Risk Management Scope

for

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

[Chemical Abstracts Service Registry Numbers (CAS RN)]

Rose Oil [8007-01-0]

Mandarin Oil [8008-31-9]

Tangerine Oil [8016-85-1]

Turpentine Oil [8006-64-2]

Turpentine [9005-90-7]

Environment and Climate Change Canada

Health Canada

March 2020

Summary of Proposed Risk Management

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

- Rose oil [CAS RN[1] 8007-01-0]
- Mandarin oil [CAS RN 8008-31-9]
- Tangerine oil [CAS RN 8016-85-1]
- Turpentine [CAS RN 9005-90-7]
- Turpentine oil [CAS RN 8006-64-2]

In particular, the Government of Canada is considering:

- Measures to reduce exposures of infants and toddlers to rose oil from certain cosmetics by describing rose oil as a prohibited or restricted ingredient on the Health Canada Cosmetic Ingredient Hotlist;
- Measures to reduce exposures to mandarin oil and tangerine oil from certain cosmetics by describing mandarin oil and tangerine oil as prohibited or restricted ingredients on the Health Canada Cosmetic Ingredient Hotlist;
- Measures to reduce an increase in exposure to mandarin oil and tangerine oil in natural health products;
- Measures to reduce exposure to turpentine and turpentine oil in certain products available to consumers and natural health products; and to prevent an increase in exposure to these substances in cosmetics.

Moreover, because certain data gaps remain, the following information should be provided (ideally on or before May 13, 2020, 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 rose oil, mandarin oil, tangerine oil, turpentine oil and turpentine in products that are available to consumers;
- Current quantities and/or concentrations of each of the components that make up rose oil, mandarin oil, tangerine oil, turpentine oil and turpentine in products that are available to consumers;
- Potential alternative substances to rose oil, mandarin oil, tangerine oil, turpentine oil and turpentine for use in cosmetics, natural health products and in certain consumer products;

[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.

- Socio-economic and technical impacts if the import and/or use of rose oil, mandarin oil, tangerine oil, turpentine oil and turpentine is prohibited or restricted in certain applications in Canada; and
- The minimum concentration of turpentine and/or turpentine oil in paint thinners and removers that will maintain performance function.

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.

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 15 substances referred to collectively as the Acyclic, Monocyclic and Bicyclic Monoterpenes Group, to the determine whether these substances present or may present a risk to the environment or human health in Canada. The substances in the Acyclic, Monocyclic and Bicyclic Monoterpenes Group are bois de rose oil, palmarosa oil, geranium oil, coriander oil, rose oil, lemongrass oil, geranyllinalool, mandarin oil, tangerine oil, sweet orange oil, alpha-pinene, turpentine oil, turpentine, fir oil and pine oil. A notice summarizing the scientific considerations of the risk assessment conclusions for these substances was published in the *Canada Gazette*, Part I*,* on March 7, 2020 (Canada 2020a).

2.1 Draft Screening Assessment Conclusion

On the basis of the information available, the draft screening assessment proposes that rose oil, mandarin oil, tangerine oil, turpentine oil and turpentine (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, 2020).

It is proposed to conclude that the 15 substances in the Acyclic, Monocyclic and Bicyclic Monoterpenes 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

[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.

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 rose oil, turpentine oil, and turpentine do not meet the persistence or bioaccumulation criteria, while mandarin and tangerine oil meet the bioaccumulation but not the persistence 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 combined dermal and inhalation exposure from rose oil in body lotions; combined dermal and inhalation exposure from mandarin and tangerine oils in body lotions; oral exposure to mandarin and tangerine oils from dietary supplements; and combined dermal and inhalation exposure from turpentine and turpentine oil in paint thinners, paint removers, topical medicated vapour products and topical counterirritant products. As such, this document will focus on these applications and exposure sources of concern (refer to section 5.2).

Of note, the proposed risk management options 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 Acyclic, Monocyclic and Bicyclic Monoterpenes Group, refer to the Terpenes and Terpenoids: Acyclic, Monocyclic and Bicyclic Monoterpenes Group dSAR.

2.2 Proposed Recommendation under CEPA

Based on the findings of the draft screening assessment conducted under CEPA, the Ministers propose to recommend that rose oil, mandarin oil, tangerine oil, turpentine oil and turpentine be added to the List of Toxic Substances in Schedule 1 of the Act[4].

