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Proposed Registration Decision

PRD2022-03

# Canola Oil, Goodnature Rat & Mouse Lure, and Goodnature Rat & Mouse Pre-Feed Lure

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# Overview

## Proposed registration decision for canola oil

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the [Pest Control Products Act](#), is proposing registration for the sale and use of Canola Oil, Goodnature Rat & Mouse Lure, and Goodnature Rat & Mouse Pre-Feed Lure, containing the technical grade active ingredient canola oil, to attract mice or rats to a trap for the purpose of rodent management.

Canola oil is currently registered to control a variety of insect and mite pests, as well as to suppress powdery mildew, on many ornamental, vegetable, fruit, and nut crops both in the field and greenhouse, as well as on indoor cannabis. For details, see Proposed Registration Decision PRD2016-24, *Canola oil*, and Registration Decision RD2016-35, *Canola oil*.

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 section provides detailed technical information on the human health, environmental and value assessments of canola oil, Goodnature Rat & Mouse Lure, and Goodnature Rat & Mouse Pre-Feed Lure.

## What does Health Canada consider when making a registration decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable<sup>1</sup> 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<sup>2</sup> when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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<sup>1</sup> "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

<sup>2</sup> "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."

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as 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 the Health Canada regulates pesticides, the assessment process and risk-reduction programs, please visit the [Pesticides section](#) of Canada.ca.

Before making a final registration decision on canola oil, Goodnature Rat & Mouse Lure, and Goodnature Rat & Mouse Pre-Feed Lure, Health Canada's PMRA will consider any comments received from the public in response to this consultation document.<sup>3</sup> Health Canada will then publish a Registration Decision<sup>4</sup> on canola oil, Goodnature Rat & Mouse Lure, and Goodnature Rat & Mouse Pre-Feed Lure, 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 section of this consultation document.

## **What is canola oil?**

Canola oil is a non-conventional biopesticide derived from seeds of the canola plant. It is also commonly used as an ingredient in many prepared foods. As rodents are attracted to foods containing energy-rich substances like oils, canola oil serves as an effective rodent attractant or lure when applied in or in the vicinity of rodent traps.

## **Health considerations**

### **Can approved uses of canola oil affect human health?**

**Canola oil is unlikely to affect human health when it is used according to label directions.**

Potential exposure to canola oil may occur when handling and applying the products Goodnature Rat & Mouse Lure and Goodnature Rat & Mouse Pre-Feed Lure. 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.

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

<sup>4</sup> "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

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.

Publicly available toxicology information was submitted for canola oil. The technical grade active ingredient, Canola Oil, is food grade and is considered to be of low acute toxicity by the oral, dermal and inhalation routes and mildly irritating to the eyes and skin. Canola oil may be a respiratory irritant. It is not expected to be a dermal sensitizer. Based on a review of the available scientific literature, exposure to canola oil is not expected to have any short- or long-term health effects.

Goodnature Rat & Mouse Lure and Goodnature Rat & Mouse Pre-Feed Lure, the end-use products, are considered to be of low acute toxicity by the oral, dermal and inhalation routes, mildly irritating to the eyes and skin and not expected to be dermal sensitizers. The end-use product labels require milk, soy and tree nut (hazelnut) allergen warning statements.

### **Residues in water and food**

#### **Dietary risks from food and water are acceptable.**

The end-use products, Goodnature Rat & Mouse Lure and Goodnature Rat & Mouse Pre-Feed Lure, are not proposed for food or feed uses. Dietary or drinking water exposure is not expected from the use of canola oil as an animal lure. 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.**

Goodnature Rat & Mouse Lure and Goodnature Rat & Mouse Pre-Feed Lure are domestic class products proposed for use as rodent lures to be used with the A24 Rat & Mouse Trap. The user loads Goodnature Rat & Mouse Lure into the device and baits the area around the device with Goodnature Rat & Mouse Pre-Feed Lure. The product labels will include measures to reduce bystander (including children and companion animals) exposure such as keeping the end-use products out of reach of children and pets, limiting the use of the products to locations not accessible to children, pets or livestock and storing the products in areas away from children, pets, and livestock. Additionally, there is a label statement identifying the hazard chocolate can pose to dogs.

