Proposed Registration Decision PRD2025-13

# Rectified Clove Leaf Oil and DECCO 070 EC

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# Overview

## Proposed registration decision for rectified clove leaf 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 Clove Leaf Oil Technical and DECCO 070 EC, belonging to DECCO U.S. Post-Harvest, Inc., containing the technical grade active ingredient rectified clove leaf oil, to control potato sprouting.

An evaluation of available scientific information found that, under the approved conditions of use, the health 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 and value assessments of rectified clove leaf oil and DECCO 070 EC.

## 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 rectified clove leaf oil and DECCO 070 EC, Health Canada's PMRA will consider any written comments received from the public directly related to the proposed decision in this consultation document.[3]

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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 rectified clove leaf oil and DECCO 070 EC, 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 rectified clove leaf oil?

Rectified clove leaf oil is an essential oil derived from the clove plant that can act as a plant growth regulator and can be used to control potato sprouts prior to shipping. Rectified clove leaf oil destroys the growing points of any sprouts present prior to packing and shipping potatoes.

## Health considerations

### Can approved uses of rectified clove leaf oil affect human health?

**Rectified clove leaf oil is unlikely to affect human health when it is used according to label directions.**

Potential exposure to rectified clove leaf oil may occur through the diet, or when handling the end-use 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.

Based on publicly available information, rectified clove leaf oil is considered to be of slight acute toxicity by the oral and dermal routes of exposure, of low acute toxicity by the inhalation route of exposure, severely irritating to the eyes, moderately irritating to the skin, irritating to the respiratory tract, and a potential skin sensitizer. It is not expected to be mutagenic or genotoxic.

Animals given repeated high doses of eugenol (the main component of clove leaf oil) in the diet showed decreased body weight or body weight gain. Exposure to eugenol in pregnant animals resulted in decreases in maternal food consumption and fetal weights, and developmental effects. Fetal and maternal effects occurred at the same dose. Consequently, there is no sensitivity of the young.

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

In laboratory animals, DECCO 070 EC is of low acute toxicity by the oral and inhalation routes of exposure, extremely irritating or corrosive to the eyes, moderately irritating to the skin, and is a skin sensitizer.

**Residues in food and drinking water**

**Dietary risks from food are acceptable.**

Dietary exposure to rectified clove leaf oil may occur through consumption of treated potatoes; however, rectified clove leaf oil, present in DECCO 070 EC, is not expected to pose a health risk when the end-use product is applied as directed by the label. Based on the indoor use, rectified clove leaf oil residues in drinking water are not expected.

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

**Risks in residential and other non-occupational environments**

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

DECCO 070 EC is a commercial class end-use product that is an anti-sprouting agent for potatoes prior to grading and packaging. It is applied in commercial storage facilities where bystanders are not expected to be present. Therefore, risk due to residential and bystander exposure is acceptable.

**Occupational risks from handling DECCO 070 EC**

**Occupational risks are acceptable when DECCO 070 EC is used according to the label directions, which include protective measures.**

Workers handling DECCO 070 EC can come into direct contact with rectified clove leaf oil through inhalation and contact with skin during mixing, loading, clean-up, and maintenance. Due to the automated nature of application, occupational exposure during application is not expected. To protect workers from exposure to DECCO 070 EC, the label requires workers to wear a long-sleeved shirt, long pants, chemical-resistant gloves, protective eyewear (goggles or face shield), socks and shoes during mixing, loading, handling, clean-up, and maintenance activities. Postapplication workers involved in handling or packing treated potatoes must wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes.

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

## Environmental considerations

An environmental risk assessment was not required due to the nature of the proposed use pattern, which would not result in significant environmental exposure.

## Value considerations

### What is the value of DECCO 070 EC?

The registration of DECCO 070 EC will provide the potato industry with a new option for the management of sprouting in potatoes and a new product for the organic potato sector specifically.

Sprouting in potatoes can lead to substantial losses in quality and marketability. DECCO 070 EC is applied to damp-dried potatoes on a roller prior to packing and shipping, which is consistent with current industry practices. DECCO 070 EC is effective at controlling potato sprouts when applied as directed.

## 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 labels of Clove Leaf Oil Technical and DECCO 070 EC to address the potential risks identified in this assessment are as follows.