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 rose oil, mandarin oil, tangerine oil, turpentine oil and turpentine 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).

[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.

3. Proposed Risk Management

3.1 Proposed Human Health Objectives

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. As such, the proposed human health objective is to reduce exposure of the general population to rose oil, mandarin oil, tangerine oil, turpentine oil and turpentine 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 reduce exposure of infants and toddlers to rose oil in certain cosmetics to levels which are protective of human health;
2. To reduce exposure of the general population to mandarin oil and tangerine oil in certain cosmetics and certain natural health products to levels which are protective of human health;
3. To reduce exposure of the general population to turpentine and turpentine oil in certain products available to consumers and certain natural health products to levels which are protective of human health and to prevent an increase of these substances in cosmetics.

Such objectives 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 may be outlined in section 6 of this document). Revised human health and risk management objectives 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.

3.3 Proposed Risk Management Options under Consideration

To achieve the proposed risk management objectives and to work towards achieving the proposed human health objective, the risk management options under consideration are:

Rose Oil

- Communicating measures to reduce exposures of infants and toddlers to rose oil from certain cosmetics. These could include addition of rose 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*.

Mandarin and Tangerine Oils

- Communicating measures to reduce exposures to mandarin and tangerine oil from certain cosmetics. These could include addition of mandarin and/or tangerine oil and their major components (i.e. gamma-terpinene), 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*.
- Measures to prevent an increase in exposure to mandarin and tangerine oil in certain natural health products by modifying the existing entry(ies) in the NHPID.

Turpentine and Turpentine Oil

- Measures to help reduce consumer exposure to turpentine and turpentine oil in paint thinners and removers, and exposure from use as non-medicinal ingredients in topical medicated vapour products and topical counterirritant products, through the implementation of regulatory or non-regulatory controls. These could include voluntary actions by industry via mechanisms such as a code of practice; and/or regulatory actions under CEPA such as application of Significant New Activity (SNAc) provisions or regulations. A SNAc would require any proposed new manufacture, import, or use of certain consumer products to be subject to further assessment and potential risk management. Measures may also include addition of concentration restrictions to turpentine and turpentine oil and their major components (i.e., alpha-pinene), to the NHPID and the application of SNAc provisions to turpentine and turpentine oil in cosmetics to prevent increases in exposure.

Note that the proposed risk management options described in this document are 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, in the instrument selection and development process[5]. The risk management options 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

Performance measurement evaluates the ongoing effectiveness and relevance of the actions taken to manage risks from toxic substances[6]. 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 ensure that risks are managed effectively over time. To achieve this, the Government of Canada will review, on a regular basis, the effectiveness of the risk management action(s) for rose oil, mandarin oil, tangerine oil, turpentine, and turpentine oil.

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, information gathering mechanisms, such as those outlined in the *Canadian Environmental Protection Act, 1999* on the presence of rose oil, mandarin oil, tangerine oil, turpentine, and turpentine oil in certain consumer products, cosmetic products and/or natural health 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.

[5] 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).

[6] 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
- Substance-based performance measurement 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).

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 rose oil, mandarin oil, tangerine oil, turpentine oil and turpentine in products that are available to consumers;
- Current quantities and/or concentrations of each of the components that make up rose oil, mandarin oil, tangerine oil, turpentine oil and turpentine in products that are available to consumers;
- Potential alternative substances to rose oil, mandarin oil, tangerine oil, turpentine oil and turpentine for use in cosmetics, natural health products and in certain consumer products;
- Socio-economic and technical impacts if the import and/or use of rose oil, mandarin oil, tangerine oil, turpentine oil and turpentine is prohibited or restricted in certain applications in Canada; and
- The minimum concentration of turpentine and/or turpentine oil in paints thinners and removers that will maintain performance function.

