Government of Canada | Gouvernement du Canada

Risk Management Scope

for

Terpenes and Terpenoids

Phenylpropanoids and Aldehydes Group:

Oils, bay (Bay oil),

Oils, tarragon (Tarragon oil),

Oils, jasmine (Jasmine oil),

Perfumes and essences, jasmin (Perfumes and essences of jasmin),

Oils, violet (Violet oil),

Benzenepropanol, 4-(1,1-dimethylethyl)-α-methyl- (Lilial)

Chemical Abstracts Service Registry Numbers (CAS RNs):

8006-78-8, 8016-88-4, 8022-96-6,

8024-43-9, 8024-08-6, and 80-54-6

Environment and Climate Change Canada

Health Canada

February 2024

Canada

Summary of proposed risk management

This document outlines the risk management options under consideration for bay oil, tarragon oil, jasmine oil, perfumes and essences of jasmin, violet oil, and lilial, which have been proposed to be harmful to human health. In particular, the Government of Canada is considering the options below to address the health concerns:

1. Cosmetics:
   - Measures to help reduce inhalation and/or dermal exposures to tarragon oil, jasmine oil, perfumes and essences of jasmin, violet oil, and lilial from certain cosmetics by describing these substances as prohibited or restricted ingredients on Health Canada's Cosmetic Ingredient Hotlist.

2. Natural health products (NHPs):
   - Measures to help reduce inhalation and/or dermal exposures to jasmine oil and perfumes and essences of jasmin from certain NHPs by describing these substances as restricted ingredients on Health Canada's Natural Health Products Ingredients Database (NHPID). Actions may aim to lower the concentration of these substances when used as non-medicinal ingredients (NMIs) in certain topical NHPs to levels that are protective of human health.

3. Certain consumer products, including air freshener products or essential oils sold directly to consumers in vials for use in do-it-yourself (DIY) applications:
   - Regulatory or non-regulatory actions to help reduce dermal and/or inhalation exposures to bay oil, tarragon oil, jasmine oil, perfumes and essences of jasmin, violet oil, and lilial from certain consumer products to levels that are protective of human health. A public communications approach for essential oils of concern for human health is also being considered.

Information on the following items should be provided (on or before April 3rd, 2024), to the contact details identified in section 8 of this document, to inform risk management decision-making:

- Potential alternative substances to tarragon oil, jasmine oil, perfumes and essences of jasmin, violet oil, and lilial for use in cosmetics;
- Potential alternative substances to jasmine oil and perfumes and essences of jasmin for use as NMIs in NHPs;
- Current quantities and concentrations of bay oil, tarragon oil, jasmine oil, perfumes and essences of jasmin, and violet oil used in consumer product DIY applications identified as a concern;

- Potential alternative substances to bay oil, tarragon oil, jasmine oil, perfumes and essences of jasmin, and violet oil for use in consumer product DIY applications identified as a concern;
- Current quantities and concentrations of lilial used in air fresheners available to consumers;
- Potential alternative substances to lilial for use in air fresheners available to consumers; and
- Socio-economic and technical impacts and benefits associated with the proposed risk management for bay oil, tarragon oil, jasmine oil, perfumes and essences of jasmin, violet oil, and lilial.

The risk management options outlined in this risk management scope may evolve through consideration of assessments and risk management options published for other Chemicals Management Plan (CMP) substances as required to ensure effective, coordinated, and consistent risk management decision-making.

Note: For the purpose of this document, the definition of “do-it-yourself” is the use of certain terpenes and terpenoids at a concentration as high as 100% (as essential oils) to create homemade products such as massage oils, body moisturizers, bath products, as well as its use in aromatic diffusers or facial steamers.

The above summary is an abridged list of options under consideration to manage these substances and to seek information on identified information gaps and uncertainties. Refer to section 3 of this document for more complete details in this regard.

