Risk Management Scope

for

Certain Terpenes and Terpenoids within the Monocyclic and Bicyclic Sesquiterpenes Group, specifically:

[Chemical Abstracts Service Registry Numbers (CAS RN)]

T & T Clove Oil [68917-29-3]

Sandalwood Oil [8006-87-9]

Guaiazulene [489-84-9]

Environment and Climate Change Canada

Health Canada

May 2021

Summary of Proposed Risk Management

This document outlines the risk management options under consideration for certain substances within the Monocyclic and Bicyclic Sesquiterpenes Group which have been proposed to be harmful to human health, specifically:

- Terpenes and terpenoids (T & T) clove oil [CAS RN[1] 68917-29-3]
- Sandalwood oil [CAS RN 8006-87-9]
- Guaiazulene [CAS RN 489-84-9]

In particular, the Government of Canada is considering:

- Regulatory and/or non-regulatory measures to prevent or reduce exposures to T & T clove oil and guaiazulene from certain cosmetics; and
- Measures to reduce exposures to sandalwood oil from certain cosmetics by describing sandalwood oil as prohibited or restricted ingredient on the Health Canada Cosmetic Ingredient Hotlist.

Moreover, because certain data gaps remain, the following information should be provided ideally on or before July 7, 2021, to the contact details identified in section 8 of this document) to inform risk management decision-making:

- Current quantities (kilograms) and/or concentrations (percent weight per weight) of T & T clove oil, sandalwood oil and guaiazulene in cosmetics, including massage oils used on infants and children up to 8 years old;
- Current quantities (kilograms) and/or concentrations (percent weight per weight) of each of the components that make up T & T clove oil, sandalwood oil and guaiazulene in cosmetics, including massage oils used on infants and children up to 8 years old; and
- Potential alternative substances to T & T clove oil, sandalwood oil and guaiazulene for use in cosmetics.

The risk management options outlined in this Risk Management Scope document may evolve through consideration of assessments and risk management options or actions published for other Chemicals Management Plan (CMP) substances, ensuring effective, coordinated, and consistent risk management decision-making.

[1] CAS RN: Chemical Abstracts Service Registry Number. The Chemical Abstracts Service information is the property of the American Chemical Society and any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the Government of Canada when the information and the reports are required by law or administrative policy, is not permitted without the prior, written permission of the American Chemical Society.

Note: The above summary is an abridged list of options under consideration to manage these substances and to seek information on identified gaps. Refer to section 3 of this document for more complete details in this regard. It should be noted that the proposed risk management options may evolve through consideration of additional information obtained from the public comment period, literature and other sources.

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1. Context

The *Canadian Environmental Protection Act, 1999* (CEPA) (Government of Canada, 1999) provides the authority for the Minister of the Environment and the Minister of Health (the ministers) to conduct assessments to determine if substances are toxic to the environment and/or harmful to human health as set out in section 64 of CEPA[2,3], and if so to manage the associated risks.

2. Issue

Health Canada and Environment and Climate Change Canada conducted a joint scientific assessment of 16 substances referred to collectively under the Chemicals Management Plan as the Terpenes and Terpenoids: Monocyclic and Bicyclic Sesquiterpenes Group, to determine whether these substances present or may present a risk to the environment and/or human health in Canada. The substances in the Monocyclic and Bicyclic Sesquiterpenes Group are ginger oil, bisabolene, alpha-bisabolene, santol pentenol, sandalore, balsams copaiba, beta-caryophyllene, T & T clove oil, guaiene, alpha-guaiene, valencene, guaiol, bulnesol, elemol, sandalwood oil and guaiazulene. A notice summarizing the scientific considerations of the proposed risk assessment conclusions for these substances was published in the *Canada Gazette*, Part I*,* on March 20, 2021 (Canada 2021a).

2.1 Draft Screening Assessment Conclusion

On the basis of the information available, the draft screening assessment proposes that T & T clove oil, sandalwood oil and guaiazulene (see Annex A) are toxic under section 64(*c*) of CEPA because they are entering or may enter the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health (Canada 2021b). It is proposed to conclude that the remaining 13 substances in the Monocyclic and Bicyclic Sesquiterpenes Group do not meet the criteria under paragraph 64(c) of CEPA as they are not entering the environment in a quantity or concentration or under

[2] Section 64 of CEPA: *For the purposes of* [Parts 5 and 6 of CEPA]*, except where the expression "inherently toxic" appears, a substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that*

(a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity;
(b) constitute or may constitute a danger to the environment on which life depends; or
(c) constitute or may constitute a danger in Canada to human life or health.