Should stakeholders have further information to help address these gaps, they should provide it ideally on or before May 13, 2020 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 Rose Oil, Mandarin Oil, Tangerine Oil, Turpentine Oil and Turpentine

Rose oil, mandarin oil, tangerine oil, turpentine and turpentine oil are organic substances within the Acyclic, Monocyclic and Bicyclic Monoterpenes Group of the Terpenes and Terpenoids, which also includes ten other substances. 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 (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. Mandarin oil and tangerine oil, and turpentine and turpentine oil, were grouped and considered together for the screening assessment based on structure, origin, and the fact that they are often used interchangeably in literature. All of the substances in the Acyclic, Monocyclic, and

Bicyclic Monoterpenes Group, except turpentine oil, have been included in surveys issued under section 71 of CEPA (Canada 2012).

4.2 Current Uses and Identified Sectors

4.2.1 Rose 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 rose oil in 2011 (Environment Canada 2013).

Canadian sectoral uses of rose oil were reported in cosmetics and natural health products. Rose oil is used in concentrations ranging from <0.1%-100% in greater than 900 cosmetic products. Some of the product types reported include body lotion, massage products, cleansers, fragrance, make-up, hair care, and bath products (Environment Canada 2013). The majority of products (>75%) contain rose oil at concentrations of ≤1%. *Rosa damascena* flower oil listed in the NHPID, which have non-medicinal roles for topical uses as well as Rose essential oil with a medicinal roles in certain natural health products (NHPID 2019). Rose essential oil has a concentration restriction of 1-2% in aromatherapy products (NHPID 2019). *Rosa damascena* flower oil, rose essential oil and rose oil are currently listed in the Licensed Natural Health Products Database (LNHPD) as being present as non-medicinal ingredients in currently licensed natural health products (i.e. skin lotions) (LNHPD 2019).

Globally, rose oil has a long history of use in traditional medicine for treating ailments including digestive and gynecological diseases, headaches and eye issues (Kirov and Vankov 1988). It is listed as a fragrance ingredient used in consumer goods by the International Fragrance Association (IFRA 2018), and in Europe as a masking and skin conditioning agent in cosmetics (COSING 2018). Rose oil is also used as a fragrance in household cleaning products, including all-purpose cleaners, dish and laundry care products (ACI 2018).

The Food Chemicals Codex indicates that rose oil functions as a flavouring agent (FCC 1996). Rose oil is also listed in Fenaroli's Handbook of Flavor Ingredients (Burdock 2010) and the US FDA Substances Added to Food Inventory (US FDA 2018a). No definitive information is available concerning the potential use of rose oil as a food flavouring agent in Canada (personal communication, emails from Foods Directorate to Existing Substances Risk Assessment Bureau, 2018; unreferenced).

4.2.2 Mandarin and Tangerine Oils

Based on information submitted pursuant to section 71 of CEPA (Canada 2012), there were no reports of manufacture above the reporting threshold of 100 kg for mandarin or tangerine oils in 2011 (Environment Canada 2013). Between 100 and 1 000 kg of mandarin and tangerine oils were imported into Canada during the same calendar year (Environment Canada 2013).

Canadian sectoral uses of mandarin oil and tangerine oil were reported in cosmetics and natural health products. Mandarin oil and tangerine oil are derived from *Citrus reticulata* plant species. Mandarin oils, tangerine oils and *Citrus reticulata* peel oil (with various synonyms such as *C. nobilis*, *C. tangerina* and *C. depressa*) are used in concentrations ranging from <0.1%-100% in more than 675 cosmetics products. The majority of products (>75%) contain these substances at a concentration of ≤1%. Mandarin and tangerine cold-pressed essential oils are listed in the NHPID with a non-medicinal role as a flavour enhancer with the restriction that when used in cosmetic products, the total concentration of furocoumarin-like substances in the finished product must not exceed 1 ppm (NHPID 2019). Mandarin and tangerine oils are currently listed in the LNHPD and are notified to be present in natural health products (LNHPD 2019). Some of the product types reported include sunscreens, body lotions, fragrances, massage products and aromatherapy (Environment Canada 2013). *Citrus reticulata* also produces *Citrus nobilis* (mandarin orange) peel oil, *Citrus reticulata* (tangerine) peel oil, and *Citrus reticulata* (tangerine) leaf oil, which are listed in the NHPID for non-medicinal roles as fragrance ingredients, flavour enhancer and skin-conditioning agents, and in the LNHPD as being in natural health products (NHPID 2019, LNHPD 2019). Reported uses as non-medicinal ingredients included vitamins, acne treatments, sunscreens, lotions, and aromatherapy essential oils (dermal and/or inhalation route).

