACO: 10.2.3.3
3255577	2017, Efficacy of ORO-030-D against Downy mildew in Solanaceae, DACO: 10.2.3.3
3255578	2019, Fungicide against Downy Mildew in Solanaceae incl potato, DACO: 10.2.3.3
3255579	2019, Evaluation of the efficacy of 030-S-3-D against *Phytophthora infestans* in potato crop, DACO: 10.2.3.3
3255580	2017, Determination of the efficacy of 030-S-3-D against Late Blight (*Phytophthora infestans*) in potato , DACO: 10.2.3.3
3255581	2017, Evaluation of the efficacy and selectivity of OR-030-D with different dose rates on late potato blight in potato 2017, DACO: 10.2.3.3
3255582	2017, Determination of efficacy of OR-030-D against Late Blight (*Phytophthora infestans*) in potato, DACO: 10.2.3.3
3255583	2019, Determination of efficacy of 030-S-3-D against Late Blight (*Phytophthora infestans*) in potato, DACO: 10.2.3.3
3255584	2017, Efficacy of OR-030-D against Downy mildew in Solanaceae, DACO: 10.2.3.3
3255585	2017, Efficacy of OR-030-D against Downy mildew in Solanaceae, DACO: 10.2.3.3
3255586	2017, Efficacy of OR-030-D against Downy mildew in Solanaceae, DACO: 10.2.3.3
3255587	2017, Efficacy of OR-030-D against Downy mildew in Solanaceae, DACO: 10.2.3.3
3255588	2017, Efficacy of OR-030-D against Downy mildew in Solanaceae, DACO: 10.2.3.3
3255589	2017, Downy Mildew on Cucumber, DACO: 10.2.3.3
3255590	2017, Efficacy of OR-030-D against downy mildew in cucurbits, DACO: 10.2.3.3
3255591	2017, Efficacy of OR-030-D against downy mildew in cucurbits, DACO: 10.2.3.3
3255592	2017, Efficacy of OR-030-D against downy mildew in cucurbits, DACO: 10.2.3.3
3255593	2019, Test OR-030-D fungicide against downy mildew in cucurbits, DACO: 10.2.3.3
3255594	2019, Efficacy of OR-030-D against Alternaria in Solanaceae, DACO: 10.2.3.3
3255595	2017, *Alternia solani* on tomatoes, DACO: 10.2.3.3

PMRA Document Number	Reference
3255596	2017, Efficacy of OR-030-D Against Alternaria in tomato, DACO: 10.2.3.3
3255597	2017, Efficacy of OR-030-D Against Alternaria in tomato, DACO: 10.2.3.3
3255598	2017, Efficacy of OR-030-D Against Alternaria in tomato, DACO: 10.2.3.3
3255599	2017, Efficacy of OR-030-D Against Alternaria in tomato, DACO: 10.2.3.3
3255600	2018, Efficacy of OR-030-D Against Alternaria in Solanaceae, DACO: 10.2.3.3
3255601	2019, Efficacy of OR-030-D Against Alternaria in Solanaceae, DACO: 10.2.3.3
3255602	2018, Efficacy of OR-030-D Against Alternaria in Solanaceae, DACO: 10.2.3.3
3255603	2017, Efficacy of OR-030-D against rust in salix trees, DACO: 10.2.3.3
3255604	2017, Efficacy of OR-030-D against rust in salix trees, DACO: 10.2.3.3
3255605	2017, Efficacy of OR-030-D against rust hypericium - for EPOMED also other non-woody ornamentals, DACO: 10.2.3.3
3255606	2016, Efficacy of OR-030-D against rust in ornamentals, DACO: 10.2.3.3
3255607	2016, Efficacy of OR-030-D against rust in ornamentals, DACO: 10.2.3.3
3255608	2017, Efficacy of OR-030-D against rust in roses, DACO: 10.2.3.3
3255609	2017, Efficacy of OR-030-D against rust in roses, DACO: 10.2.3.3
3255610	2017, Efficacy of OR-030-D against rust in roses, DACO: 10.2.3.3
3255611	2017, Efficacy of OR-030-D against rust in roses, DACO: 10.2.3.3
3255612	2018, Efficacy of OR-030-D against rust (*Phragmidium* sp) in roses. Spain, 2018, DACO: 10.2.3.3
3255613	2018, Efficacy of OR-030-D against rust (*Phragmidium* sp) in roses. Spain, 2018, DACO: 10.2.3.3
3255723	2021, Summary of Alternatives, DACO: 10.5.1