Residential and non-occupational exposure to Goodnature Rat & Mouse Lure and Goodnature Rat & Mouse Pre-Feed Lure is therefore expected to be low when label directions are observed. Consequently, the risk to residents, companion animals and the general public is acceptable.

## **Occupational risks from handling Goodnature Rat & Mouse Lure and Goodnature Rat & Mouse Pre-Feed Lure**

### **Occupational risk assessments are not required for Goodnature Rat & Mouse Lure and Goodnature Rat & Mouse Pre-Feed Lure.**

Since Goodnature Rat & Mouse Lure and Goodnature Rat & Mouse Pre-Feed Lure are domestic products, an occupational risk assessment is not required.

## **Environmental considerations**

### **What happens when canola oil is introduced into the environment?**

**Due to the proposed use pattern, environmental exposure is expected to be minimal and therefore the risks to the environment are acceptable.**

The products are canola oil lures that attract rats and mice to a device, which kills the rodent by swift physical force. The active ingredient in the lure, canola oil, is food grade and is not toxic to wildlife. Similarly, other formulants in the lure are not toxic to wildlife. It is possible the device could cause some mortalities of small non-target wildlife. However, exposure of non-target wildlife to the device is expected to be limited given the proposed uses, which target rodent infestation locations. From an environmental perspective, these products pose no risk of primary or secondary poisoning and very limited overall risk to non-target wildlife.

## **Value considerations**

### **What is the value of Goodnature Rat & Mouse Pre-Feed Lure and Goodnature Rat & Mouse Lure?**

**Goodnature Rat & Mouse Pre-Feed Lure and Goodnature Rat & Mouse Lure, containing canola oil, are paste lures that are used to attract rodents to the vicinity of or into, respectively, a trap that is designed to kill rodents by lethal head trauma.**

Goodnature Rat & Mouse Pre-Feed Lure is an effective, ready-to-use rat and mouse lure that is applied directly to surfaces in the vicinity of rodent traps in indoor and outdoor domestic settings.

Goodnature Rat & Mouse Lure is a ready-to-use rat and mouse lure that is applied to a A24 Rat & Mouse Trap in a canister for the purpose of attracting rats and mice to the trap mechanism when traps are placed in rodent-infested indoor and outdoor domestic settings.

Goodnature Rat & Mouse Lure and Goodnature Rat & Mouse Pre-Feed Lure are the first non-conventional products proposed for registration in Canada with a claim to “lure” mice or rats for the purpose of rodent management.

When used with the A24 Rat & Mouse Trap, both Goodnature lure products may be used as alternatives to toxic food baits in a rodenticide resistance management program or in conjunction with other rodent control practices, such as rodent repellents, hygienic practices and chemical rodenticides, as part of an integrated pest management program.

## **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 Canola Oil, Goodnature Rat & Mouse Lure and Goodnature Rat & Mouse Pre-Feed Lure to address the potential risks identified in this assessment are as follows.

### **Key risk-reduction measures**

#### **Human health**

The signal words “PREVENT ACCESS BY UNAUTHORIZED PERSONNEL” and “CAUTION – EYE AND SKIN IRRITANT” are required on the principal display panel for Canola Oil, along with standard hazard and precautionary statements to inform workers of the potential for respiratory, eye and skin irritation of the technical grade active ingredient.

The signal words “KEEP OUT OF REACH OF CHILDREN AND PETS,” “CAUTION – EYE AND SKIN IRRITANT” and “Warning: Contains the allergens milk, soy and tree nuts (hazelnut)” are required on the principal display panels of the labels for Goodnature Rat & Mouse Lure and Goodnature Rat & Mouse Pre-Feed Lure. Standard hazard and precautionary statements are required on the labels for the end-use products to inform users of the potential for eye and skin irritation.

“Do not use in areas accessible to children, pets or domestic animals.” and “Do not store in areas accessible to children, pets and domestic animals.” statements are required on the end-use product labels to mitigate exposure to bystanders (including children) and companion animals in residential areas.

