Proposed Re-evaluation Decision

PRVD2018-03

# Oil of Geranium, Camphor Oil, Eucalyptus Oil, Lemon Oil, and Pine Needle Oil and Their Associated End-use products

Consultation Document

(publié aussi en français)

**6 February 2018** 

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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ISSN: 1925-0959 (print) 1925-0967 (online)

Catalogue number: H113-27/2018-03E (print)

H113-27/2018-03E-PDF (PDF version)

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# **Proposed Re-evaluation Decision**

### Overview

Under the authority of the *Pest Control Products Act*, all registered pesticides must be regularly re-evaluated by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they continue to meet current health and environmental safety standards and that they continue to have value. The re-evaluation considers data and information from pesticide manufacturers, published scientific reports, and other regulatory agencies. The PMRA applies internationally accepted risk assessment methods as well as current risk management approaches and policies.

Oil of geranium, camphor oil, eucalyptus oil, lemon oil, and pine needle oil (as mixtures) are used as an insect repellent for application to human skin (personal insect repellent) or the fur of dogs and horses (animal insect repellent). In addition, camphor oil and eucalyptus oil, when coformulated with methyl salicylate and cornmint oil, are registered as an animal repellent to repel Norway rats (common brown rats) and raccoons. All insect repellent end-use products are readyto-use domestic products formulated as a liquid. The animal repellent products are manufacturing concentrates impregnated into plastics for use in the manufacture of trash bags.

This document presents the proposed regulatory decision for the re-evaluation of oil of geranium, camphor oil, eucalyptus oil, lemon oil, and pine needle oil and includes proposed label updates to meet current standards, as well as the science evaluation on which the proposed decision was based. All products containing oil of geranium, camphor oil, eucalyptus oil, lemon oil, and pine needle oil registered in Canada are subject to this proposed re-evaluation decision. This document is subject to a 90-day public consultation period, during which the public, including the pesticide manufacturers and stakeholders, may submit written comments and additional information to the PMRA. The final re-evaluation decision will be published taking into consideration the comments and information received.

### **Outcome of Science Evaluation**

Oil of geranium, camphor oil, eucalyptus oil, lemon oil, and pine needle oil end-use products are registered for domestic use, and they have value in offering Canadians a non-conventional choice to repel certain insects and animals. These essential oils are manufactured from naturally occurring plants, and they have a long history of use in natural health and consumer products with no observed adverse effects.

Mixtures of oil of geranium, camphor oil, eucalyptus oil, lemon oil, and pine needle oil were of low acute toxicity by the oral and dermal routes of exposure and, are expected to be irritating to the skin, eyes, and lungs and, potential skin sensitizers. The technical grade ingredient mixtures of camphor oil, eucalyptus oil, methyl salicylate, and cornmint oil are expected to be moderately acutely toxic by the oral route and severely irritating to the skin and eyes, and likely to cause

irritation of the respiratory tract upon inhalation; however, these active ingredients are unlikely to be skin sensitizers.

When current label directions are followed, the potential risks from residential exposures to products containing these oils are not of concern.

Mixtures of these essential oils are not registered for use on food, nor are they expect to contaminate drinking water sources. Dietary (food and drinking water) exposure to these active ingredients is not anticipated and a dietary risk assessment is therefore not required.

When used under the current label directions, risks of concern to the environment from these essential oil mixtures are not expected.

# **Proposed Regulatory Decision**

Under the authority of the *Pest Control Products Act* and based on the evaluation of currently available scientific information, Health Canada is proposing that products containing oil of geranium, camphor oil, eucalyptus oil, lemon oil, and pine needle oil (used as insect repellents and animal repellents) are acceptable for continued registration for use and sale in Canada.

Registered pesticide product labels include specific instructions for use. Directions include risk mitigation measures to protect human health and the environment that must be followed by law. As a result of the re-evaluation, no additional risk mitigation measures are proposed by the PMRA. To meet current labelling standards updates to the storage and disposal label statements are proposed (Refer to the details in Appendix II):

### **International Context**

Camphor oil, eucalyptus oil, and lemon oil are currently acceptable for use in other Organisation for Economic Co-operation and Development (OECD) member countries, including Australia. Camphor oil and eucalyptus oil are acceptable for use in the United States of America. As of August 9th, 2017, no decision by an OECD member country to prohibit all uses of these oils for health or environmental reasons has been identified.