ii) Studies/Information submitted in support of insecticide uses

PMRA Document Number	Reference
3255469	2021, Value Summary Document, DACO: 10.1, 10.2.1, 10.2.2, 10.2.3.1, 10.4, 10.5.2, 10.5.3
3255614	2019, Chrysanthemum sp/*Tetranychus urticae*: Test OR-030-D Insecticide against mites in ornamentals, DACO: 10.2.3.3
3255615	2018, Hibiscus sp (*Tetranychus urticae*): Test OR-030-D Insecticide against mites in ornamentals, DACO: 10.2.3.3
3255616	2017, Efficacy of OR-030-D Against Mites, DACO: 10.2.3.3
3255617	2017, Efficacy of OR-030-D Against Mites, DACO: 10.2.3.3
3255618	2017, Efficacy of OR-030-D Against Mites, DACO: 10.2.3.3
3255619	2017, Efficacy of OR-030-D Against Mites, DACO: 10.2.3.3
3255620	2017, Efficacy of OR-030-D Against Mites, DACO: 10.2.3.3
3255621	2019, Efficacy of OR-030-D Against Mites in Woody Ornamentals, DACO: 10.2.3.3
3255622	2017, Determination of Efficacy of OR-030-D Against *Tetranychus urticae* on Citrus Tree under Field Condition in One Site in Spain, DACO: 10.2.3.3
3255623	2017, Determination of Efficacy of OR-030-D Against *Tetranychus urticae* on Citrus Tree under Field Condition in One Site in South Europe Under Field Conditions, DACO: 10.2.3.3
3255624	2017, Determination of Efficacy of OR-030-S-3-D Against *Panonychus citri* on Citrus in One Site in South Europe Under Field Conditions, DACO: 10.2.3.3

PMRA Document Number	Reference
3255625	2017, Study of efficacy and selectivity of formulation 030-S-3-D on citrus (sweet orange) against mites (*Panonychus citri*) In Spain in 2017, DACO: 10.2.3.3
3255626	2017, Study of efficacy and selectivity of formulation 030-S-3-D on citrus (sweet orange) against mites (*Eutetranychus orientalis*) In Spain in 2017, DACO: 10.2.3.3
3255627	2017, Determination of Efficacy of 030-S-3-D Against Eutetranychus sp. on Citrus in One Site in South Europe Under Field Conditions, DACO: 10.2.3.3
3255628	2017, A field study on the efficacy of 030-S-1-A and 030-S-3-D against spider mites on citrus, DACO: 10.2.3.3
3255629	2016, Evaluate the efficacy and selectivity of 030-S-3-D and 030-S-1-A for the Control of Spider Mites in Citrus, Italy 2016, DACO: 10.2.3.3
3255630	2016, Evaluate the efficacy and selectivity of 030-S-3-D and 030-S-1-A for the Control of Spider Mites in Citrus, Italy 2016, DACO: 10.2.3.3
3255631	2016, Efficacy and selectivity of 030-S-3-D & 030-S-1-A against Texas citrus mite (*Eutetranychus banksi*) on Citrus, Portugal 2016, DACO: 10.2.3.3
3255632	2018, Efficacy of 030-S-3-D against Two-spotted spider mite (*Tetranychus urticae*) in Garden strawberry in Germany, 2017, DACO: 10.2.3.3
3255633	2017, Determination of efficacy of 030-S-3-D against spider mites (*Tetranychus urticae*) in strawberry, DACO: 10.2.3.3
3255634	2017, Determination of efficacy of 030-S-3-D against spider mites (*Tetranychus urticae*) in strawberry, DACO: 10.2.3.3
3255635	2016, Determination of Efficacy of OR-030-A against Red Spider mites (*Tetranychus urticae*) in tomatoes in Greenhouse, 1 site in Germany 2015, DACO: 10.2.3.3
3255636	2017, Determination of Efficacy of OR-030-A against Red Spider mites (*Tetranychus urticae*) in tomatoes in Greenhouse or Plastic tunnel, 1 site in Germany 2015, DACO: 10.2.3.3
3255637	2017, Determination of Efficacy of OR-030-A against Red Spider mites (*Tetranychus urticae*) in tomatoes in Greenhouse, 1 site in Spain 2016, DACO: 10.2.3.3
3255638	2016, Determination of Efficacy of OR-030-A against Red Spider mites (*Tetranychus urticae*) in tomatoes in Greenhouse, 1 site in Greece 2015, DACO: 10.2.3.3
3255639	2017, Determination of Efficacy of OR-030-A against Red Spider mites (*Tetranychus urticae*) in tomatoes in Greenhouse, 1 site in Greece 2016, DACO: 10.2.3.3
3255640	2017, Determination of Efficacy of OR-030-A against Red Spider mites (*Tetranychus urticae*) in tomatoes in Greenhouse, 1 site in Greece 2016, DACO: 10.2.3.3
3255641	2017, Determination of Efficacy of OR-030-A against Red Spider mites (Tetranychus urticae) in tomatoes in Greenhouse, 1 site in Greece 2016, DACO: 10.2.3.3
3255642	2016, Determination of Efficacy of OR-030-A against Red Spider mites (*Tetranychus urticae*) in tomatoes in Greenhouse, 1 site in Hungary 2015, DACO: 10.2.3.3
3255643	2015, Efficacy and Selectivity of OR-030-A (Orange oil 60 g/l) against tomato russet mite (*Aculops lycopersici*) on tomato in Italy 2014 Greenhouse, DACO: 10.2.3.3