Mandarin and tangerine oils are listed as fragrance ingredients used in consumer goods by the International Fragrance Association (IFRA 2018) and mandarin oil is also used in aromatherapy. In Europe, mandarin oil is used as a deodorant, flavouring, masking, perfuming and skin protection agent in cosmetics, and tangerine oil is used for similar functions as a fragrance, skin conditioning and masking agent (COSING 2018). Mandarin oil is also used as a fragrance in household cleaning products, including all-purpose cleaners, dish and laundry care products (ACI 2018).

Both oils are listed in the Food Chemicals Codex as a flavouring agent (FCC 1996), in Fenaroli's Handbook of Flavor Ingredients (Burdock 2010) and the US FDA Substances Added to Food Inventory (US FDA 2018a). No definitive information is available concerning the potential use of mandarin and tangerine oils as a food flavouring agent in Canada (personal communication, emails from Foods

Directorate to Existing Substances Risk Assessment Bureau, 2017; unreferenced).

4.2.3 Turpentine and Turpentine Oil

Based on information submitted pursuant to section 71 of CEPA (Canada 2012), 18 388 123 kg of turpentine was manufactured in Canada and there were no reports of import above the reporting threshold of 100 kg for turpentine in 2011 (Environment Canada 2013). Turpentine oil was not included in the survey, however according to the Canadian International Merchandise Trade Database (CIMT), 17227 kg of 'gum, wood or sulphate turpentine oils', with the HS Code (380510), were imported between 2014-2017 (CIMT 2018).

Canadian sectoral uses of turpentine or turpentine oil were reported for natural health products, cosmetics, paints and coatings, adhesives and sealants, and automotive sectors. Turpentine oil is listed in the NHPID as being permitted for non-medicinal, topical uses; Turpentine essential oil and turpentine oil are also permitted as a medicinal ingredient in counterirritant products (6-50%) (NHPID 2019). Turpentine oil is listed in the LNHPD as being present as a medicinal ingredient in counterirritant products, and as a non-medicinal ingredient in natural health products, including skin, hair care, counterirritants and decongestants (LNHPD 2019). Turpentine essential oil is also listed on the LNHPD and is reported to be used as a medicinal ingredient in licensed products including counterirritant products (LNHPD 2019). Turpentine/turpentine oil were also reported in a limited number of cosmetic products ($\leq$0.1%). Turpentine is listed as a fragrance ingredient used in consumer goods by the International Fragrance Association (IFRA 2018). In Europe, turpentine and turpentine oil are listed as substances which cosmetic products must not contain except subject to the restriction that peroxide levels be <10 mmoles/L (COSING 2018).

Turpentine or turpentine oil may also be used as an odour agent in cleaning and furniture care products, laundry and dishwashing products, as well as automotive care products, shoe polishes, and turpentine solvents. Previously, turpentine was used as the most popular paint and varnish thinner, however the introduction of newer formulations of paints and coatings products have reduced the need for turpentine solvents, and they are currently mostly used in specialty applications such as spray painting, pottery and ceramic coatings, and artist's paints (NTP 2002).

Turpentine and turpentine oil are listed in the Food Chemicals Codex (FCC) as a flavouring agent (FCC 1996), in Fenaroli's Handbook of Flavor Ingredients (Burdock 2010), and the US FDA Substances Added to Food Inventory (US FDA 2018a). No definitive information is available concerning the potential use of turpentine or turpentine oil as a food flavouring agent in Canada (personal communication, emails from Foods Directorate to Existing Substances Risk Assessment Bureau, 2017; unreferenced). Turpentine oil has also been identified as an incidental food additive from cleaners, however there is no potential for direct

food contact since use of the cleaners is followed by a potable water rinse (personal communications, emails from Food Directorate, Health Canada, to Existing Substances Risk Assessment Bureau, Health Canada, 2017; unreferenced).

5. Exposure Sources and Identified Risks

5.1 Rose Oil

Exposure of the general Canadian population to rose oil is likely to occur from the daily use of cosmetics. The critical health effect associated with rose oil identified in the draft screening assessment (Canada 2020b) is based on a significant and dose related decrease in hematocrit and hemoglobin values and spleen effects. Estimated combined dermal and inhalation exposure from body lotions containing 3% rose oil was compared to the critical effect levels which resulted in margins of exposure (MOEs) considered inadequate to address uncertainties in the health effects and exposure databases, specifically for infants and toddlers.