# **Next Steps**

The public, including registrants and stakeholders, are encouraged to submit comments during the 90-day public consultation period which begins upon publication of this proposed reevaluation decision.

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

All comments received during the 90-day public consultation period will be taken into consideration in preparation of the re-evaluation decision document. This document will include the final re-evaluation decision, the reasons for it, and a summary of comments received on the proposed re-evaluation decision along with the PMRA's responses.

# **Additional Scientific Information**

No additional data are required.

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<sup>&</sup>lt;sup>2</sup> "Decision statement" as required by subsection 28(5) of the Pest Control Products Act.

### **Science Evaluation**

### 1.0 Introduction

Oil of geranium, camphor oil, eucalyptus oil, lemon oil, and pine needle oil (as mixtures) are used as personal mosquito repellents. These products are registered as domestic class products for direct application on human skin by hand. These active ingredients are also used as a mosquito, horn fly, face fly, house, and stable fly repellent for dogs and horses, and they are registered as domestic class products for application to the fur coat of dogs and horses with a pump spray. In addition, camphor oil and eucalyptus oil, when co-formulated with methyl salicylate and cornmint oil, are registered (domestic product) for use as an animal repellent. The co-formulations are impregnated onto plastic to be used in the manufacture of trash bags to repel Norway rats (common brown rats) and raccoons.

The currently registered products containing these essential oils are listed in Appendix I.

## 2.0 The Technical Grade Active Ingredient, Its Properties and Uses

### 2.1 Identity of the Technical Grade Active Ingredient

Common Name Insect repellent:

Blend of geranium, camphor, eucalyptus, lemon, and pine needle

oils for Reg. No. 31191.

Animal repellent:

Blend of methyl salicylate, camphor, cornmint and eucalyptus oils

for Reg. No. 30503.

**Function** Insect repellent for Reg. No. 31191

Animal repellent for Reg. No. 30503

**Chemical Family** Essential oils

**Chemical Name** 

1 International Union of Pure and

**Applied Chemistry** 

(IUPAC)

The essential oils are comprised of a mixture of complex components and therefore they do not have distinct chemical

names.

2 Chemical Abstracts

Service (CAS)

The essential oils are comprised of a mixture of complex components and therefore they do not have distinct chemical

names.

<b>CAS Registry Number</b>	Oil of Geranium	8000-46-2
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**Molecular Formula** The essential oils are comprised of a mixture of complex

components and cannot be adequately represented by a single

molecular formula.

**Structural Formula** The essential oils are comprised of a mixture of complex

components and cannot be adequately represented by a single

structural formula.

**Molecular Weight** The essential oils are comprised of a mixture of complex

components and cannot be adequately represented by a single

molecular weight.

TGAI Reg. No.	Active ingredient	<b>Nominal Concentration</b>
31191	Oil of geranium	23.11%
(personal, dog, and horse	Camphor oil	7.54%
insect repellent)	Eucalyptus oil	23.13%
	Lemon oil	23.11%
	Pine needle oil	23.11%
30503	Methyl salicylate	36.0%
(animal repellent)	Cornmint oil	36.0%
	Camphor oil	23.0%
	Eucalyptus oil	5.0%

### 3.0 Human and Animal Health

Based on the registered use pattern, exposure to oil of geranium, camphor oil, eucalyptus oil, lemon oil, and pine needle oil can occur when applying the insect repellent products to skin (as a personal repellent) and / or the fur of dogs and horses. Postapplication exposure to bystanders (adults, children, and toddlers) who handle animals after they have been sprayed with the repellent is also a possibility. Exposure to individuals (consumers) and bystanders can also occur from the use of treated trash bags when used as an animal repellent.

When assessing health risks, two key factors are considered: the levels at which 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. In the case of oil of geranium, camphor oil, eucalyptus oil, lemon oil, and pine needle oil, the levels to which animals (dogs and horses) may be exposed is also considered. Continued registration is only supported for uses that are determined as having no health risks of concern.

### 3.1 Toxicology Summary

Oil of geranium, camphor oil, eucalyptus oil, lemon oil, and pine needle oil are manufactured from naturally occurring plants. These oils are present in various consumer products available to the Canadian public (for example, natural health products and cosmetics), including products with similar "on skin" uses. As such, there is a long history of human exposure without any observed adverse effects.