### Key risk-reduction measures

### Human health

The following signal words and hazard statements are required on the principal display panel of the Clove Leaf Oil Technical label: “DANGER”, “POISON”, “Eye and Skin Irritant”, and “Potential Skin Sensitizer”. Additionally, the standard precautionary statement “Irritating to Respiratory Tract” is required on the label, to notify users of the irritation potential.

The following signal words and hazard statements are required on the DECCO 070 EC label: “DANGER – Corrosive to Eyes”, “Skin Irritant”, “Potential Skin Sensitizer”, and “Warning: Contains the allergen soy.”

Personal protective equipment (PPE) and standard precautionary statements are required on the labels to inform users that products are corrosive to the eyes and moderately irritating to skin, and to warn of the potential for sensitization.

For DECCO 070 EC, workers are required to wear a long-sleeved shirt, long pants, chemical-resistant gloves, protective eyewear (goggles or face shield), socks and shoes during mixing, loading, handling, clean-up and maintenance activities. Postapplication workers involved in handling or packing treated potatoes must also wear appropriate PPE.

## Next steps

Before making a final registration decision on rectified clove leaf oil and DECCO 070 EC, 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 27 November 2025) of this document. If more time is required to provide comments, a request for an extension of an additional 15 days can be made. Your request must be submitted in writing to the PMRA's Publications Section (pmra.publications-arla@hc-sc.gc.ca) within the 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

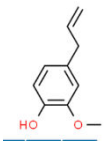
When Health Canada's PMRA makes its registration decision, it will publish a Registration Decision on rectified clove leaf oil and DECCO 070 EC (based on the Science evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public 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

## Rectified clove leaf oil and DECCO 070 EC

## 1.0 The active ingredient, its properties and uses

### 1.1 Identity of the active ingredient

| | |
|---|---|
| **Active substance** | Rectified clove leaf oil |
| **Function** | Plant growth regulator |
| **Chemical name** | |
| **1. International Union of Pure and Applied Chemistry (IUPAC)** | Not applicable |
| **2. Chemical Abstracts Service (CAS)** | Not applicable |
| **CAS number** | 8015-97-2 |
| **Molecular formula** | $C_{10}H_{12}O_2$: for eugenol, the main component in clove leaf oil |
| **Molecular weight** | 164.2 |
| **Structural formula** |  for eugenol |
| **Purity of the active ingredient** | 100% |

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

**Technical product—Clove Leaf Oil Technical**

| Property | Result |
|---|---|
| Colour and physical state | Golden amber to amber, liquid at 20.9°C |
| Odour | Spicy odour at 20.9°C |
| Melting point | -47.4°C |
| Boiling point | 252.85°C |
| Density | 1.0446 g/cm$^3$ at 20.01°C |
| Vapour pressure at 20°C | 295 Pa |

| Property | Result |
|---|---|
| Ultraviolet (UV)-visible spectrum | $\lambda_{max}$ = 281.50, 230.00, 213.00 – neutral<br>$\lambda_{max}$ = 281.50, 230.00, 212.17 – acidic<br>$\lambda_{max}$ = 296.17, 247.67, 219.67 – basic |
| Solubility in water | 1.90 mg/mL at pH of approximately 7 |
| Solubility in organic solvents at 20°C | The product is soluble in most solvents. |
| *n*-Octanol-water partition coefficient ($K_{ow}$) | Log $K_{ow}$ = 2.33 |
| Dissociation constant (p$K_a$) | Not applicable |
| Stability (temperature, metal) | The product is determined to be stable at 20°C and 54°C for a 14-day storage duration. |

**End-use product—DECCO 070 EC**

| Property | Result |
|---|---|
| Colour | Amber clear to translucent |
| Odour | Clove odour |
| Physical state | Liquid |
| Formulation type | Emulsifiable concentrate (EC) |
| Label concentration | Rectified clove leaf oil at 70% |
| Container material and description | Plastic (HDPE) bottle, jug, drum or tote (0.5 – 1000 L) |
| Specific gravity | 1.009 at 25°C |
| pH of 1% dispersion in water | 8.5 |
| Oxidizing or reducing action | The product does not contain agents with oxidizing or reducing characteristics. |
| Storage stability | The main component, eugenol, was shown to be stable after a storage of two weeks at 54°C in commercial HDPE package. |
| Corrosion characteristics | No changes were observed on the commercial packaging after a storage of two weeks at 54°C. |
| Explodability | Not applicable |

## 1.3 Directions for use

DECCO 070 EC is applied by spray to damp-dried potatoes on a roller prior to packing and shipping. Care must be taken to apply DECCO 070 EC when the sprouts first appear and are still fairly small.