Exposures to rose oil from environmental media, and food flavouring were not considered to pose a risk to human health.

5.2 Mandarin and Tangerine Oils

Exposure of the general Canadian population to mandarin and tangerine oils is likely to occur from the use of cosmetics and natural health products. The critical health effect associated with mandarin and tangerine oils identified in the draft screening assessment (Canada 2020b) is based on developmental effects. Estimated combined dermal and inhalation exposure from body lotions containing 5% mandarin or tangerine oil, and oral exposure from dietary supplements that contain 3.53% mandarin and tangerine oils per capsule (recommended twice daily) were compared to the critical effect levels which resulted in MOEs considered inadequate to address uncertainties in the health effects and exposure databases.

Exposures to mandarin oil and tangerine oil from food flavouring and consumer products including household all-purpose cleaners and laundry soaps were not considered to pose a risk to human health.

5.3 Turpentine and Turpentine Oil

Exposure of the general Canadian population to turpentine and turpentine 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 turpentine/turpentine oil identified in the draft screening assessment (Canada 2020b) are, depending on the exposure duration liver and kidney effects, or effects on the bladder and male reproductive system. Estimated combined short-term dermal and inhalation exposure from paint thinners and paint removers with a

concentration of 100% turpentine, from a topical medicated vapour product with 2% turpentine oil, and from a topical counterirritant product with 25% turpentine oil, was compared to the critical effect levels which resulted in MOEs for considered inadequate to address uncertainties in the health effects and exposure databases.

Exposures to turpentine and turpentine oil from environmental media, food flavouring, cosmetics, and consumer products including shoe polish, furniture paste wax and car wax were not considered to pose a risk to human health.

6. Risk Management Considerations

6.1 Alternatives and Alternate Technologies

Alternative cosmetic and natural health products are available that do not use rose oil, mandarin oil, tangerine oil, turpentine oil or turpentine.

- For products that use the aforementioned substances as a fragrance, masking or skin conditioning agent, in cosmetics and natural health products, substances are available that have a similar function.
- For dietary supplements there are substances available other than mandarin oil or tangerine oil for use as non-medicinal flavouring ingredients.
- For topical medicated vapour products and topical counterirritant products, there are substances available other than turpentine oil for use as non-medicinal ingredients (HC 2015; LNHPD 2019; NHPID 2019).

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 Regulatory Management* (TBS 2012) and the guidance provided in the Treasury Board document *Assessing, Selecting, and Implementing Instruments for Government Action* (TBS 2007).

7. Overview of Existing Risk Management

7.1 Related Canadian Risk Management Context

Domestically, the existing risk management actions are as follows:

7.1.1 Rose Oil

Food and Drugs Act

Food: Rose oil may be used as a food flavouring agent in Canada. In Canada, the safety of food flavouring agents is subject to the provisions of section 4(1)(a) of the Food and Drugs Act. The safety of chemicals used in food packaging materials is subject to the provisions of Division 23 of the Food and Drug Regulations and section 4(1)(a) of the Food and Drugs Act.

Cosmetics: Rose oil is present in cosmetics based on notifications submitted under the *Cosmetic Regulations*; it is not currently included on Health Canada's Cosmetic Ingredient Hotlist (HC 2015).

Natural Health Products: Provence rose essential oil, and Rosa Damascena Flower oil, and as medicinal ingredients in aromatherapy products with a quantity restriction of 1-2%, under the *Natural Health Products Regulations* (NHPID 2019).

Pesticides: Rose oil is listed on the Pest Management Regulatory Agency (PMRA) formulant list for pest control products currently registered in Canada under the Pest Control Products Act and Regulations (PMRA, 2017).

7.1.2 Mandarin and Tangerine Oils

Food and Drugs Act

Food: Mandarin oil and tangerine oil may be used as a food flavouring agent in Canada. In Canada, the safety of food flavouring agents is subject to the provisions of section 4(1)(a) of the Food and Drugs Act. The safety of chemicals used in food packaging materials is subject to the provisions of Division 23 of the Food and Drug Regulations and section 4(1)(a) of the Food and Drugs Act.