[3] A determination of whether one or more of the criteria of section 64 are met is based upon an assessment of potential risks to the environment and/or to human health associated with exposures in the general environment. For humans, this includes, but is not limited to, exposures from ambient and indoor air, drinking water, foodstuffs, and products used by consumers. A conclusion under CEPA is not relevant to, nor does it preclude, an assessment against the hazard criteria specified in the *Hazard Product Regulations*, which are a part of the regulatory framework for the Workplace Hazardous Materials Information System for products intended for workplace use. Similarly, a conclusion on the basis of the criteria contained in section 64 of CEPA does not preclude actions being taken under other sections of CEPA or other Acts.

conditions that constitute or may constitute a danger in Canada to human life or health.

It is proposed to conclude that the 16 substances in the Monocyclic and Bicyclic Sesquiterpenes Group do not meet the criteria under paragraphs 64(*a*) or (*b*) of CEPA as they are not entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity or that constitute or may constitute a danger to the environment on which life depends.

The draft screening assessment also proposes that both T & T clove oil and guaiazulene meet the persistence and bioaccumulation criteria while sandalwood oil does not meet the persistence or bioaccumulation criteria as set out in the *Persistence and Bioaccumulation Regulations* under CEPA (Government of Canada, 2000).

The human health exposures and sources of concern identified in the draft screening assessment are as follows:

T & T clove oil

- When it is a 100% essential oil and used as a body fragrance, there are combined dermal and inhalation exposure concerns for children aged 2 to 8 years old.

Sandalwood oil

- When used as a massage oil, there are dermal exposure concerns for infants and children up to 8 years old.
- When used as a body lotion or an essential oil as a body fragrance, there are dermal exposure concerns for the general population.

Guaiazulene

- When it used as a hair perm or straightening product, there are combined dermal and inhalation exposure concerns for the general population.

As such, this document will focus on these applications and exposure sources of concern (refer to section 5).

Of note, the proposed risk management option described in this document and the proposed conclusion outlined in the draft screening assessment may be subject to change. For further information on the draft screening assessment for the Monocyclic and Bicyclic Sesquiterpenes Group, refer to the Terpenes and Terpenoids: Monocyclic and Bicyclic Sesquiterpenes Group draft screening assessment.

2.2 Proposed Recommendation under CEPA

Based on the findings of the draft screening assessment conducted under CEPA, the ministers propose to recommend that T & T clove oil, sandalwood oil and guaiazulene be added to the List of Toxic Substances in Schedule 1 of the Act[4].

Under certain circumstances, the ministers are required to make a specific proposal to recommend addition to the List of Toxic Substances and, where applicable, to recommend the implementation of virtual elimination[5]. Given that T & T clove oil and guaiazulene are also proposed to meet the criteria for virtual elimination as set out in paragraph 77(4) of CEPA, the process for substances targeted for virtual elimination will be followed, taking into account relevant environmental or health risks and social, economic, and technical matters, such as those outlined in section 6 of this document.

The ministers will take into consideration comments submitted by stakeholders during the 60-day public comment period on the draft screening assessment and Risk Management Scope document in the preparation of the final screening assessment and Risk Management Approach document, if required.

If the ministers finalize the recommendation to add T & T clove oil, sandalwood oil and guaiazulene to Schedule 1, risk management instruments will be proposed within 24 months from the date on which the final screening assessment is published, and finalized within 18 months from the date on which the risk management instruments are proposed, as outlined in sections 91 and 92 of CEPA (refer to section 8 of this document for publication timelines applicable to this group of substances).

3. Proposed Risk Management

3.1 Proposed Human Health Objective

Proposed human health objectives are quantitative or qualitative statements of what should be achieved to address human health concerns.