PMRA Document Number	Reference
3255644	2016, Efficacy and crop Selectivity of OR-030-A (Orange oil 60 g/l) against *Tetranychus urticae* (TETRUR) and *Solanum lycopersicum* (LYPES) Greenhouse, Italy 2015, DACO: 10.2.3.3
3255645	2016, Efficacy and crop Selectivity of OR-030-A (Orange oil 60 g/l) against *Tetranychus urticae* (TETRUR) and *Solanum lycopersicum* (LYPES) Greenhouse, Italy 2015, DACO: 10.2.3.3
3255646	2016, Determination of Efficacy of ORO-030-A against red spider mites (*Tetranychus urticae*) in tomatoes in Greenhouse, 1 site in the Netherlands, DACO: 10.2.3.3
3255647	2016, Determination of Efficacy of ORO-030-A against red spider mites (*Tetranychus urticae*) in tomatoes in Greenhouse, 1 site in the Netherlands 2015, DACO: 10.2.3.3
3255648	2017, Efficacy of OR-030-D against Pseudococcus species, DACO: 10.2.3.3
3255649	2017, Planococcus citrii on Oleander, DACO: 10.2.3.3
3255653	2017, Efficacy of OR-030-D against Coccidae, DACO: 10.2.3.3
3255654	2018, Efficacy of OR-030-D against Pseudococcus species in woody ornamentals, DACO: 10.2.3.3
3255655	2018, Efficacy of OR-030-D against *Aonidiella aurantii* (Coccidae) In *Laurus nobilis* (woody ornamental) Spain 2018, DACO: 10.2.3.3
3255656	2018, Efficacy of OR-030-D against Coccidae in woody ornamentals, DACO: 10.2.3.3
3255657	2017, Box tree pyralid (Cydalima perspectalis) in boxwood, DACO: 10.2.3.3
3255658	2017, Efficacy of OR-030-D against box-tree pyralid, DACO: 10.2.3.3
3255659	2017, Efficacy of OR-030-D against box-tree pyralid, DACO: 10.2.3.3
3255660	2018, Efficacy of 030-S-30D against box-tree pyralid, DACO: 10.2.3.3
3255661	2017, Efficacy of ORO-030-D against *Myzus persicae*, DACO: 10.2.3.3
3255662	2018, Efficacy of ORO-030-D against *Aphis gossypii* in woody ornamentals, DACO: 10.2.3.3
3255663	2018, Efficacy of ORO-030-D against *Aphis gossypii* in *Pittosporum tobira*. Spain 2018, DACO: 10.2.3.3
3255664	2017, Efficacy of ORO-030-D against *Aphis gossypii*, DACO: 10.2.3.3
3255665	2017, Efficacy of ORO-030-D against *Aphis gossypii* in Hibiscus, France 2017, DACO: 10.2.3.3
3255666	2017, Aphids on the Roses (*Aphis gossypii*), DACO: 10.2.3.3
3255667	2017, Efficacy of OR-030-D against *Aphis gossypii*, DACO: 10.2.3.3
3255668	2017, Aphids on roses (*Macrosiphum rosae*), DACO: 10.2.3.3
3255669	2017, Efficacy of OR-030-D against *Macrosiphum rosae*, DACO: 10.2.3.3
3255670	2019, Efficacy evaluation of 030-S-3-D against *Sitobion avenae* in cereals, DACO: 10.2.3.3
3255671	2019, Efficacy evaluation of 030-S-3-D against aphids on cereals, DACO: 10.2.3.3
3255672	2018, Efficacy evaluation of 030-S-3-D against *Sitobion avenae* in cereals, DACO: 10.2.3.3
3255673	2018, Efficacy and selectivity of 030-S-3-D against cereals aphids (*Sitobion avenae*) on durum wheat in Southern Italy, DACO: 10.2.3.3
3255674	2017, Determination of Efficacy of 030-S-3-D Against Woolly Apple Aphid (*Eriosoma lanigerum*) in Apple in Hungary, 2017, DACO: 10.2.3.3