Cosmetics: Mandarin oil and tangerine oil are present in cosmetics based on notifications submitted under the *Cosmetic Regulations*; they are not currently included on Health Canada's Cosmetic Ingredient Hotlist (HC 2015).

Natural Health Products: Mandarin essential oil is permitted for non-medicinal use as a flavour enhancer in natural health products, with the restriction that when used in cosmetic products, the total concentration of furocoumarin-like substances in the finished product must not exceed 1 ppm, under the *Natural Health Products Regulations* (NHPID 2019). There are other oils such as has *Citrus nobilis* (mandarin orange) peel essential oil (NMI), *Citrus reticulata* (tangerine) peel essential oil (NMI), *Citrus reticulata* (tangerine) leaf oil (NMI), *Citrus reticulata* (Tangerine) Peel Oil (NMI), *Citrus nobilis* Peel Oil (NMI)- refer to dSAR

Pesticides: Mandarin oil and tangerine oil are listed on the Pest Management Regulatory Agency (PMRA) formulant list for pest control products currently registered in Canada under the Pest Control Products Act and Regulations (PMRA, 2017).

Feeds Act, 1985

Feeds Regulations, 1983 (Government of Canada, 1983) under the *Feeds Act,* lists flavouring agents that have been evaluated and approved for manufacture, import and sale for use in livestock feed in Canada, including mandarin/tangerine oil.

7.1.3 Turpentine and Turpentine Oils

Canada Consumer Product Safety Act (CCPSA)

Toys: The *Toys Regulations SOR/2011-17* (Government of Canada, 2010) states that toys must not contain turpentine, or any substance that contains more than 10% weight to volume of turpentine, if they could become accessible to children or released on breakage/leakage.

Food and Drugs Act

Food: Turpentine and turpentine oil may be used as a food flavouring agent in Canada. In Canada, the safety of food flavouring agents is subject to the provisions of section 4(1)(a) of the Food and Drugs Act. The safety of chemicals used in food packaging materials is subject to the provisions of Division 23 of the Food and Drug Regulations and section 4(1)(a) of the Food and Drugs Act.

Cosmetics: Turpentine and turpentine oil are present in cosmetics based on notifications submitted under the *Cosmetic Regulations*; they are not currently included on Health Canada's Cosmetic Ingredient Hotlist (HC 2015).

Natural Health Products: Turpentine oil is permitted for topical use as a non-medicinal as a fragrance, base, or viscosity decreasing agent, and turpentine essential oil permitted as a medicinal ingredient in topical counterirritants (6-50%), under the *Natural Health Products Regulations* (NHPID 2019).

Pesticides: Turpentine and turpentine oil are listed on the Pest Management Regulatory Agency (PMRA) formulant list for pest control products currently registered in Canada under the Pest Control Products Act and Regulations (PMRA, 2017).

Provincial & Territorial Legislation

There are several provincial and territorial occupational health and safety regulations regarding both short-term and long-term exposures to turpentine:

- There are *Occupational Health and Safety Regulations* in Nunavut, Northwest Territories, Ontario and Saskatchewan that limit the exposure to workers from turpentine and turpentine oil to a 20 ppm for an 8 hour period and to 30 ppm for a 15 minute exposure (Nunavut 2016, NWT 2015, Ontario, 1990, Saskatchewan 1996*)*.

- Yukon's *Occupational Health and Safety Regulations* limit the exposure to workers to 100 ppm for an 8 hour time period and to 150 ppm for a 15 minute exposure (Yukon 1986).
- Quebec's *Occupational Health and Safety Regulations* limit the exposure of workers to 100 ppm in gases, dusts, fumes, vapours or mists, and the Regulation Respecting the Quality of the Work Environment, limit exposure to 20 ppm in air, both for an 8 hour period (Quebec 2018, Quebec 2018).
- The *Hazardous Substances and Waste Dangerous Goods Regulations* from Saskatchewan, lists restrictions to ensure safe storage and disposal of hazardous materials, including turpentine (Saskatchewan 1989).