The labels for the end-use products require a first aid statement to contact a veterinarian if pet poisoning is suspected, and the PMRA supports a statement under TOXICOLOGICAL INFORMATION proposed by the Registrant that mitigates against incidental oral exposure of dogs to chocolate.



## **Next steps**

Before making a final registration decision on canola oil, Goodnature Rat & Mouse Lure and Goodnature Rat & Mouse Pre-Feed Lure, Health Canada's PMRA will consider any comments received from the public in response to this consultation document. Health Canada will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). 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 the Health Canada makes its registration decision, it will publish a Registration Decision on canola oil, Goodnature Rat & Mouse Lure and Goodnature Rat & Mouse Pre-Feed Lure (based on the Science evaluation section 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.

## Science evaluation

### Canola Oil, Goodnature Rat & Mouse Lure, and Goodnature Rat & Mouse Pre-Feed Lure

#### 1.0 The active ingredient, its properties and uses

##### 1.1 Identity of the active ingredient

Active substance	Canola Oil
Function	Rodenticide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	Canola Oil
2. Chemical Abstracts Service (CAS)	Canola Oil
CAS number	120962-03-0
Molecular formula	Mixed triglycerides
Molecular weight	900 g/mol average
Structural formula	$\begin{array}{c} R_1\text{-COO-CH}_2 \\   \\ R_2\text{-COO-CH} \\   \\ R_3\text{-COO-CH}_2 \end{array}$
	Where R = alkyl chain from C16 to C22
Purity of the active ingredient	100%

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

###### Technical product - Canola oil

Property	Result
Colour and physical state	Pale yellow liquid
Odour	Odourless
Melting range	Not applicable

Boiling point or range	340 °C
Specific gravity at 20 °C	0.9175
Vapour pressure at 20 °C	< 13.33 Pa
Ultraviolet (UV)-visible spectrum	Not applicable
Solubility in water at 20 °C	Not soluble in water
Solubility in organic solvents at 20°C	Soluble in most organic solvents
<i>n</i> -Octanol-water partition coefficient ( $K_{ow}$ )	Not applicable
Dissociation constant ( $pK_a$ )	Not applicable
Stability (temperature)	May generate breakdown products, which include acrolein and acrolein-like substances when heating for prolonged periods or at high temperature. Decomposition temperature is 360 °C.

### End-use products - Goodnature Rat & Mouse Lure and Goodnature Rat & Mouse Pre-Feed Lure

Property	Result
Colour	Brown
Odour	Chocolate and peppermint
Physical state	Paste
Formulation type	Paste
Label concentration	81%
Container material and description	Plastic pouch 50 g for Goodnature Rat & Mouse Lure, 200 g for Goodnature Rat & Mouse Pre-Feed Lure
Density	0.97–0.99 g/cm <sup>3</sup> at 20 °C
pH of 1% dispersion in water	Not applicable
Oxidizing or reducing action	The product does not contain any oxidizing or reducing agents.
Storage stability	Canola oil is relatively stable and is not expected to react with other components or produce toxic substances.
Corrosion characteristics	The commercial containers are designed to use with oil based food grade products.
Explosibility	Not explosive as it does not contain any explosive ingredients.

### 1.3 Directions for use

Goodnature Rat & Mouse Pre-Feed Lure is a ready-to-use paste containing 81% canola oil that is applied as a thumbnail-sized dollop and re-applied as necessary to surfaces in the vicinity of a A24 Rat & Mouse Trap positioned in indoor and outdoor domestic settings.

Goodnature Rat & Mouse Lure is a ready-to-use paste containing 81% canola oil that is provided to users in a 50 g canister that is affixed to a A24 Rat & Mouse Trap. A small quantity of the lure paste, approximately 8 g of product per month, is automatically extruded into the trap portal. Rodents are lured to the portal where lethal head trauma is administered by the action of a bolt driven by compressed air. The product is suitable for use in indoor and outdoor domestic settings, with reapplication of a new canister to the trap every six months.

Removal of alternative food sources in the vicinity of the trap is required when using either product.