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1. Context

The *Canadian Environmental Protection Act, 1999* (CEPA) (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 harmful or dangerous to the environment or human health as set out in section 64 of CEPA[1,2], and if so to manage the associated risks.

The substances bay oil, tarragon oil, jasmine oil, perfumes and essences of jasmin, violet oil, lilial, verdantiol, myrac-aldehyde, myrmac-aldehyde, myrmac-carboxaldehyde, cetonal, and vernaldehyde, are included in the Terpenes and Terpenoids: Phenylpropanoids and Aldehydes Group of the Chemicals Management Plan (CMP) (Canada 2024). Refer to Annex A for a list of the substances and their respective Chemical Abstracts Service Registry Numbers (CAS RNs)[3].

2. Issue

2.1 Draft assessment conclusion

Health Canada and Environment and Climate Change Canada conducted a joint scientific assessment of the 12 substances that are part of the Terpenes and Terpenoids: Phenylpropanoids and Aldehydes Group. A notice summarizing the scientific considerations of the draft assessment for these 12 substances was

[1] 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.*

[2] A determination of whether one or more of the criteria of section 64 of CEPA 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 *Hazardous Products Regulations*, which are part of the regulatory framework for the Workplace Hazardous Materials Information System for products intended for workplace use. Similarly, a conclusion based on the criteria contained in section 64 of CEPA does not preclude actions being taken under other sections of CEPA or other Acts.

[3] 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.

published in the *Canada Gazette*, Part I, on February 3rd, 2024 (Canada 2024). For further information, refer to the draft assessment for the Phenylpropanoids and Aldehydes Group.

Based on the information available, the draft assessment proposes that bay oil, tarragon oil, jasmine oil, perfumes and essences of jasmin, violet oil, and lilial meet the criteria for toxic under paragraph 64(*c*) of CEPA as 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 2024).

The draft assessment also proposes that verdantiol, myrac-aldehyde, myrmac-aldehyde, myrmac-carboxaldehyde, cetonal, and vernaldehyde do not meet the criteria under section 64(*c*) of CEPA (Canada 2024).

It is also proposed that the 12 substances in the Phenylpropanoids and Aldehydes Group 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 under paragraphs 64(*a*) or (*b*) of CEPA, respectively (Canada 2024).

Although a risk to human health or the environment has not been identified at current levels of exposure, there may be a concern to human health if exposures to verdantiol, myrac-aldehyde, myrmac-aldehyde, myrmac-carboxaldehyde, cetonal, or vernaldehyde were to increase. As a result, these substances may be considered in future initiatives to track their commercial status or identify new uses.

The draft assessment also proposes that lilial meets the persistence criteria, but not the bioaccumulation criteria as set out in the *Persistence and Bioaccumulation Regulations* of CEPA (Canada 2000).

The exposure sources of concern, identified in the draft assessment, are based on potential dermal absorption and/or inhalation of tarragon oil, jasmine oil, perfumes and essences of jasmin, violet oil, and lilial from the use of certain cosmetics; inhalation and/or dermal exposures to jasmine oil and perfumes and essences of jasmin from the use of certain natural health products (NHPs); and dermal and/or inhalation exposures to bay oil, tarragon oil, jasmine oil, perfumes and essences of jasmin, violet oil, and lilial from the use of certain consumer products [for example, air fresheners or essential oils sold for use in do-it-yourself (DIY) applications]. As such, this document will focus on these specific exposure sources of concern (refer to section 5).

Of note, the proposed risk management options described in this document and the proposed conclusion outlined in the draft assessment are preliminary and may be subject to change.

2.2 Proposed recommendation under CEPA

On the basis of the findings of the draft assessment conducted pursuant to CEPA, the Ministers propose to recommend that bay oil, tarragon oil, jasmine oil, perfumes and essences of jasmin, violet oil, and lilial be added to Part 2 in Schedule 1 to CEPA[4].