For these substances, the proposed objectives are focused on addressing the exposure sources of concern outlined in section 5 of this document. In the case of

[4] When a substance is found to meet one or more of the criteria under section 64 of CEPA, the ministers can propose to take no further action with respect to the substances, add the substance to the Priority Substances List for further assessment, or recommend the addition of the substance to the List of Toxic Substances in Schedule 1 of the Act.

[5] Under CEPA, a substance meets Virtual Elimination criteria if it is persistent and bioaccumulative, is harmful to the environment or human health, is recommended for addition to Schedule 1, is present in the environment primarily from human activity, and is not a naturally-occurring radionuclide or naturally-occurring inorganic substance.

toxic substances that result predominantly from human activity and that are persistent and bioaccumulative, the proposed environmental or human health objective is usually the virtual elimination of the release of these substances into the environment[6]. Releases of T & T clove oil and guaiazulene from products available to consumers are dispersive, and it therefore may not be possible to implement virtual elimination by establishing a level of quantification for releases. As such, the proposed human health objective is to reduce exposure of the general population to T & T clove oil, sandalwood oil and guaiazulene to levels that are protective of human health.

3.2 Proposed Risk Management Objectives

Proposed risk management objectives set quantitative or qualitative targets to be achieved by the implementation of risk management regulations, instruments and/or tools for a given substance or substances. In this case, the proposed risk management objectives for these substances for the protection of human health are:

1. To prevent or reduce dermal and inhalation exposures of children aged 2 to 8 years old to T & T clove oil from certain cosmetics, such as essential oil, to levels which are protective of human health;
2. To reduce dermal exposures of infants and children up to 8 years to sandalwood oil from certain cosmetics, such as massage oil, to levels which are protective of human health;
3. To reduce dermal exposures of the general population to sandalwood oil from certain cosmetics, such as body lotion, and essential oil, to levels which are protective of human health; and
4. To prevent or reduce dermal and inhalation exposures of the general population to guaiazulene from certain cosmetics, such as hair perm or straightening products, to levels which are protective of human health.

Such objective(s) will be refined on the basis of consultation with stakeholders, the proposed risk management, consideration of further information received, the outcome of the final screening assessment, and socio-economic and technical considerations (such as those outlined in section 6 of this document). Revised human health and risk management objective(s), if the conclusions are confirmed in the final screening assessment, should next be presented in the Risk Management Approach document that will be published concurrently with the final screening assessment for these substances, or in subsequent risk management documents (e.g., consultation document on proposed instrument), as the case may be.

[6]According to CEPA, virtual elimination means, in respect of a toxic substance released into the environment as a result of human activity, the ultimate reduction of the quantity or concentration of the substance in the release below the Level of Quantification (LoQ) specified in the Virtual Elimination List. The LoQ is the lowest concentration that can be accurately measured using sensitive but routine sampling and analytical methods.

3.3 Proposed Risk Management Option under Consideration

To achieve the proposed risk management objective and to work towards achieving the proposed human health objective, the risk management option under consideration is:

- Regulatory and/or non-regulatory measures to prevent or reduce exposures to T & T clove oil and guaiazulene from certain cosmetics; and
- Measures to reduce exposures to sandalwood oil from certain cosmetics. These could include describing sandalwood oil and/or its main components as prohibited or restricted ingredients to Health Canada's Cosmetic Ingredient Hotlist. The Hotlist is used to communicate that certain substances may not be compliant with requirements of the *Food and Drugs Act* or provisions of the *Cosmetic Regulations*.

Note that the proposed risk management option described in this document is preliminary and subject to change. Following the publication of this document, additional information obtained from the public comment period and from other sources will be considered, along with the information presented in this document and in the instrument selection and development process[7]. The risk management option outlined in this document may also evolve through consideration of assessments and risk management options or actions published for other CMP substances to ensure effective, coordinated, and consistent risk management decision-making.

3.4 Performance Measurement Evaluation

Performance measurement evaluates the ongoing effectiveness and relevance of the actions taken to manage risks from toxic substances[8]. The aim is to determine whether human health and/or environmental objectives have been met and whether there is a need to revisit the risk management approach for that substance. To achieve this, the Government of Canada plan to review the effectiveness of the risk management action(s) for T & T clove oil, sandalwood oil and guaiazulene.