#### **1.4 Mode of action**

The mode of action of canola oil as a lure for rats and mice is based on the known attraction of rodents to food substances containing a source of food energy, such as fats or oils. Attraction of mice to a lure containing only canola oil was established in trials. Formulation of canola oil as a paste, as in the subject products, permits the user to offer the active ingredient to rodents in a non-messy format.

### **2.0 Methods of analysis**

#### **2.1 Methods for analysis of the active ingredient**

Not applicable.

#### **2.2 Method for formulation analysis**

Not applicable.

#### **2.3 Methods for residue analysis**

No methods are required to quantify residues of canola oil because there are no proposed food uses.

### **3.0 Impact on human and animal health**

#### **3.1 Toxicology summary**

A detailed review of the available toxicological information was conducted in support of Canola Oil, Goodnature Rat & Mouse Lure and Goodnature Rat & Mouse Pre-Feed Lure. The data package for Canola Oil, Goodnature Rat & Mouse Lure and Goodnature Rat & Mouse Pre-Feed Lure is considered acceptable to assess the toxic effects that may result from exposure to canola oil.

The data package consisted of publicly available toxicology information on canola oil. Canola oil is refined vegetable oil obtained from the seeds of *Brassica* rape plants and is readily metabolized by humans. It is a mixture of esters (triglycerides of different fatty acids). The main

fatty acids in canola oil are oleic acid, linoleic acid, and linolenic acid. Fatty acids are an integral part of cell membranes of every living organism. They also occur as a food substrate in the form of their triglycerides (fats and oils). Linoleic and linolenic acid are essential fatty acids in the human diet. The source of the proposed canola oil technical grade active ingredient is certified food grade edible.

Based on information in the published literature, canola oil is not a developmental, reproductive or nervous system toxicant, a carcinogen or a genotoxicant. Furthermore, no adverse effects to the endocrine or immune systems are expected for canola oil.

Based on the available toxicology information, the technical grade active ingredient Canola Oil is considered to be of low acute toxicity by the oral, dermal, and inhalation routes, and mildly irritating to the eyes and skin. Canola oil may also be a respiratory irritant. It is not expected to be a dermal sensitizer.

The end-use products Goodnature Rat & Mouse Lure and Goodnature Rat & Mouse Pre-Feed Lure have identical compositions. All of the formulants in the end-use products are permitted in non-food use products. The toxicology profiles of Goodnature Rat & Mouse Lure and Goodnature Rat & Mouse Pre-Feed Lure are considered to be of low acute toxicity by the oral, dermal and inhalation routes, mildly irritating to the eyes and skin, and not expected to be dermal sensitizers.

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

### **3.2.1 Dermal absorption**

Based on the available information on long chain fatty acids (carbon chain length > 12), limited dermal uptake is expected.

### **3.2.2 Use description**

Goodnature Rat & Mouse Lure and Goodnature Rat & Mouse Pre-Feed Lure are domestic rodent lures intended for use with the A24 Rat & Mouse Trap. The lures, in conjunction with the device, are primarily intended for outdoor use or use in non-domestic spaces (for example, garage, shed, barn, roof space, compost bin). For use in buildings, the lures and device would typically be placed at points of rodent entry. The lures and device could be used inside homes (kitchen cupboards, ceiling spaces, hot water cylinder cupboards or cleaning product cupboards) in the case of major rodent problems (in other words, evidence of rat droppings or chewed wires). The Goodnature Rat & Mouse Lure is contained in a plastic pouch that fits directly into the A24 Rat & Mouse Trap while the Goodnature Rat & Mouse Pre-Feed Lure is packaged in a squeezable plastic pouch that should be applied as a “thumbnail-sized dollop” of approximately 10 g in the area around or under the A24 Rat & Mouse Trap. The Goodnature Rat & Mouse Lure requires replacement every six months and the Goodnature Rat & Mouse Pre-Feed can be reapplied as necessary, as often as once a week.

Two devices are recommended to be placed per hectare for the outdoor use, spaced 50 m apart. Clean-up activities are minimal as excess lure from both end-use products can further serve as bait around the lure device. Deceased rodents require disposal. For the outdoor use, natural predators are expected to aid in the removal the deceased rodents.

### **3.2.3 Occupational exposure and risk**

There is no potential for occupational mixer, loader, applicator, or post-application exposure since the products are for domestic use.