7.2 Pertinent International Risk Management Context

Internationally, existing risk management actions are as follow:

7.2.1 Rose Oil

United States

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

Food: Rose oil is listed as a flavouring agent for food for human consumption, as a substance generally recognized as safe; essential oils, oleoresins (solvent-free), and natural extractives (including distillates) (as specified in 21CFR 182.20; United States Food and Drug Administration [US FDA 2017]).

Cosmetics: Rose oil is not currently included on the US FDA's List of Prohibited and Restricted Ingredients from use in cosmetics.

***Federal Insecticide, Fungicide and Rodenticide Act* (FIFRA)**
Rose oil is listed as an inert ingredient on the US EPA's Fragrance Ingredient List, and is approved for use in pesticide products as a fragrance use only. As an approved fragrance, it is subject to the requirements under the US EPA's Pesticide Fragrance Notification Pilot Program (US 2015).

European Union

Feeds Regulations
Rose oil is listed under the *Commission Implementing Regulation (EU) No 230/2013 of 14 March 2013 on the withdrawal from the market of certain feed additives belonging to the group of flavouring and appetising substances*, which states that rose oil must be withdrawn from feed stocks on the market, for all species (EU 2013).

7.2.2 Mandarin and Tangerine Oils

United States

***Federal Food, Drug and Cosmetic Act* (FD&C Act)**
Food: Mandarin oil and tangerine oil are listed as flavouring agents for food for human consumption, as substances generally recognized as safe; essential oils, oleoresins (solvent-free), and natural extractives (including distillates) (as specified in 21CFR 182.20; United States Food and Drug Administration [US FDA 2017]).

Cosmetics: Mandarin oil and tangerine oil are not currently included on the US FDA's List of Prohibited and Restricted Ingredients from use in cosmetics.

***Federal Insecticide, Fungicide and Rodenticide Act* (FIFRA)**
Mandarin oil is listed as an inert ingredient on the US EPA's Fragrance Ingredient List, and is approved for use in pesticide products as a fragrance use only while tangerine oil is approved for use in pesticide products as a fragrance for non-food use only. As approved fragrances, both mandarin oil and tangerine oil are subject to the requirements under the US EPA's Pesticide Fragrance Notification Pilot Program (US 2015).

European Union

Cosmetics Products Regulations
Mandarin oil is listed under *Commission Regulation (EC) No 1223/2009 of the European Parliament and of the Council of November 2009 on cosmetic products* with restriction that furocoumarines (e.g. trioxysalen, 8-methoxypsoralen, 5-methoxypsoralen) are prohibited in cosmetic products, except for if normal content in natural essences used, and that in sun protection and in bronzing products, furocoumarines shall be below 1 mg/kg (EU 2009, COSING 2018).

Feeds Regulations
Mandarin oil and tangerine oil are listed under the *Commission Implementing Regulation (EU) No 230/2013 of 14 March 2013 on the withdrawal from the market of certain feed additives belonging to the group of flavouring and appetising substances*, which state these substances, must be withdrawn from feed stocks on the market, for all species (EU 2013).

7.2.3 Turpentine and Turpentine Oils

United States

***Federal Food, Drug and Cosmetic Act* (FD&C Act)**
Food: Turpentine and turpentine oil are listed as flavouring agents for food for human consumption, as substances generally recognized as safe; essential oils, oleoresins (solvent-free), and natural extractives (including distillates) (as specified under 21CFR 182.20; United States Food and Drug Administration [US FDA 2017]). Turpentine and turpentine oil are also permitted as flavouring directly

added to foods intended for human consumption under 21 CFR §172.510 Food Additives Permitted for Direct Addition to Food for Human Consumption Subpart F- Flavoring Agents and Related Substances (US FDA 2018b). Additionally, adhesives which contain turpentine and turpentine oil may be safely used as components of articles intended for use in packaging, transporting, or holding food (in accordance with the prescribed conditions) under 21 CFR §175.105 Indirect Food Additives: Adhesive components of coatings (US FDA 2018c).

Cosmetics: Turpentine and turpentine oil are not currently included on the US FDA's List of Prohibited and Restricted Ingredients from use in cosmetics.