PMRA Document Number	Reference
3255675	2018, Evaluation of the efficacy of 030-S-3-D Against *Eriosoma lanigerum* in apple tree, GEP Trial, Austria, 2018, DACO: 10.2.3.3
3255676	2019, Efficacy evaluation of 030-S-3-D against *Eriosoma lanigerum* in apple trees, DACO: 10.2.3.3
3255677	2017, Determination of Efficacy of 030-S-3-D Against *Eriosoma lanigerum* on Apple under Field Conditions in One Site in Spain, DACO: 10.2.3.3
3255678	2019, Efficacy of 030-S-30D against *Eriosoma lanigerum* on apple. Spain, 2018, DACO: 10.2.3.3
3255679	2018, Efficacy evaluation of 030-S-30D against *Eriosoma lanigerum* in apple trees, DACO: 10.2.3.3
3255680	2018, Efficacy evaluation of 030-S-30D against *Eriosoma lanigerum*, DACO: 10.2.3.3
3255681	2018, Determination of efficacy of 030-S-30D against Woolly Apple Aphid (*Eriosoma lanigerum*) in apple, DACO: 10.2.3.3
3255682	2017, Determination of efficacy of 030-S-30D against Woolly Apple Aphid (*Eriosoma lanigerum*) in apples, DACO: 10.2.3.3
3255683	2018, Efficacy of 030-S-3-D in control of *Eriosoma lanigerum* in apple, Poland 2018, DACO: 10.2.3.3
3255684	2018, Efficacy of 030-S-3-D in control of *Eriosoma lanigerum* in apple, Poland 2018, DACO: 10.2.3.3
3255685	2018, Efficacy of 030-S-3-D in control of *Eriosoma lanigerum* in apple, Poland 2018, DACO: 10.2.3.3
3255686	2018, Efficacy evaluation of 030-S-3-D against *Eriosoma lanigerum* - Romania, 2018, DACO: 10.2.3.3
3255687	2017, Efficacy evaluation of 030-S-3-D against aphids in lettuce, DACO: 10.2.3.3
3255688	2017, Efficacy of 030-S-3-D against aphids (NASORN) in lettuce (LACSP) Germany in 2017, DACO: 10.2.3.3
3255689	2017, Efficacy of 030-S-3-D against aphids (NASORN) in lettuce (LACSP) Germany in 2017, DACO: 10.2.3.3
3255690	2018, Determination of Efficacy of 030-S-3-D against aphids on lettuce under Field Conditions in One Site in Spain, DACO: 10.2.3.3
3255691	2018, Determination of Efficacy of 030-S-3-D against aphids on lettuce under Field Conditions in One Site in Spain, DACO: 10.2.3.3
3255692	2018, Efficacy Evaluation of 030-S-3-D against aphids in lettuce, DACO: 10.2.3.3
3255693	2018, Efficacy Evaluation of 030-S-3-D against aphids in lettuce, DACO: 10.2.3.3
3255694	2018, Efficacy of 030-S-3-D against Lettuce aphid (*Nasonovia ribisnigri*) on Lettuce in Open Field Italy in 2018, DACO: 10.2.3.3
3255695	2018, Efficacy of 030-S-3-D against Lettuce aphid (*Nasonovia ribisnigri*) on Lettuce in Open Field Italy in 2018, DACO: 10.2.3.3
3255696	2009, Biological Efficacy Evaluation of Prevan (60 sl) Against the Pear Sucker Psylla pyri (L) in Pear, DACO: 10.2.3.3
3255697	2010, Biological Efficacy Evaluation of Prevan (60 sl) Against the Pear Sucker Psylla pyri (L) in Pear, DACO: 10.2.3.3
3255698	2018, An evaluation of the efficacy of 030-S-3-D against Pear psylla (*Cacopsylla* sp.) on pear in Germany 2018, DACO: 10.2.3.3