### **3.2.4 Residential and bystander exposure and risk**

Goodnature Rat & Mouse Lure and Goodnature Rat & Mouse Pre-Feed Lure are proposed for domestic use only. There are no mixing or loading activities for the end-use products because they are ready-to-use products. When Goodnature Rat & Mouse Lure and Goodnature Rat & Mouse Pre-Feed Lure are used according to label directions, exposure to residential users is characterized as short-term in duration with the potential for intermediate- or long-term exposure depending on the level of pest infestation. User exposure will occur primarily by the dermal route with limited potential for inhalation exposure.

Precautionary statements on the end-use product labels aimed at mitigating exposure are adequate to protect individuals from risk due to user exposure. Overall, risks to residential users are acceptable when the precautionary statements on the labels are followed.

Access to bait present in the area surrounding the device or to the stored lures could result in incidental oral exposure to residential bystanders (including children) and companion animals. Goodnature Rat & Mouse Lure and Goodnature Rat & Mouse Pre-Feed Lure contain chocolate, which can be toxic to dogs and potentially other species, as well as containing known allergens.

Bystander, residential and companion animal (in other words, dogs) exposure will be mitigated by the inclusion of precautionary statements on the Goodnature Rat & Mouse Lure and Goodnature Rat & Mouse Pre-Feed Lure labels. The end-use products require allergen label statements for milk, soy and tree nuts (hazelnuts), a statement to keep the products out of reach of children and pets, and a statement that the products cannot be used or stored in areas accessible to children, pets, and domestic animals. The labels will also inform users of the hazard chocolate can pose to dogs.

Adhering to label instructions will minimize potential exposure to individuals in residential areas (including bystanders and children) and companion animals. Given the low toxicity and minimal potential for exposure, the health risks to individuals in residential areas and bystanders are acceptable.

### **3.3 Food residue exposure assessment**

#### **3.3.1 Food**

Goodnature Rat & Mouse Lure and Goodnature Rat & Mouse Pre-Feed Lure are not proposed for food or feed use. Consequently, dietary exposure to canola oil from the proposed use is not of concern and a dietary risk assessment is not required.

#### **3.3.2 Drinking water**

Based on the proposed use pattern (see section 3.2.2), exposure from drinking water exposure is not expected. Consequently, health risks from potential canola oil residues in drinking water are acceptable.

#### **3.3.3 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.

The active ingredient canola oil is registered for use on greenhouse and field food and non-food crops as well as indoor cannabis. The aggregate risk from dietary, drinking water, consumer, and residential exposure from the currently registered uses were assessed in PRD2016-24, *Canola oil*, and determined to be acceptable. As noted in section 3.2.4, the potential exposure from Goodnature Rat & Mouse Lure use is minimal.

The use pattern of Goodnature Rat & Mouse Lure and Goodnature Rat & Mouse Pre-Feed Lure is limited to use as domestic lures with the A24 Rat & Mouse Trap. When the end-use products are used as labelled, there is reasonable certainty that no harm will result from aggregate exposure of residues from canola 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.

#### **3.3.4 Cumulative exposure and risk**

*The Pest Control Products Act* requires that the PMRA consider the cumulative exposure to pesticides with a common mechanism of toxicity. Accordingly, assessments of potential common mechanisms of toxicity with other pesticides was undertaken for canola oil. While components of canola oil may share a common moiety with other registered fatty acid-based pesticide active ingredients, the potential health risks from cumulative exposure to food grade

canola oil and other fatty acid-based pest control products are acceptable given that food grade canola oil and other fatty acids can be consumed as food, and the inherent low toxicity of canola oil.

### **3.3.5 Maximum residue limits**

Maximum residue limits (MRLs) for canola oil were not required for the proposed non-food use of Goodnature Rat & Mouse Lure and Goodnature Rat & Mouse Pre-Feed Lure.

### **3.4 Health incident reports**

As of 16 August 2021, two minor human incident reports have been submitted to the PMRA. One of the two human incident reports was considered to be at least possibly related to the reported exposure. A woman spraying an insecticide containing pyrethrins and canola oil reported getting too close to the product “mist”. She experienced a sensation of her “nostrils burning” for an hour. Based on the proposed use pattern for both canola oil lure products, no mitigation measures are recommended.