## 1.4 Mode of action

Rectified clove leaf oil, consisting of a complex mixture of naturally occurring botanical components, is the active ingredient of DECCO 070 EC. Although the mode of action is not known, it has been successfully used in the United States and the European Union for over ten years to control sprouting in potatoes. Similar compounds (essential oils) are known to destroy meristematic tissues (such as potato sprouts) in plants.

# 2.0 Methods of analysis

## 2.1 Methods for analysis of the active ingredient

The methods provided for the analysis of eugenol, the main component in clove leaf oil, 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 eugenol, the main component of clove leaf oil, in the formulation has been validated and assessed to be acceptable for use as an enforcement analytical method.

## 2.3 Methods for residue analysis

No methods are required to quantify residues of clove leaf oil (including eugenol) due to its low toxicity (see Section 3.0 for more details).

# 3.0 Impact on human and animal health

## 3.1 Toxicology summary

Information to address the toxicology of Clove Leaf Oil Technical consisted of publicly available information on clove oil, and its principal chemical constituent eugenol, comprising greater than 80% of clove leaf oil. Information from the European Food Safety Authority and the Environment and Climate Change Canada and Health Canada Chemicals Management Plan Screening Assessment Report for eugenol was relied upon to complete the toxicology review for eugenol, and was considered adequate surrogate data to address the toxic effects that may result from exposure to rectified clove leaf oil.

Based on the review of eugenol and publicly available information on clove oil, Clove Leaf Oil Technical is considered to be of slight acute toxicity by the oral and dermal routes of exposure, of low toxicity by the inhalation route (yet it is a respiratory irritant), severely irritating to eyes, moderately irritating to skin, and a potential skin sensitizer.

In 13-week dietary toxicity studies, high doses of eugenol or clove oil resulted in decreased body weight or body weight gain in rats, with no observed adverse effect levels (NOAELs) ranging from 300 to 600 mg/kg bw/day. In mice, the NOAEL was 780 mg/kg bw/day (the highest dose tested).

In prenatal developmental toxicity studies of eugenol in both rats and rabbits, the parental NOAEL was 100 mg/kg bw/day based on clinical signs (both species) and reduced feed consumption (rabbit only). The developmental NOAEL was 250 mg/kg bw/day based on decreased fetal weight and delayed ossification (rat) and increased post-implantation loss (rabbit). Therefore, there is no evidence of sensitivity of the young.

Four carcinogenicity studies conducted with eugenol (one in rat, three in mice) were reviewed by Health Canada under the Chemicals Management Plan. The overall conclusion of the review was that eugenol is unlikely to be carcinogenic.

Eugenol was not mutagenic in bacterial mutation assays, and showed positive and negative results in in vitro mammalian gene mutation assays and in vivo cytogenetic assays. A review of the positive in vitro assays suggested that most assays were performed at concentrations that resulted in cytotoxicity or severe cell cycle delay and that in vivo assays mainly gave negative results even at very high doses of eugenol. Based on the collective evidence, eugenol is likely not mutagenic.

A detailed review of toxicology information was conducted in support of DECCO 070 EC and the database was found to be acceptable (Appendix I, Table 1) to assess the toxic effects that may result from exposure to rectified clove leaf oil from use of the proposed end-use product. The database for DECCO 070 EC consisted of acute toxicity (via the oral and inhalation routes of exposure), eye and skin irritation, and skin sensitization studies. These were carried out in accordance with currently accepted international testing protocols and Good Laboratory Practices.

DECCO 070 EC is of low acute toxicity by the oral and inhalation routes of exposure, extremely irritating or corrosive to the eye, moderately irritating to the skin, and is a potential skin sensitizer.