Until regulations specifying criteria for the classification of substances that pose the highest risk or that are carcinogenic, mutagenic or toxic to reproduction are available, bay oil, tarragon oil, jasmine oil, perfumes and essences of jasmin, violet oil, and lilial are proposed to be recommended for addition to Part 2 of Schedule 1. Following the availability of the aforementioned criteria, the substance may be moved to Part 1 of Schedule 1, if applicable.

CEPA sets out a 2-track approach for managing risks.

Under sub-section 77(3), the Ministers are required to propose recommending the addition of a substance that poses the highest risk, as defined in paragraph (a), (b) or (c), to Part 1[5] of Schedule 1 of the Act and, in developing a proposed regulation or instrument respecting preventive or control actions, to give priority to the total, partial or conditional prohibition of activities in relation to the substance or to the release of the substance into the environment.

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[4] After an assessment of a given substance under Part 5 of CEPA, other than section 83, the Ministers shall propose one of the following measures: take no further action with respect to the substance, add the substance to the List referred to in section 75.1 of the Act (unless the substance is already on that List), recommend the addition of the substance to Part 1 of the list of toxic substances in Schedule 1 to CEPA (for substances that pose the highest risk) or recommend the addition of the substance to Part 2 of the list of toxic substances in Schedule 1 to CEPA (for other CEPA-toxic substances).

[5] Under subsection 77(3), a substance must be recommended for addition to Part 1 of Schedule 1 to the Act when the substance is determined to be toxic and the Ministers are satisfied that:

(a) the substance may have a long-term harmful effect on the environment and
    (i) is inherently toxic to human beings or non-human organisms, as determined by laboratory or other studies,
    (ii) is persistent and bioaccumulative in accordance with the regulations,
    (iii) is present in the environment primarily as a result of human activity, and
    (iv) is not a naturally occurring radionuclide or a naturally occurring inorganic substance;

(b) the substance may constitute a danger in Canada to human life or health and is, in accordance with the regulations, carcinogenic, mutagenic or toxic for reproduction; or

(c) the substance is, in accordance with the regulations, a substance that poses the highest risk.

For other substances recommended for addition to Part 2 of Schedule 1 of the Act, the Ministers shall give priority to pollution prevention, and this could include regulatory or non-regulatory measures such as prohibition if warranted.

The ministers will take into consideration comments submitted by stakeholders during the 60-day public comment period on the draft assessment and risk management scope. If the Ministers finalize the recommendation to add bay oil, tarragon oil, jasmine oil, perfumes and essences of jasmin, violet oil, and lilial to Part 2 of Schedule 1, risk management instruments must be proposed within 24 months from the date on which the Ministers recommended that bay oil, tarragon oil, jasmine oil, perfumes and essences of jasmin, violet oil, and lilial be added to Schedule 1 to CEPA, 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 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.

The proposed human health objective for bay oil, tarragon oil, jasmine oil, perfumes and essences of jasmin, violet oil, and lilial (the six proposed toxic substances in the Phenylpropanoids and Aldehydes Group) is to reduce exposure of the general population to these substances, 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 regulation(s), instrument(s) and/or tool(s) for a given substance or substances. In this case, the proposed risk management objectives for the six proposed toxic substances in the Phenylpropanoids and Aldehydes Group for the protection of human health are to:

- reduce dermal and/or inhalation exposures of the general public to tarragon oil, jasmine oil, perfumes and essences of jasmin, violet oil, and lilial from certain cosmetics (see detailed list below);
- reduce dermal and/or inhalation exposures of the general population to jasmine oil and perfumes and essences of jasmin from certain NHPs including facial moisturizer/acne treatment, sunscreens, and antiseptic skin cleansers;
- reduce dermal and/or inhalation exposures of the general population to bay oil, tarragon oil, jasmine oil, perfumes and essences of jasmin, violet oil, and lilial from certain consumer products, including air freshener products or essential oils sold directly to consumers in vials for use in DIY applications (see detailed list below).