A toxicology review for mixtures of oil of geranium, camphor oil, eucalyptus oil, lemon oil, and pine needle oil – the five technical grade active ingredients (TGAIs) – found that they are of low acute oral and dermal toxicity. Based on available information, these oils are considered to be moderately irritating to the skin and eyes, potentially irritating to the respiratory tract, and are considered potential skin sensitizers. For further information, please refer to PRD2017-16.

The toxicology review of technical grade mixtures of camphor oil, eucalyptus oil, methyl salicylate, and cornmint oil found that they are moderately acutely toxic by the oral route and severely irritating to the skin and eyes. The technical grade co-formulations are expected to cause irritation of the respiratory tract upon inhalation; however, based on a long history of use of the actives in consumer products, the mixtures of camphor oil, eucalyptus oil, methyl salicylate, and cornmint oil are not expected to be skin sensitizers. For further information, please refer to PRD2012-13.

Considering the long history of use as medicinal and non-medicinal ingredients in consumer products in Canada with similar use patterns (such as in ointments, liniments, or other preparations that are applied to human skin), these oils are neither expected to be mutagens nor developmental toxicants, and they are not expected to be carcinogens. In general, mixtures of these oils have a low toxicity profile.

Based on their low toxicity profile and long history of use in consumer products, no toxicological endpoints have been established for quantitative risk assessments by the PMRA. As a result, the PMRA has used a qualitative approach to assess the potential risks of oil of geranium, camphor oil, eucalyptus oil, lemon oil, and pine needle oil to human health.

### 3.2 Residential Exposure and Risk

### Personal Insect Repellent

Personal insect repellents are packaged as ready-to-use solutions for direct application onto human skin. As such, dermal exposure is expected to be the primary exposure route for all individuals (adults, children, and toddlers) using the product. For toddlers, oral exposure via hand-to-mouth transfer from the skin is also a possible route. Inhalation exposure is not expected to be of concern for all populations, as inhalation of concentrated vapours from volatilization of the product is unlikely to occur, and, in general, end-use products are expected to be applied in well-ventilated areas, most likely outdoors. Current label directions limit application to twice per day, and they contain adequate mitigation statements (such as "Apply sparingly, only when necessary, and not under clothing." and "Always supervise applications on children and do not

apply to the hands of young children.") to minimize dermal and oral exposure. Considering the low toxicity profile of these essential oil mixtures, their long history of use in various consumer products, and provided end-use products are used according to label directions, the potential risk to all populations is not expected to be of concern. No additional mitigation measures are proposed.

### Animal Insect Repellent

Animal insect repellent products are packaged as ready-to-use solutions for direct application on the fur of dogs and horses. Inhalation exposure is not expected to be of concern for all populations, and dermal exposure is thus expected to be the primary exposure route for individuals applying the product. In addition, dermal exposure in individuals (adults, children, and toddlers) from handling treated dogs and horses, and non-dietary oral exposure from hand-to-mouth activities in toddlers are also likely. However, the increased exposure to adults, children, and toddlers from applying the insect repellent to dogs and horses and /or from handling of treated animals is expected to be low when compared to the exposure from personal insect repellent use. Considering the current use pattern and low toxicity profile of these active ingredients, the potential risk to all populations is not expected to be of concern. No additional mitigation measures are proposed. For further details, please refer to PRD2017-16.

### Animal Repellent

When used as an animal repellent in domestic ready-to-use trash bags, individuals (such as workers, homeowners) can be exposed to camphor oil and eucalyptus oil from handling the impregnated trash bags via both the dermal and inhalation routes. For bystanders, only inhalation of the fragrance emanating from the scented bag is anticipated. Because technical grade mixtures are impregnated into plastic, direct exposure to harmful concentrations is not expected, and based on the current use pattern, only short-term exposure at low levels is expected for all populations. On this basis and considering the low toxicity profile of the active ingredients, the long history of use of the actives in consumer products, and provided that the products are used according to label directions, the potential risk to all populations from exposure to animal repellent end-use products is not expected to be of concern. No additional mitigation measures are proposed.

### 3.3 Dietary Exposure

Domestic end-use products containing these oils are not registered for use on any food commodity nor are they expected to contaminate drinking water sources based on the current use pattern. On this basis, dietary (food and drinking water) exposure and risk from these products is not expected to be of concern for all populations. No mitigation measures are proposed.