## 3.2 Occupational, residential and bystander exposure and risk assessment

### 3.2.1 Use description

DECCO 070 EC is a commercial-class product for post-harvest use on potatoes as an anti-sprouting agent. Potatoes on the grading line are sprayed with DECCO 070 EC prior to packing for shipping.

Prior to application, 1 L of DECCO 070 EC is diluted in 70 L of water, creating a 1.4% solution. The diluted spray solution is applied to washed and damp-dried potatoes using an automated spray nozzle system. The diluted DECCO 070 EC solution is applied at a rate of 1 L per 1000 kg of potatoes. There is only one application.

### 3.2.2 Occupational exposure and risk assessment

#### 3.2.2.1 Mixer, loader, and applicator exposure and risk assessment

When DECCO 070 EC is used according to label directions, occupational exposure is characterized as intermediate-term in duration and is expected to be mainly by the dermal and inhalation routes of exposure during mixing, loading, and clean-up/maintenance, when the product is being diluted and loaded into the sprayer, and when the equipment is rinsed after the application is finished for the day. Occupational exposure during application does not occur, as the diluted end-use product solution is applied using an automated spray nozzle system that is set up on the conveyor belt where the potatoes are laid out.

Precautionary statements on the end-use product label such as the wearing of personal protective equipment (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 labels are followed, which include PPE.

Methyl eugenol is a genotoxic carcinogen that is naturally occurring in some spices, herbs, fruit, and essential oils, including in clove oil. Existing mitigative label statements are expected to be sufficient to minimize any unnecessary risk due to occupational exposure to methyl eugenol. Additionally, the level present in the diluted end-use product solution 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 methyl eugenol in DECCO 070 EC is considered acceptable.

#### 3.2.2.2 Postapplication exposure and risk

Postapplication exposure is possible mainly by the dermal route from contact with treated potatoes. To a lesser extent, inhalation exposure may occur if the spray has not settled.

Precautionary statements on the end-use product label such as the wearing of PPE aimed at mitigating exposure are adequate to protect workers from risk due to postapplication exposure. Consequently, the risks to workers due to postapplication exposure are acceptable.

### 3.2.3 Residential and bystander exposure and risk

There are no residential uses for DECCO 070 EC. In addition, bystander exposure is not expected to be of concern from its use. The end-use product will be used in commercial facilities where bystanders are not expected to be present during applications. Consequently, the health risks to bystanders and individuals in residential areas from the use of DECCO 070 EC are acceptable.

## 3.3 Dietary exposure and risk assessment

#### 3.3.1.1 Food

While dietary exposure to rectified clove leaf oil may occur through consumption of tubers treated with DECCO 070 EC, residues are expected to be low based on the low concentration of the active ingredient in the diluted end-use product solution, and the single application of DECCO 070 EC. In addition, rectified clove leaf oil has a low toxicity profile, and humans are already exposed to clove leaf oil in the diet, as a flavouring agent and in various consumer products.

Batch data for Clove Leaf Oil Technical indicated that methyl eugenol is present in the technical grade active ingredient and is expected to be carried over into DECCO 070 EC. Residue estimates on treated tubers following treatment with DECCO 070 EC were found to be below published background dietary intake levels of methyl eugenol from flavouring agents, spices, and other sources. Consequently, it is not expected that the use of DECCO 070 EC on potatoes will result in dietary intakes of methyl eugenol greater than existing background dietary intakes.

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

### 3.3.2 Drinking water

As DECCO 070 EC is proposed for indoor, post-harvest use on potatoes, exposure to rectified clove leaf oil in drinking water is not expected. The label has the necessary mitigative measures to prevent contamination of drinking water from the proposed use of rectified clove leaf oil.

Consequently, no risk due to exposure from drinking water is anticipated.

### 3.3.3 Acute and chronic dietary risks for sensitive subpopulations

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

## 3.4 Aggregate exposure and risk

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal, and inhalation).

In an aggregate risk assessment, the combined potential risk associated with food, drinking water, and various residential exposure pathways 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.

Rectified clove leaf oil is considered to be of slight acute toxicity by the oral and dermal routes of exposure and of low toxicity by the inhalation route of exposure. The end-use product is not to be applied near or to drinking water, and the label has the necessary mitigative measures to limit contamination of drinking water. Furthermore, the use pattern of DECCO 070 EC is limited to use as a commercial post-harvest potato sprout inhibitor, in commercial facilities. Therefore, when used as directed on the label, non-occupational exposure to DECCO 070 EC will be low.