## **4.0 Impact on the environment**

Due to the proposed use pattern, environmental exposure is expected to be minimal and therefore the risks to the environment are acceptable.

A detailed environmental review was not required. The products are canola oil lures that attract rats and mice to a device, which kills the rodent by swift physical force. The active ingredient in the lure, canola oil, is food grade and is not toxic to wildlife. Similarly, other formulants in the lure are not toxic to wildlife. It is possible the device could cause some mortalities of small non-target wildlife. However, exposure of non-target wildlife to the device is expected to be limited given the proposed uses, which target rodent infestation locations.

From an environmental perspective, these products pose no risk of primary or secondary poisoning and very limited overall risk to non-target wildlife.

## **5.0 Value**

Domestic rodent infestations result in the deterioration of building structures, fouling of stored contents and food, and the deposition of urine and feces that may transmit diseases to humans. When used in combination with an A24 Rat & Mouse Trap, Goodnature Rat & Mouse Pre-Feed Lure and Goodnature Rat & Mouse Lure are proposed as reduced-risk alternatives to chemical rodenticides for domestic users when applied indoors and outdoors.



One field efficacy trial conducted in Brookfield, New Zealand in 2020 was submitted to support the designation of canola oil as the product active ingredient. Equal numbers of rats were killed when traps were supplied with the subject product formula or canola oil alone. Therefore, it is reasonable to conclude that canola oil is an effective rodent lure and that it constitutes the active ingredient in the subject products.

Two valid field efficacy trials conducted in Hart's Hill, New Zealand from 2014 to 2015 were submitted to support efficacy of the product formulation as a rodent lure. Trials were conducted in outdoor areas naturally infested with rats. A24 Rat & Mouse Traps loaded with canisters containing Goodnature Rat & Mouse Lure reduced rat populations by between 86–100% and 100% compared to the pre-treatment population sizes over six months. These results support the attractiveness of the lure formulation in both products to rats outdoors. Because rats and mice are similarly attracted to food ingredients, whether provided indoors or outdoors, inside the trap or adjacent to it, trial results showing efficacy of the product applied inside the trap against rats outdoors were extrapolated to use of the formulation adjacent to traps, to rats indoors and to mice indoors and outdoors.

Goodnature Rat & Mouse Pre-Feed Lure and Goodnature Rat & Mouse Lure used in combination with an A24 Rat & Mouse Trap constitute effective, non-conventional alternatives to conventional rodenticides. Therefore, these products may reduce the reliance on conventional rodenticides and thereby reduce the potential for the development of resistance to these chemicals in rodent populations.

Based on the submitted information, it was determined that when Goodnature Rat & Mouse Pre-Feed Lure is applied as a thumbnail-sized dollop in the vicinity of traps or when Goodnature Rat & Mouse Lure is extruded from a canister affixed to an A24 Rat & Mouse Trap, these products serve as effective rat and mouse lures for the purpose of rodent control in indoor and outdoor domestic settings.

## **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 product.

During the review process, canola oil and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03<sup>5</sup> and evaluated against the Track 1 criteria. The PMRA has reached the conclusion that canola oil and its transformation products do not meet all of the Track 1 criteria.

## 6.2 Formulants and contaminants of health concern

During the review process, contaminants in the technical 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*.<sup>6</sup> The list is used as described in the PMRA Notice of Intent NOI2005-01<sup>7</sup> and is based on existing policies and regulations, including the *Toxic Substances Management Policy* and *Formulants Policy*<sup>8</sup> and taking into consideration the *Ozone-depleting Substance Regulations*, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol).

The PMRA has reached the following conclusions:

- Technical grade canola oil and its end-use products Goodnature Rat & Mouse Lure and Goodnature Rat & Mouse Pre-Feed Lure do not contain any formulants or contaminants identified in the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*. The end-use products, Goodnature Rat & Mouse Lure and Goodnature Rat & Mouse Pre-Feed Lure, contain the allergens, milk, soy, and tree nuts (hazelnut), which are on the *List of Pest Control Product Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions*.