### 3.4 Aggregate Exposure

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential and other non-occupational sources as well as from all known or plausible routes (oral, dermal and inhalation). For mixtures and / or co-formulations of oil of geranium, camphor oil, eucalyptus oil, lemon oil, and pine needle oil, aggregate exposures are limited to residential exposures. Nonetheless, these exposures are expected to be negligible based on the low toxicity profile of these essential oils and current label use directions. On this basis, aggregate exposure and risk is not expected to be of concern under the current conditions of use for all populations.

### 3.5 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. While all essential oil-based pest control products are comprised of chemically-similar constituent active ingredients, the PMRA did not identify information indicating that oil of geranium, camphor oil, eucalyptus oil, lemon oil, and pine needle oil share a common mechanism of toxicity with other pest control products for the current re-evaluation. Furthermore, the potential risks from cumulative exposure of these oils with other such pest control products is not of concern, given the inherent low toxicity profile of the active ingredients.

### 3.6 Animal Exposure and Risk (for animal Insect Repellents):

Animal insect repellent end-use products containing mixtures of essential oils are packaged as ready-to-use solutions for direct application to the fur of dogs and horses. As such, dermal exposure is expected to be the primary animal exposure route. In addition, oral exposure via grooming or licking of the fur is also identified as a potential exposure scenario in treated animals following application of the insect repellent. Inhalation exposure is not expected to be of concern, as the physical-chemical characteristics of the oil mixtures suggest that volatilization of concentrated vapours is unlikely to occur, and end-use products are expected to be applied in well-ventilated areas, most likely outdoors. To minimize exposure to animals being treated, several risk reduction measures are currently included on the label (for example, limit application to twice per day; product is not to be massaged into the skin of the animal; apply as a thin layer of the product; and avoid application on the animal's eyes, mouth and sensitive skin areas).

Considering the low toxicity profile of oil of geranium, camphor oil, eucalyptus oil, lemon oil, and pine needle oil mixtures and provided end-use products are used according to label directions, the potential risk to dogs and horses treated with products containing these active ingredients is not expected to be of concern. No additional mitigation measures are proposed. For further details, please refer to PRD2017-16.

### 4.0 Environment

When the current label directions are followed, environmental exposure to these active ingredients is minimal, and risks of concern to the environment are not expected.

Storage and disposal statements are proposed to be updated to meet current labelling standards (Appendix II).

### 5.0 Value

Mosquitoes are an outdoor nuisance pest to both humans and companion animals across all of Canada. Moreover, they can vector diseases. Horn, face, house, and stable flies are further nuisance pests for dogs and horses. Mixtures of geranium oil, camphor oil, eucalyptus oil, lemon oil, and pine needle oil have value in providing Canadians and their companion animals with an additional choice to repel insects. These actives also have value in that they can be used in conjunction with other pest control practices and/or in situations where alternatives to conventional pest control products are desired.

Common brown rats (Norway rats) and raccoons are also nuisance pests in Canada. Camphor oil and eucalyptus oil (when co-formulated with methyl salicylate and cornmint oil) impregnated into trash bags have value in limiting the annoyances .There are few active ingredients registered for use by homeowners to repel raccoons and Norway rats from trash, and these end-use products have value in providing an additional option for homeowners to repel these animals.

# **6.0** Pest Control Product Policy Considerations

### **6.1** Toxic Substances Management Policy Considerations

In accordance with the PMRA Regulatory Directive DIR99-03, assessments of oil of geranium, camphor oil, eucalyptus oil, lemon oil, and pine needle oil against Track 1 criteria of Toxic Substances Management Policy (TSMP) under the *Canadian Environmental Protection Act* were conducted. It was determined that:

 Based on the use pattern, environmental releases are expected to be minimal. Therefore, these essential oils are not considered CEPA-toxic equivalent to the environment and they do not meet the Track 1 criteria

### 6.2 Formulants and Contaminants of Health or Environmental Concern

As part of re-evaluation, contaminants in the technical grade active ingredient are compared against the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*.<sup>3</sup> The list is used as described in the PMRA Notice of Intent NOI2005-01 and is based on existing policies and regulations including: DIR99-03 and DIR2006-02, and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). With respect to oil of geranium, camphor oil, eucalyptus oil, lemon oil, and pine needle oil, the PMRA has reached the following conclusion:

- Impurities and formulants of human health or environmental concern as identified in the *Canada Gazette*, are not expected to be present in the technical grade active ingredients.
- 1. Insect repellent end-use products contain a petroleum distillate as a formulant at a concentration greater than 10%, and current label contains adequate statements related to petroleum distillates.