[7] The proposed risk management tools will be selected using a thorough, consistent and efficient approach and take into consideration available information in line with the Government of Canada's Cabinet Directive on Regulatory Management (Canada, 2012a), the Red Tape Reduction Action Plan (Canada, 2012b), and in the case of a regulation the *Red Tape Reduction Act* (Canada, 2015).

[8] Performance measurement can be performed at two levels:

- Instrument-based performance measurement evaluates the effectiveness of an individual instrument in meeting the specific risk management objectives that were set out when the risk management tool was designed. The results of performance measurement will help determine if additional risk management or assessment is needed (i.e., evaluate whether risk management objectives have been met); and
- Performance measurement evaluation considers performance of all final risk management instruments applied to a chemical substance and relevant data or indicators of exposure to the environment or human health (i.e., evaluate whether human health and/or environmental objectives have been met).

The Government of Canada plans to measure the effectiveness of the risk management action(s) by collecting and analyzing data to measure progress towards meeting the risk management objective(s).

In addition, the Government of Canada plans to collect and analyze data, such as data obtained from notifications submitted under the *Cosmetic Regulations* to Health Canada, product testing, and information gathering mechanisms, such as those outlined in the *Canadian Environmental Protection Act, 1999* on the presence of T & T clove oil, sandalwood oil and guaiazulene in certain cosmetic products in order to establish a baseline human exposure and again, over time, to measure progress towards meeting the human health objectives.

The results of performance measurement evaluation will be used to inform whether further risk management action is warranted and will be made available to Canadians along with recommendations for further action if applicable.

3.5 Risk Management Information Gaps

In order to make informed decisions on the proposed risk management, interested stakeholders are invited to provide further information on the following:

- Current quantities (kilograms) and/or concentrations (percent weight per weight) of T & T clove oil, sandalwood oil and guaiazulene in cosmetics;
- Current quantities and/or concentrations of each of the components that make up T & T clove oil, sandalwood oil and guaiazulene in cosmetics;
- Potential alternative substances to T & T clove oil, sandalwood oil and guaiazulene for use in cosmetics.

Should stakeholders have further information to help address these gaps, they should provide it ideally on or before July 7, 2021 to inform the risk management decision-making process, within the timelines (and to the contact) identified in section 8 of this document.

4. Background

4.1 General Information on T & T clove oil, sandalwood oil and guaiazulene

T & T clove oil, sandalwood oil and guaiazulene are organic substances within the Monocyclic and Bicyclic Sesquiterpenes Group within the broader chemical group of terpenes and terpenoids. Terpenes have repeating isoprene units, and are classified according to the number of isoprene units they contain. Monoterpenes are the smallest unit and contain two isoprene units. Sesquiterpenes are bigger and contain three isoprene units. Like monoterpenes, sesquiterpenes may be acyclic or cyclic, including many unique combinations (Aldred, Buck and Vall, 2009).

These plant-derived essential oils have several components which can be extracted from different parts of the plant. The concentrations of these components can be affected by different factors such as the origin of the plant, species, temperature, soil, and geography (Tisserand and Young 2014). Many of these oils also have different chemical components even when produced from plants with the same genus and species. Guaiazulene is a discrete substance, while T & T clove oil and sandalwood oil are essential oils. T & T clove oil, sandalwood oil and guaiazulene have been included in surveys issued under section 71 of CEPA (Environment Canada 2013).

4.2 Current Uses and Identified Sectors

4.2.1 T & T Clove Oil

Based on information submitted in response to a CEPA section 71 survey (Canada 2012), there were no reports of import or manufacture above the reporting threshold of 100 kg for T & T clove oil in 2011 (Environment Canada 2013).

T & T clove oil is a by-product from the process of producing different clove oils, which contains caryophyllene (minimum 70%) and eugenol (maximum 5%). The crude oil extracted from the leaves, bud and stem of plants from the *Myrtaceae* family is steam distilled and then further processed to produce various grades of clove oil and its derivatives (Ultra International B.V. 2018; TDS 2018; Specification Sheet 2009). In contrast, clove oil (CAS RN 8000-34-8) contains a higher percentage of eugenol (minimum 76%), and a lower percentage of caryophyllene (maximum 17%) (Tisserand and Young 2014; Jirovetz 2006). Canadian uses of T & T clove oil include various products available to consumers such as body lotions, hair care products, fragrances, cleansers, bath products, massage products, deodorants/antiperspirants, and oral care products. There is a degree of uncertainty as to whether the notifications under the *Cosmetic Regulations* for the above-noted products contain T & T clove oil or clove oil. In the absence of any additional information, it was assumed that the above-noted products contain T & T clove oil (Canada 2021b). T & T clove oil, was also reported to be used as a formulant in pesticides (Canada 2021b).