When the end-use product is used as labelled, there is reasonable certainty that no harm will result from aggregate exposure of residues from rectified clove leaf oil to the general population in Canada, including infants and children. This includes all anticipated non-pesticidal (food) exposure, drinking water exposure, and all other non-occupational exposures (incidental oral, 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 mechanisms of toxicity with other pesticides was undertaken.

While constituents of rectified clove leaf 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, methyl eugenol (a genotoxic carcinogen) is a natural component of clove oil and certain other essential oils (for example, tea tree oil, lemon eucalyptus oil) and other active ingredients (cis-jasmone), which are registered for use as agricultural pesticides with food uses and as personal insect repellents.

In terms of dietary exposure, the active ingredients rectified clove leaf oil 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 methyl eugenol from these food uses is expected to be below existing dietary background levels of methyl eugenol.

The other active ingredient, 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 methyl eugenol from this active ingredient would be below existing dietary background levels, by several orders of magnitude.

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

In addition to existing background dietary exposure, exposure to methyl eugenol occurs from other consumer products containing essential oils (for example, cosmetics, natural health products, cleaning products), which includes personal insect repellents. The PMRA has established an allowable limit for methyl eugenol in personal insect repellents at 0.0002%. Further non-occupational exposure to methyl eugenol 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 subparagraph 7(7)(b)(i) of the *Pest Control Products Act*, the PMRA has determined that the non-occupational exposure (dietary and residential) of methyl eugenol in rectified clove leaf oil for the limited use on potatoes would have little impact over the overall cumulative health risk. Based on the qualitative approach, the cumulative risks from potential co-exposure to methyl eugenol 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.

Maximum residue limits 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 Clove Leaf Oil Technical is acceptable, given the low toxicity profile of rectified clove leaf oil, as well as the low application rates for DECCO 070 EC and its proposed single application, post-harvest use on potatoes. Furthermore, clove leaf oil has a history of use as a flavouring agent in various food products, and the proposed technical grade active ingredient meets the FCC requirements for clove leaf oil. Consequently, the specification of an MRL, under the *Pest Control Products Act*, will not be required for rectified clove leaf oil.

### 3.7 Health incident reports

As of 3 June 2025, no human or domestic animal incidents involving rectified clove leaf oil had been submitted to the PMRA.

## 4.0 Impact on the environment

An environmental risk assessment was not required due to the nature of the proposed use pattern, which would not result in significant environmental exposure.

## 5.0 Value

Once potatoes are harvested and placed in storage, it is only a matter of time before they start to sprout, a naturally occurring process. Sprouts on potatoes cause loss of quality, weight, water content, etc. and therefore reduce marketability, leading to waste and economic losses. Potatoes are often treated to inhibit or control sprouting during storage and shipping.

The following alternatives to rectified clove leaf oil are registered in Canada for the inhibition or control of sprouting in potatoes:

- Spearmint oil;
- Chlorpropham (CIPC) (sprout inhibitor);
- 2,6-Diisopropylnaphthalene;
- 1-Octanol;
- Ethylene (sprout inhibitor); and
- 3-decen-2-one.

Presently, fogging potatoes in storage facilities with CIPC is the industry standard and CIPC is the most widely used potato sprout inhibitor in Canada. Chlorpropham is a true sprout inhibitor, similar to ethylene, where the product effectively stops the potatoes from sprouting. Fogging is used for potatoes in storage and not generally used for the shipment of fresh potatoes. DECCO 070 EC is similar to 1-Octanol and 3-decen-2-one, which control sprouts as they emerge by destroying meristematic tissues, and is used on fresh market potatoes.

A thorough review of the information provided, including use history information and scientific rationales, was conducted. Collectively, the information reviewed supports a claim of control of sprouting in potatoes prior to packing and shipping.

# 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 Product Act* requires that the TSMP be given effect in evaluating the risks of a product.