# 7.0 Incident Reports

As of 10 July 2017, no incident reports involving the active ingredients camphor oil, eucalyptus oil, lemon oil, geranium oil and pine needle oil have been submitted to the PMRA. There were, however, 9 domestic animal incidents for the active d-limonene, which is a major component of lemon oil. No human or environment incidents were submitted for the active d-limonene.

All 9 domestic animal incidents occurred in the U.S. Death as well as various other symptoms was reported in six cats and four dogs. Most incidents involved one U.S product, a flea and tick shampoo containing d-limonene. Three other incidents were associated with a spot-on product that contained multiple active ingredients including d-limonene. Exposure scenarios reported in incidents include product misuse or indirect product contact. Given the low number of incident reports, no additional mitigation action is being proposed.

All relevant information received through the PMRA incident reporting program were considered in the re-evaluation of lemon oil, eucalyptus oil, pine needle oil, geranium oil, camphor oil.

Concern.

Canada Gazette, Part II, Volume 139, Number 24, pages 2641–2643: List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern and in the order amending this list in the Canada Gazette, Part II, Volume 142, Number 13, pages 1611-1613. Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental

### 8.0 Conclusion

Oil of geranium, camphor oil, eucalyptus oil, lemon oil, and pine needle oil mixtures and coformulations have value in providing Canadians and their pets with an additional choice for certain insect and animal annoyances. The active ingredients are manufactured from naturally occurring plants and have a history of use in various consumer products, including products with "on skin" uses. Oil of geranium, camphor oil, eucalyptus oil, lemon oil, and pine needle oil have a low toxicity profile, and when used according to current label directions, the potential risk to human health is not of concern. Similarly, when products containing these essential oils are used in accordance with the current label directions, risks of concern to non-target terrestrial and aquatic organisms are not expected.

On this basis, Health Canada's Pest Management Regulatory Agency, under the authority of the *Pest Control Products Act* and Regulations, is proposing continued registration of products containing oil of geranium, camphor oil, eucalyptus oil, lemon oil, and pine needle oil for sale and use in Canada.

Updates to label directions related to disposal and storage are proposed to meet the current labeling standards.

# Appendix I Registered Oil of Geranium, Camphor Oil, Eucalyptus Oil, Lemon Oil, and Pine Needle Oil Products as of 25 January 2018

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
31191	Technical	Héloïse Laboratoire Inc.	Citrobug Formula He-5000 Essential Oils	Liquid	Lemon Oil 23.11% Eucalyptus Oil 23.13% Pine Needle Oil 23.11% Geranium Oil 23.11%
25797	Domestic	Héloïse Laboratoire Inc.	Citrobug Mosquito repellent oil	Solution	Camphor Oil 7.54%  Lemon Oil 0.64%  Eucalyptus Oil 0.64%  Pine Needle Oil 0.64%  Geranium Oil 0.64%  Camphor Oil 0.21%
32733	Domestic	Héloïse Laboratoire Inc.	Citrobug Mosquito repellent oil for kids	Solution	Lemon Oil 0.64% Eucalyptus Oil 0.64% Pine Needle Oil 0.64% Geranium Oil 0.64% Camphor Oil 0.21%
32954	Domestic	Héloïse Laboratoire Inc.	Citrobug Insect Repellent for Dogs and Horses	Solution	Lemon Oil 0.64% Eucalyptus Oil 0.64% Pine Needle Oil 0.64% Geranium Oil 0.64% Camphor Oil 0.21%
30503	Technical	Mint-X Corporation	Mint-X Super Perfume Blend	Solution	Methyl Salicylate 36% Cornmint Oil 36% Camphor Oil 23% Eucalyptus Oil 5%
30504	Manufacturing concentrate	Mint-X Corporation	Mint-X Treated Plastic	Impregnated Fabric	Methyl Salicylate 0.288% Cornmint Oil 0.288% Camphor Oil 0.184% Eucalyptus Oil 0.04%
31383	Manufacturing concentrate	Mint-X Corporation	Mint-X Treated Compostable Plastic	Impregnated Fabric	Methyl Salicylate 0.288% Cornmint Oil 0.288% Camphor Oil 0.184% Eucalyptus Oil 0.04%

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# Appendix II Label Amendments for Products Containing Oil of Geranium, Camphor Oil, Eucalyptus Oil, Lemon Oil, and Pine Needle Oil

The label amendments presented below do not include all label requirements for individual enduse products, such as first aid statements, disposal statements, precautionary statements, and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the label statements provided below.