Commercial Practices Regulations: Turpentine and turpentine oil are used in consumer products such that these substances are regulated for commercial practices. These include:

- *16 CFR §1500.14 Products Requiring Special Labeling Under Section 3(b) of the Act* (US 1973b), which states that products containing ≥10% by weight of turpentine shall be labelled with the signal word for "danger" and the statement of hazard "harmful or fatal if swallowed".
- *16 CFR §1700.14 Substances Requiring Special Packaging* (US 1973c) states that household substances in liquid form containing ≥10% by weight of turpentine shall be packaged in accordance with the provisions of *§1700.15 Poison prevention packaging standards.*
- *16 CFR §1500.83 Exemptions for Small Packages, Minor Hazards, and Special Circumstances (*US 1973a) that provides a labeling exemption for certain products that contain turpentine based on the viscosity of the product (US 1973d).

Transportation: Turpentine is listed in the *49 CFR §172.101 Hazardous Materials Table,* which regulates the safe transportation of hazardous materials including, packaging, spills, emergency response measures, etc. (US 1990).

***Federal Insecticide, Fungicide and Rodenticide Act* (FIFRA)**
Turpentine oil is listed as an inert ingredient on the US EPA's Fragrance Ingredient List, and is approved for use in pesticide products as a fragrance use only while turpentine is approved for use in pesticide products as a non-food use only. As approved fragrances, both turpentine oil and turpentine are subject to the requirements under the US EPA's Pesticide Fragrance Notification Pilot Program (US 2015).

Occupational Health and Safety Regulations
Occupational Health and Safety concerns regarding turpentine and turpentine oil are addressed under 29 CFR §1910.1000 Occupational Safety and Health Standards; Air contaminants, and 29 CFR §1926.55 Safety and Health Regulations for Construction (US 2011, US 2018).

<u>European Union</u>

Cosmetics Products Regulations
Turpentine and turpentine oil are listed under *the Commission Regulation (EU) No 344/2013* including amending Annexes II, III, V and VI to *Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products*, which states that cosmetic products must not contain turpentine and turpentine oil, except subject to the restriction that the peroxide value is less than 10 mmoles/L (EU 2009, COSING 2018).

Consumer Products Regulations
Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, implemented to harmonize criteria for classification and labeling within the EU (EU 2008). Products that contain turpentine require labeling with a GHS pictogram, and hazard or precautionary statement (dependent on product).

7.2.3 Other Jurisdictions

In Australia, turpentine and turpentine oil are listed under the Poisons Standard—the Standard for the Uniform Scheduling of Medicines and Poisons in Schedule 5 such that these substances cannot be sold except in preparations containing ≤25% of turpentine or turpentine oil (Australian Government, 2018).

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 May 13, 2020. The Risk Management Approach document, which will outline and seek input on the proposed risk management instruments, will be published 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 rose oil, mandarin oil, tangerine oil, turpentine oil and turpentine are encouraged to identify themselves as stakeholders. The stakeholders will be informed of future decisions regarding rose oil, mandarin oil, tangerine oil, turpentine oil and turpentine and may be contacted for further information.

8.2 Timing of actions

Action	Date
Electronic consultation on the Risk Management Scope	March 14, 2020 to May 13, 2020
Submission of public comments, additional studies and information on rose oil, mandarin oil, tangerine oil, turpentine oil and turpentine	On or before May 13, 2020
Publication of the follow-up s.71 Notice or other data collection initiatives	2020
Publication of responses to public comments on the draft screening assessment and Risk Management Scope	No later than the time of publication of the final screening assessment
Publication of the final screening assessment and, if required, the Risk Management Approach document	2021 (tentatively)
Publication of responses to public comments on the Risk Management Approach, if applicable and if required, the proposed instruments	At the latest, 24-month from the publication of the final screening assessment
Consultation on the proposed instruments, if required	60-day public comment period starting upon publication of the proposed instruments
Publication of the final instrument(s), if required	At the latest, 18-month from the publication of each proposed instrument

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[US FDA] US Food and Drug Administration. 2018c. Code of Federal Regulations Title 21, Volume 3: Section 175.105 Indirect Food Additives: Adhesives and Components of Coatings.

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ANNEX A. List of targeted substances

CAS RN	DSL Name (English)	Common name/ Simplified name
8007-01-0	Oils, rose	rose oil
8008-31-9	Oils, mandarin	mandarin oil
8016-85-1	Oils, tangerine	tangerine oil
8006-64-2	Turpentine, oil	turpentine oil
9005-90-7	Turpentine	turpentine