Globally, T & T clove oil is listed as a fragrance ingredient used in consumer goods by the International Fragrance Association (IFRA 2017).

4.2.2 Sandalwood Oil

Based on information submitted pursuant to section 71 of CEPA (Canada 2012), there were no reports of import or manufacture above the reporting threshold of 100 kg for sandalwood oil in 2011 (Environment Canada 2013).

Canadian uses of sandalwood oil were reported in cosmetics. Sandalwood oil (with various synonyms such as sandalwood essential oil, *Santalum album* (bark) oil, *Santalum album* (sandalwood) essential oil, *Santalum album* (sandalwood) oil, *Santalum album* (sandalwood) seed oil, and *Santalum album* oil) is used in the

majority of products (approximately 90%) at a concentration less than or equal to 3% (personal communication, email communication from the Consumer and Hazardous Products Safety Directorate, Health Canada, to Existing Substances Risk Assessment Bureau, Health Canada, October 2019; unreferenced) in more than 650 cosmetics products. Sandalwood oil is listed in the Natural Health Products Ingredients Database (NHPID) as a homeopathic ingredient, medicinal ingredient (Sandalwood essential oil) and as a non-medicinal ingredient with flavour enhancer and fragrance ingredient purposes (NHPID 2019). *Santalum album* (sandalwood) oil is present as a non-medicinal ingredient in some licensed natural health products such as acne medications and sunscreens (LNHPD 2018). According to the American Cleaning Institute (ACI), sandalwood oil is used as a fragrance in liquid all-purpose cleaners, dish care products, and laundry care products (ACI 2018). Sandalwood oil is also a formulant in pesticides (personal communication, emails from the Pest Management Regulatory Agency, 2015; unreferenced).

Sandalwood oil has reported uses internationally in food, including alcoholic and non-alcoholic beverages, baked goods, chewing gum, frozen dairy, and candy (Burdock 2010). Sandalwood oil is listed in the US FDA Substances Added to Food Inventory as a flavouring agent or adjuvant (US FDA 2018). No definitive information is available concerning the potential use of sandalwood oil as a food flavouring agent in Canada; however, since the substance is known to be used as a food flavouring agent in the US, it is possible that the substance is present as a flavouring agent in foods sold in Canada.

4.2.3 Guaiazulene

Based on information submitted in response to a CEPA section 71 survey (Canada 2012), there were no reports of import or manufacture above the reporting threshold of 100 kg for guaiazulene in 2011 (Environment Canada 2013).

Guaiazulene is a bicyclic sesquiterpene that is a component of various essential oils like guaiac wood oil and *Matricaria chamomilla* (Kourounakis et al. 1997).

Guaiazulene imparts a blue colour to cosmetics (Andersen 1999) and is used in a number of products available to consumers such as body and facial moisturizers, shampoos, conditioners, bath products, hair removal after-care products, massage oils, antiperspirants, exfoliants, and makeup. Based on notifications submitted under the *Cosmetic Regulations* to Health Canada, guaiazulene is present in over 90 cosmetics with the majority of the products (approximately 70%) having a concentration less than 0.1% (personal communication, email communication from Consumer and Hazardous Products Safety Directorate, Health Canada, to Existing Substances Risk Assessment Bureau, Health Canada, October 2019).

Guaiazulene is listed in the NHPID as a non-medicinal ingredient with a colour additive and fragrance ingredient purpose (NHPID 2019). However, no licensed natural health products were identified (LNHPD 2018).

There is no information available to indicate that guaiazulene has any direct or indirect food uses in Canada or internationally. No other consumer uses of guaiazulene were identified.