During the review process, rectified clove leaf oil was assessed in accordance with the PMRA Regulatory Directive DIR99-03[5] and evaluated against the Track 1 criteria. The PMRA has reached the conclusion that rectified clove leaf oil is a naturally occurring substance and does not 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.*[6] The list is used as described in the PMRA Science Policy Note SPN2020-01[7] and is based on existing policies and regulations including the Toxic Substances Management Policy and Formulants Policy,[8] and taking into consideration the *Ozone-depleting Substances and Halocarbon Alternatives Regulations* under the *Canadian Environmental Protection Act, 1999*, (substances designated under the Montreal Protocol).

The PMRA has reached the conclusion that Clove leaf Oil Technical does not contain formulants of human health or environmental concern as identified in the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* (SI/2005-114), including TSMP Track 1 substances and allergens known to cause anaphylactic-type reactions.

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5 DIR99-03, The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy.

6 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.

7 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.*

8 DIR2006-02, Formulants Policy and Implementation Guidance Document.

The end-use product, DECCO 070 EC, contains the allergen soy, which is on the List of Pest Control Product Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions.

Based on the formulating process used, other impurities and formulants of human health or environmental concern as identified in the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* (SI/2005-114), including TSMP Track 1 substances are not expected to be present in this product.

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA 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 Clove Leaf Oil Technical and DECCO 070 EC, containing the technical grade active ingredient rectified clove leaf oil, to control potato sprouting.

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 |
| $\lambda_{max}$ | wavelength of maximum absorption |
| = | equal to |
| > | greater than |
| °C | degree Celsius |
| bw | body weight |
| CAS | Chemical Abstracts Service |
| CIPC | chlorpropham |
| $cm^3$ | cubic centimetre |
| DIR | Regulatory Directive |
| DPRA | direct peptide reactivity assay |
| EC | emulsifiable concentrate |
| FCC | Food Chemicals Codex |
| g | gram |
| HDPE | high density polyethylene |
| IUPAC | International Union of Pure and Applied Chemistry |
| kg | kilogram |
| $K_{ow}$ | *n*-octanol-water partition coefficient |
| L | litre |
| $LC_{50}$ | lethal concentration 50% |
| $LD_{50}$ | lethal dose 50% |
| MAS | maximum average score |
| MIS | maximum irritation score |
| mg | milligram |
| mL | millilitre |
| MMAD | mass median aerodynamic diameter |
| MRL | maximum residue limit |
| NOAEL | no observed adverse effect level |
| OECD | Organisation for Economic Co-operation and Development |
| Pa | pascal |
| p$K_a$ | dissociation constant |
| PMRA | Pest Management Regulatory Agency |
| PPE | personal protective equipment |
| ppm | parts per million |
| SI | Statutory Instrument |
| SPN | Science Policy Note |
| TSMP | *Toxic Substances Management Policy* |
| UV | ultraviolet |

# Appendix I Tables

## Table 1 Toxicity profile of DECCO 070 EC (70% rectified clove leaf oil)

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

| Study type/Animal/ PMRA No. | Study results |
|---|---|
| Acute oral toxicity (acute toxic class method)<br>Rat, Han-Wistar (♀)<br>PMRA No. 3467897 | $LD_{50}$ > 2000 mg/kg bw<br>No mortalities.<br>**Low acute toxicity.** |
| Acute inhalation toxicity (nose-only exposure)<br>Rat, Sprague-Dawley<br>PMRA No. 3467898 | $LC_{50}$ (combined) > 2.28 mg/L<br>MMAD = 2.88 µm<br>Irregular respiration following exposure to test material. All animals recovered by Day 10.<br>**Low acute toxicity.** |
| Eye irritation<br>Rabbit, New Zealand albino (♀)<br>PMRA No. 3467899 | MAS = 19/110 (at 24, 48, and 72 hours)<br>MIS = 38.7/110 (Day 4)<br>Irreversible irritation; unresolved by Day 21 (end of study).<br>**Extremely irritating or corrosive to the eye.** |
| Skin Irritation<br>Rabbit, New Zealand albino (♂)<br>PMRA No. 3467900 | MAS = 3.2/8 (at 24, 48, and 72 hours)<br>MIS = 4.6/8 (30–60 minutes)<br>All signs of irritation resolved by 7 days.<br>**Moderately irritating to the skin** |
| Skin sensitization: direct peptide reactivity assay (DPRA)<br>In chemico<br>PMRA No. 3467903 | Excessive precipitation.<br>**Inconclusive. No prediction possible.** |
| Skin sensitization: KeratinoSens™ assay<br>In vitro<br>PMRA No. 3467902 | **Positive** |
| Skin sensitization: human Cell Line Activation Test (h-CLAT) assay<br>In vitro<br>PMRA No. 3467901 | **Positive** |
| Skin sensitization: defined approach using the three skin sensitization studies listed above | Using the Organisation for Economic Co-operation and Development (OECD) “2 out of 3” defined approach, two tests out of three gave positive results.<br>**Predicted to be a skin sensitizer.** |