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:

1. Cosmetics:
    - Measures to help reduce exposures to tarragon oil, jasmine oil, perfumes and essences of jasmin, violet oil, and lilial from certain cosmetics, listed below, by describing these substances as prohibited or restricted ingredients on 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 reduce inhalation exposure to:
            - Violet oil in massage oil (for children younger than 9 years of age).
        - Measures to reduce inhalation and dermal exposures to:
            - Tarragon oil in body moisturizer, body fragrance, and facial moisturizer.
            - Jasmine oil and perfumes and essences of jasmin in body moisturizer and body fragrance.
            - Lilial in body moisturizer, massage oil (for children younger than 9 years of age), body fragrance, facial moisturizer, solid antiperspirant/deodorant, permanent hair colour product, and hair straightening, waving, and curling product.

2. NHPs:
    - Measures to help reduce exposures to jasmine oil and perfumes and essences of jasmin from certain NHPs, listed below, by describing these substances as restricted ingredients on Health

Canada's Natural Health Products Ingredients Database (NHPID). Actions may aim to lower the concentration of these substances when used as non-medicinal ingredients (NMIs) in NHPs such as facial moisturizer/acne treatment, sunscreens, and antiseptic skin cleansers, to levels that are protective of human health, including:

- Measures to reduce inhalation and dermal exposures to:
  - Jasmine oil and perfumes and essences of jasmin when used as NMIs in facial moisturizer/acne treatment.
  - Jasmine oil and perfumes and essences of jasmin when used as NMIs in antiseptic skin cleansers.
- Measures to reduce dermal exposure to:
  - Jasmine oil and perfumes and essences of jasmin when used as NMIs in sunscreens (for children up to one year of age).

3. Certain consumer products, including air freshener products or essential oils sold directly to consumers in vials for use in DIY applications:

- Regulatory or non-regulatory actions that may include a public communications approach for essential oils of concern to human health to help reduce exposures to bay oil, tarragon oil, jasmine oil, perfumes and essences of jasmin, violet oil, and lilial from certain consumer products, listed below, to levels that are protective of human health, including:
  - Measures to reduce inhalation and dermal exposures to:
    - Bay oil sold to consumers for use in the following DIY applications: aromatic diffuser and body moisturizer.
    - Tarragon oil sold to consumers for use in the following DIY applications: aromatic diffuser, massage oil, body moisturizer, and bath oil product.
    - Jasmine oil and perfumes and essences of jasmin sold to consumers for use in the following DIY applications: aromatic diffuser, massage oil, body moisturizer, and facial steamer.
  - Measures to reduce inhalation exposure to:
    - Violet oil sold to consumers for use in the following DIY applications: aromatic diffuser and facial steamer (during use and for children younger than 9 years of age when the device is turned off after 20 minutes of use).
    - Lilial in solid gel air fresheners and in liquid plug-in air fresheners (for children younger than two years of age).

Following the publication of this risk management scope, 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[6]. The risk management options outlined in this document may evolve through consideration of assessments and risk management options published for other CMP substances to ensure effective, coordinated, and consistent risk management decision-making.

3.4 Risk management information gaps

In order to make informed decisions on proposed risk management, more information is requested on the following:

- Potential alternative substances to tarragon oil, jasmine oil, perfumes and essences of jasmin, violet oil, and lilial for use in cosmetics;
- Potential alternative substances to jasmine oil and perfumes and essences of jasmin for use as NMIs in NHPs;
- Current quantities and concentrations of bay oil, tarragon oil, jasmine oil, perfumes and essences of jasmin, and violet oil used in consumer product DIY applications identified as a concern;
- Potential alternative substances to bay oil, tarragon oil, jasmine oil, perfumes and essences of jasmin, and violet oil for use in consumer product DIY applications identified as a concern;
- Current quantities and concentrations of lilial used in air fresheners available to consumers;
- Potential alternative substances to lilial for use in air fresheners available to consumers; and
- Socio-economic and technical impacts and benefits associated with the proposed risk management for bay oil, tarragon oil, jasmine oil, perfumes and essences of jasmin, violet oil, and lilial.