5. Exposure Sources and Identified Risks

5.1 T & T Clove Oil

Exposure of the general Canadian population to T & T clove oil is likely to occur from the use of certain products available to consumers. The critical health effect associated with T & T clove oil identified in the draft screening assessment (Canada 2021b) is based on effects on the male lymphoid system. The highest daily exposures are expected to occur from the use of the essential oil as a body fragrance with an upper concentration of 100%. The margin of exposure between the critical effect level and the estimate of daily exposure, via the dermal and inhalation route, to T & T clove oil from use of the essential oil as a body fragrance for 2 to 8 year olds are considered potentially inadequate to account for uncertainties in the health effects and exposure databases.

Exposures to T & T clove oil from products available to consumers including body lotion, massage oil and mouthwash were not considered to pose a risk to human health. In addition, exposures to T & T clove oil from environmental media was not considered to pose a risk to human health.

5.2 Sandalwood Oil

Exposure of the general Canadian population to sandalwood oil is likely to occur from the use of cosmetics, natural health products, and certain products available to consumers. The critical health effect associated with sandalwood oil identified in the draft screening assessment (Canada 2021b) is based on effects on liver function. The margins of exposure between the critical effect level and the estimate of daily exposure, via the dermal route, to sandalwood oil from body lotions (concentration of 30%), massage oils (concentration of 3%) (i.e., infants and children up to 8 years), and use of the essential oil as a body fragrance (concentration of 100%), are considered potentially inadequate to account for uncertainties in the health effects and exposure databases.

Exposures to sandalwood oil from foods where it may be used as a food flavouring agent and in products available to consumers including shampoo, sunscreen, aromatherapy and various cleaning products were not considered to pose a risk to human health. Moreover, exposures to sandalwood oil from environmental media were not considered to pose a risk to human health.

5.3 Guaiazulene

Exposure of the general Canadian population to guaiazulene is likely to occur from the use of certain products available to consumers. The critical health effect

associated with guaiazulene identified in the draft screening assessment (Canada 2021b) is based on degeneration or hyperproliferation of cells in several organs and effects on respiratory system, especially lungs and nose. The margins of exposure between the critical effect level and the estimate of daily exposure to guaiazulene via the dermal or inhalation route from hair perm or straightening products (1%) are considered potentially inadequate to account for uncertainties in the health effects and exposure databases.

Exposures to guaiazulene from cosmetic products including aftershave, body lotion and leave-on conditioner were not considered to pose a risk to human health. Furthermore, exposure to guaiazulene from environmental media was not considered to pose a risk to human health.

6. Risk Management Considerations

6.1 Alternatives and Alternate Technologies

Alternative cosmetic products are available that do not use T & T clove oil, sandalwood oil or guaiazulene. For products that use the aforementioned substances as a fragrance, masking or skin conditioning agent in cosmetics, other substances are available that have a similar function.

6.2 Socio-economic and Technical Considerations

Socio-economic factors will be considered in the selection process for a regulation and/or instrument respecting preventive or control actions, and in the development of the risk management objectives(s). Socio-economic factors will also be considered in the development of regulations, instruments and/or tools as identified in the Cabinet Directive on Regulation (TBS 2018), the Red Tape Reduction Action Plan (TBS 2012) and the *Red Tape Reduction Act* (Canada 2015).

7. Overview of Existing Risk Management

7.1 Related Canadian Risk Management Context

Domestically, there are no relevant existing risk management actions for T & T clove oil, sandalwood oil, and guaiazulene. However, if sandalwood oil may be used as a food flavouring agent, and if used as a food flavouring agent in foods sold in Canada, the safety of sandalwood oil would be subject to provisions under section 4(1)a of the *Food and Drugs Act.*

7.2 Pertinent International Risk Management Context

Internationally, existing risk management actions are as follows:

7.2.1 T & T Clove Oil

United States

Pesticides: Included on EPA's List of Inert Ingredients (Pesticides) as approved for fragrance use (US EPA 2019).

7.2.2 Sandalwood Oil

United States

***Federal Food, Drug and Cosmetic Act* (FD&C Act)**

Food: Sandalwood oil is permitted for use as a flavouring agent or adjuvant under 21CFR172.510, at the minimum quantity required to produce its intended physical or technical effect and in accordance with all the principles of good manufacturing practice (US FDA 2019).