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

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<sup>5</sup> DIR99-03, The Pest Management Regulatory Agency's Strategy for Implementing the *Toxic Substances Management Policy*

<sup>6</sup> SI/2005-114, last amended on June 25, 2008. See Justice Laws website, *Consolidated Regulations, List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*

<sup>7</sup> PMRA's Notice of Intent NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*

<sup>8</sup> DIR2006-02, *Formulants Policy and Implementation Guidance Document*

## **7.0 Proposed regulatory decision**

Health Canada's PMRA, under the authority of the *Pest Control Products Act*, is proposing registration for the sale and use of Canola Oil, Goodnature Rat & Mouse Lure, and Goodnature Rat & Mouse Pre-Feed Lure, containing the technical grade active ingredient canola oil, to attract mice or rats to a trap for the purpose of rodent management.

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**

°C	degrees centigrade
CAS	Chemical Abstracts Service
cm	centimetre(s)
g	gram(s)
IUPAC	International Union of Pure and Applied Chemistry
$K_{ow}$	<i>n</i> -octanol-water partition coefficient
MRL	maximum residue limit
Pa	Pascal(s)
$pK_a$	dissociation constant
PMRA	Pest Management Regulatory Agency
TSMP	Toxic Substances Management Policy
UV	ultraviolet

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## References

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

#### Chemistry

<b>PMRA Document No.</b>	<b>Reference</b>
3199027	2021, DACO 2.14, DACO: 2.14
3159188	2020, Recipe and Procedure, DACO: 3.2.2 CBI
3159189	2020, Quality Assurance Document, DACO: 3.2.2
3196713	2021, RatLure Properties, DACO: 3.5

#### Human and animal health

<b>PMRA Document No.</b>	<b>Reference</b>
3114786	2018, Chocolate Truffle Specification, DACO: 3.2.1 CBI
3128711	2020, ECHA Substance Information Canola Oil, DACO: 4.2
3128712	2009, EPA Canola Oil Fact Sheet, DACO: 4.2
3128713	2020, EPA Inert Details, DACO: 4.2
3128772	2020, Exposure to 50g Lure, Unpublished, DACO 5.2
3129014	2020, Exposure, DACO 5.2
3167008	2020, Clarification email – trial and use-site clarification
3177239	2020, Allergens and Toxicity to Pets, DACO: 4.8
3180323	2021, Chemistry for EP or MA, DACO: 3.0
3255385	2021, Indoor Installation Sites, DACO 5.2
3260301	2021, DACO 4.8 20210812, DACO 4.8

#### Value

<b>PMRA Document No.</b>	<b>Reference</b>
3114773	2015, Case Study Fiordland New Zealand, DACO: 10.2.3
3114775	2015, Case Study Rat Control Fiordland, DACO: 10.2.3
3170948	DACO: Email_message_MSG

### B. Additional information considered

#### Published information

#### Human and animal health

<b>PMRA Document No.</b>	<b>Reference</b>
3258775	Gwaltney-Brant, S.M. 2020, Merck Veterinary Manual, Chocolate, DACO:4.8

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<b>PMRA Document No.</b>	<b>Reference</b>
3276619	Kreiling, R., Hollnagel, H.M., Hareng, L. Eigler, D., Lee, M.S., Griem, P. DreeBen, G., Kleber, M., Albrecht, A., Gracia, C., Wendel, A., 2008, Comparison of the skin sensitizing potential of unsaturated compounds as assessed by the murine local lymph node assay (LLNA) and the guinea pig maximization test (GPMT), Food and Chemical Toxicology, 46, 1896–1904, DACO 4.8
3276620	Burnett, C.L., Fiume, M.M., Bergfeld, W.F., Belsito, D.V., Hill, R.A., Klaassen, C.D., Liebler, D., Marks, J.G. Jr., Shank, R.C., Slaga, T.J., Snyder, P.W., and Andersen, F.A., 2017, Safety Assessment of Plant-Derived Fatty Acid Oils, International Journal of Toxicology Vol. 36 (Supplement 3), 51S-129S, DACO 4.8