PMRA Document Number	Reference
3255699	2018, An evaluation of the efficacy of 030-S-3-D against Pear psylla (*Cacopsylla* sp.) on pear in Germany 2018, DACO: 10.2.3.3
3255700	2018, Efficacy evaluation of 030-S-3-D against *Cacopsylla pyricola* in Pear, DACO: 10.2.3.3
3255701	2018, Efficacy evaluation of 030-S-3-D against *Cacopsylla pyricola* in Pear, DACO: 10.2.3.3
3255702	2018, Efficacy evaluation of 030-S-3-D against *Cacopsylla pyricola* in Pear, DACO: 10.2.3.3
3255703	2017, Determination of efficacy of 030-S-3-D against Pear Sucker (Cacopsylla pyr) in Pear, DACO: 10.2.3.3
3255704	2018, Efficacy evaluation of 030-S-3-D against Pear Psylla, DACO: 10.2.3.3
3255705	2017, Efficacy evaluation of 030-S-3-D applied on pear crop against pear sucker (*Cacopsylla pyri*), DACO: 10.2.3.3
3255706	2018, Efficacy evaluation of 030-S-3-D against *Cacopsylla pyricola* in Pear, DACO: 10.2.3.3
3255707	2017, Determination of efficacy of 030-S-3-D against Pear sucker (*Cacopsylla pyricola*) in pear, DACO: 10.2.3.3
3255708	2017, Determination of efficacy of 030-S-3-D against Pear sucker (*Cacopsylla pyricola*) in pear, DACO: 10.2.3.3
3255709	2018, Efficacy Evaluation of 030-S-3-D against Pear Psylla. Portugal 2018, DACO: 10.2.3.3
3255710	2017, Efficacy of OR-030-D against white fly in solanaceae, DACO: 10.2.3.3
3255711	2017, Efficacy of OR-030-D against white fly in cucurbits, DACO: 10.2.3.3
3255712	2017, Efficacy of OR-030-D against white fly in cucurbits, DACO: 10.2.3.3
3255713	2017, Efficacy of OR-030-D against white fly in cucurbits, DACO: 10.2.3.3
3255714	2017, Efficacy of OR-030-D against white fly in solanaceae, DACO: 10.2.3.3
3255715	2017, Efficacy of OR-030-D against white fly in solanaceae, DACO: 10.2.3.3
3255716	2018, Efficacy of OR-030-D against white fly in cucurbits, DACO: 10.2.3.3
3255717	2018, Efficacy of OR-030-D against *Trialeurodes* sp. in tomatoes. Spain 2018, DACO: 10.2.3.3
3255718	2009, Weibe Fliege an Tomate, DACO: 10.2.3.3
3255719	2015, The effectiveness, crop safety and minimum effective rate of OR-030-A against glasshouse whitefly (*Trialeurodes vaporariorum*) on tomatoes under protected conditions, DACO: 10.2.3.3
3255720	2015, The effectiveness, crop safety and minimum effective rate of OR-030-A against glasshouse whitefly (*Trialeurodes vaporariorum*) on tomatoes under protected conditions, DACO: 10.2.3.3
3255721	2015, The effectiveness, crop safety and minimum effective rate of OR-030-A against glasshouse whitefly (*Trialeurodes vaporariorum*) on tomatoes under protected conditions, DACO: 10.2.3.3
3255722	2015, The effectiveness, crop safety and minimum effective rate of OR-030-A against glasshouse whitefly (*Trialeurodes vaporariorum*) on tomatoes under protected conditions, DACO: 10.2.3.3
3255723	2021, Summary of Alternatives, DACO: 10.5.1

B. Additional information considered

i) Published information

1.0 Human and animal health

PMRA Document Number	Reference
3749606	Environment and Climate Change Canada and Health Canada. 2020, Available online (accessed 27 August 2025): Draft screening assessment - Terpenes and Terpenoids - Acyclic, Monocyclic, and Bicyclic Monoterpenes Group - Canada.ca, DACO: 12.5.4, 4.8, 7.1
3713146	Environment and Climate Change Canada and Health Canada, 2010, Screening Assessment for the Challenge Benzene, 1,2-dimethoxy-4-(2-propenyl)- (Methyl eugenol) Chemical Abstracts Service Registry Number 93-15-2, DACO: 4.8, 7.1
3713170	Miele, M., Dondero, R., Ciarallo, G., and M., Mazzei, 2001, Methyleugenol in Ocimum basilicum L. Cv. Genovese Gigante., Journal of Agricultural and Food Chemistry, 49: 517-521, DACO: 7.1
3713175	Food and Agriculture Organization of the United Nations/World Health Organization (FAO/WHO), 2009, Evaluation of certain food additives: sixty-ninth report of the Joint FAO/WHO Expert Committee on Food Additives, WHO Technical Report Series No. 952, DACO: 7.1