Pesticides: Included on EPA's List Inert Ingredients (Pesticides) as approved for fragrance use (US EPA 2019).

7.2.3 Guaiazulene

United States

Cosmetics: Guaiazulene is part of the Listing of Color Additives Exempt from Certification under the US Code of Federal Regulation Title 21: Food and Drugs, Subpart C - Cosmetics. Color additive mixtures of guaiazulene for cosmetic use may contain the following diluent: Polyethylene glycol-40 castor oil (PEG-40 castor oil), Saponification No., 60 to 70, Hydroxyl No., 63 to 78, Acid No., 2, Specific gravity, 1.05 to 1.07. Guaiazulene shall conform to certain specifications and shall be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice (US FDA 2020).

7.2.4 Other Jurisdictions

In the Association of Southeast Asian Nations, the ASEAN cosmetic directive annex IV-2008- listed guaiazulene to be a colouring agent allowed in all cosmetic products except those intended to be applied in the vicinity of eyes (ASEAN 2015).

8. Next Steps

8.1 Public Comment Period

Industry and other interested stakeholders are invited to submit comments on the content of this Risk Management Scope or other information that would help to inform decision-making (such as outlined in section 3.2 and 3.3). Please submit

additional information and comments prior to July 7, 2021. The Risk Management Approach document, which will outline and seek input on the proposed risk management instruments, will be published if required at the same time as the final screening assessment. At that time, there will be further opportunity for consultation.

Comments and information submissions on the Risk Management Scope should be submitted to the address provided below:

Environment and Climate Change Canada
Gatineau, Quebec K1A 0H3
Telephone: 1-800-567-1999 (in Canada) or 819-938-3232
Fax: 819-938-5212
Email: eccc.substances.eccc@canada.ca

Companies who have a business interest in T & T clove oil, sandalwood oil and guaiazulene are encouraged to identify themselves as stakeholders. The stakeholders will be informed of future decisions regarding T & T clove oil, sandalwood oil and guaiazulene and may be contacted for further information.

8.2 Timing of Actions

Electronic consultation on the draft screening assessment report and Risk Management Scope: May 8, 2021 to July 7, 2021. This should include the submission of public comments, additional studies and information on T & T clove oil, sandalwood oil and guaiazulene.

Publication of responses to public comments on the draft screening assessment report and Risk Management Scope: concurrent to the publication of the screening assessment and, if required, the Risk Management Approach document.

Publication of responses to public comments on the Risk Management Approach, if applicable and if required, the proposed instrument(s): At the latest, 24-months from the date on which the ministers recommended that T & T clove oil, sandalwood oil and guaiazulene be added to Schedule 1 of CEPA.

Consultation on the proposed instrument(s), if required: 60-day public comment period starting upon publication of the proposed instrument(s).

Publication of the final instrument(s), if required: At the latest, 18-months from the publication of the proposed instrument.

These are planned timelines, and are subject to change. Please consult the schedule of risk management activities and consultations for updated information on timelines.

9. References

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ANNEX A. List of Targeted Substances

CAS RN	Subgroup[a]	DSL Name (English)	Common Name/ Simplified Name
68917-29-3[c]	2	Terpenes and terpenoids, clove oil	T & T clove oil
8006-87-9[b,c]	Individual	Oils, sandalwood	sandalwood oil
489-84-9	Individual	Azulene, 1,4-dimethyl-7-(1-methylethyl)-	guaiazulene

[a] Subgroup 1 includes substances where a qualitative risk assessment approach was taken based on low hazard potential. For subgroup 2, hazard information for beta-caryophyllene was used to inform the risk characterization. Beta-caryophyllene is a unique substance in subgroup 2, the main component of T & T clove oil, and was identified as a read-across analogue for for guaiene, alpha-guaiene, and valencene. For subgroup 3, the read-across analogue, alpha-terpineol, was used to inform the hazard characterization. Sandalwood oil and guaiazulene were assessed individually.

[b] This substance was not identified under subsection 73(1) of CEPA, but was included in this assessment as it was considered a priority on the basis of other human health concerns.

[c] This CAS RN is a UVCB (unknown or variable composition, complex reaction products, or biological materials).