# References

## A. List of studies/Information submitted by Registrant

### 1.0 Chemistry

| PMRA Document Number | Reference |
|---|---|
| 3467852 | 2022, 5-Batch Preliminary Analysis for Clove Leaf Oil, DACO: 2.13.1, 2.13.2,2.13.3,2.13.4 CBI |
| 3467854 | 2022, Rectified Clove Leaf Oil: Determination of Physical Properties, DACO: 2.14.1,2.14.15,2.14.2,2.14.3,2.14.5,2.14.6 |
| 3467855 | 2022, Eurofins EAG Expert Statement on Justification of a Waiver of Requirement for Determination of the Dissociation Constant by OECD Guideline for Testing Chemicals, OECD 112 for the Test Substance Clove Leaf Oil (Rectified) Technical Grade Active Ingredient (TGAI), DACO: 2.14.10,2.6 |
| 3467856 | 2022, Clove Leaf Oil: Estimation of *n*-Octanol/Water Partition Coefficient Using High Performance Liquid Chromatography (HPLC), DACO: 2.14.11 |
| 3467857 | 2022, Determination of the Ultraviolet-Visible Absorption Spectrum of Clove Leaf Oil, DACO: 2.14.12 |
| 3467859 | 2022, Clove Leaf Oil: Determination of Stability to Normal and Elevated Temperature, DACO: 2.14.13 |
| 3467861 | 2022, Clove Leaf Oil: Determination of Water Solubility by the Shake Flask Method, DACO: 2.14.7 |
| 3467862 | 2022, Determination of the Vapor Pressure of Clove Leaf Oil, DACO: 2.14.9 |
| 3673715 | 2025, Manufacturing of Clove Oil, DACO: 2.11.3 CBI |
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| 3467894 | 2023, Manufacturing Process for DECCO 070 EC, DACO: 3.2.1,3.2.2,3.2.3, 3.3.1 CBI |
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### 2.0 Human and animal health

| PMRA Document Number | Reference |
|---|---|
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| | |
|---|---|
| 3467899 | 2022, DECCO 070 EC: Primary Eye Irritation in Rabbits, DACO: 4.6.4 |
| 3467900 | 2022, DECCO 070 EC: Primary Skin Irritation in Rabbits, DACO: 4.6.5 |
| 3467901 | 2022, In vitro Skin Sensitisation: Human Cell Line Activation Test (h-CLAT) with DECCO 070 EC, DACO: 4.6.6 |
| 3467902 | 2022, In vitro Skin Sensitisation: ARE-Nrf2 Luciferase Test Method (KeratinoSens$^{TM}$) with DECCO 070 EC, DACO: 4.6.6 |
| 3467903 | 2022, In Chemico Skin Sensitisation: Direct Peptide Reactivity Assay (DPRA) with DECCO 070 EC, DACO: 4.6.6 |
| 3467904 | 2023, Use Description Scenario (Application and Post-Application) for DECCO 070 EC, a Plant Growth Regulator for Use on Potatoes for Sprout Inhibition, DACO: 5.2 |
| 3467905 | 2023, Food Residue Exposure Assessment Clove Oil and for DECCO 070 EC for Use on Potatoes for Sprout Inhibition, DACO: 6.1,7.1 |

### 3.0 Value

| PMRA Document Number | Reference |
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| 3467875 | 2023, History of Use - Clove Oil, DACO: 10.2.4 |
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| 3467877 | 2023, History of Use - Clove Oil, DACO: 10.2.4 |

## B. Additional information considered

### i) Published information

#### 1.0 Human and animal health

| PMRA Document Number | Reference |
|---|---|
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