1. Add the following statement to all domestic end use products under the STORAGE heading:

"To prevent contamination, store this product away from food or feed."

2. Add the following statement to all domestic end use products under the DISPOSAL heading:

"DO NOT reuse the empty containers. Dispose in household garbage. Unused or partially used products should be disposed at provincially or municipally designated hazardous waste disposal sites."

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# References

# A. LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT(S)

# **Unpublished Information**

PMRA No.	Reference
1963126	TABLEAU CODO 0.8 FOR COMMERCIAL PRODUCT 25797, DACO: 2.0,2.14,3.5,4.1,5.1,M12.5.2 CBI
2224118	2.11.2 100169 NOVO JM, DACO: 2.11.2 CBI
2224120	2.11.2 100380 Novo ER, DACO: 2.11.2 CBI
2224121	2.11.2 100451 Novo BV, DACO: 2.11.2 CBI
2224122	2.11.2 100630-Novo CM, DACO: 2.11.2 CBI
2224123	2.11.2 103115 Novo SC, DACO: 2.11.2 CBI
2224124	2.11.3 100169-Novo, DACO: 2.11.3 CBI
2224126	2.11.3 100380-Novo, DACO: 2.11.3 CBI
2224127	2.11.3 100451-Novo, DACO: 2.11.3 CBI
2224128	2.11.3 100630-Novo, DACO: 2.11.3 CBI
2224136	2.13.3 Data #3, DACO: 2.13.3 CBI
2224137	2.13.3 Data #4, DACO: 2.13.3 CBI
1963128	CHROMATOGRAPHIES DES HUILES ESSENTIELLE, DACO: 2.14, 3.4, 3.5, M12.5.2 CBI
2030029	CUDO, DACO: 2.0 CBI
2247442	MS Geranium oil lot 36718 ANNEXE 3., DACO: 2.13.3 CBI
2247443	MS [CBI removed] Standard ANNEXE 2., DACO: 2.13.3 CBI
2030028	Chromatographies sur toutes les huiles essentielles, DACO: 2.14 CBI
2002778	2010, C of As, DACO: 2.13.3 CBI

	Reference
2002775	2010, Chemistry Requirements, DACO: 2.1, 2.2, 2.3, 2.3.1, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9 CBI
2002777	2010, Detailed Production Process, DACO: 2.11.3, 2.12.1, 2.13.2 CBI
2002776	2010, Starting Material Food Grade Certificates and MSDS, DACO: 2.11.2, 2.14.13, 2.14.2, 2.14.6, 2.14.7, 2.14.8 CBI
2064323	2011, Eucalyptus Specis Information and rationale for reduced requirements, DACO: 2.11.2, 2.16 CBI
2064149	Camphor Food Grade Certificate, DACO: 2.16 CBI
2632040	2016, Five-batch analysis for [CBI removed] in Camphor Oil White, DACO: 2.13.4 CBI
2632041	2016, Five-batch analysis for [CBI removed] in Eucalyptus Oil Nat. 80%, DACO: 2.13.4 CBI
2632042	2016, Five-batch analysis for [CBI removed] in Nutmeg Oil, DACO: 2.13.4 CBI

# B. ADDITIONAL INFORMATION CONSIDERED

# **Published Information**

PMRA No.	Reference
2285145	Evaluation Report for Submission Number 2010-4840
2285141	Evaluation Report for Submission Number 2010-4843
2193119	Proposed Registration Decision, Mint-X Super Perfume Blend, PRD2012-13
2259608	Registration Decision, Mint-X Super Perfume Blend, RD2012-28
2825014	Proposed Registration Decision, Eucalyptus oil, pine needle oil, oil of geranium, lemon oil and camphor oil, and Citrobug Insect Repellent for Dogs and Horses, PRD2017-16