3.5 Performance measurement and evaluation

Performance measurement evaluates the ongoing effectiveness and relevance of the actions taken to manage risks from toxic substances[7]. Environment and Climate Change Canada and Health Canada have developed a Performance Measurement Evaluation Strategy that sets out the approach to evaluate the

[6] The proposed risk management regulation(s), instrument(s) or tool(s) 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 Regulation (TBS 2018a), the Policy on Regulatory Development (TBS 2018b), the Red Tape Reduction Action Plan (TBS 2012), and in the case of a regulation the *Red Tape Reduction Act* (Canada 2015).

[7] Performance measurement strategy.

effectiveness of actions taken on substances found toxic under CEPA. 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 those substances. In evaluating progress and revisiting risk management, as warranted, these activities together will aim to manage risks effectively over time. To achieve this, the Government of Canada plans to review the effectiveness of the risk management action(s) for the six proposed toxic substances in the Phenylpropanoids and Aldehydes Group.

The Government of Canada plans to measure the effectiveness of the risk management actions by collecting and analyzing data to measure progress towards meeting the risk management objectives and human health objective.

The results of performance measurement and 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.

4. Background

Phenylpropanoids (that is, bay oil, tarragon oil, jasmine oil, and perfumes and essences of jasmin) are characterized by having a chain of three carbon atoms attached to a benzene ring, whereas the aldehydes (that is, violet oil and lilial) contain the –CHO functional group, and are considered as partially oxidized primary alcohols (Tisserand and Young 2014).

All of the substances in the Phenylpropanoids and Aldehydes Group, were included in a survey issued pursuant to a CEPA section 71 survey (Canada 2012). Based on the information submitted in response to this survey (Canada 2012), there were no reports of import or manufacture above the reporting threshold of 100 kg in 2011 for all of the substances except lilial (Environment Canada 2013). For lilial, 910 kg was manufactured in Canada in 2008 and 24 460 kg was imported into Canada during the same calendar year (Environment Canada 2013).

The 12 substances in the Phenylpropanoids and Aldehydes Group consist of discrete substances as well as substances that are of unknown or variable composition, complex reaction products, or biological materials (UVCBs). These UVCB substances are essential oils found in a wide variety of plants and are generally used as fragrances in cosmetics, NHPs, non-prescription and prescription drugs, cleaning products, and air fresheners. Some of them are also present in pest control products as formulants and some of them occur naturally in food and may be used as food flavouring agents.

For the human health risk assessment, nine of the 12 substances in this group were addressed under two subgroups, due to similarities in chemical structure, properties and/or toxicity. Phenylpropanoids Subgroup 1 included jasmine oil and perfumes and essences of jasmine. Aldehydes Subgroup 2 is comprised of the discrete substances lilial, verdantiol, myrac-aldehyde, myrmac-aldehyde, myrmac-carboxaldehyde, cetonal, and vernaldehyde. The remaining three substances (that is, bay oil, tarragon oil, and violet oil) were addressed individually. Owing to these similarities, it was also possible to assess many of the substances using read-across analogues. Furthermore, given the potential for these substances to be used in similar ways and applications, the potential for risk to human health was assessed using similar exposure assumptions across the subgroups as outlined below. The primary area of concern is the use of these substances in cosmetics, NHPs, and certain consumer products, including air freshener products and essential oil use in DIY applications. Certain substances in this group with aromatic properties are currently available on the Canadian market at a concentration of up to 100%. These undiluted substances can be purchased and used by consumers in aromatic diffusers and facial steamers, or to make DIY products such as homemade massage oils, bath products, or body moisturizers that may result in high consumer exposures.

5. Exposure sources and identified risks

5.1 Bay oil

The draft assessment considered the possible risks from exposure to bay oil based on the critical oral health effect of genotoxic carcinogenicity and subsequent extrapolation to dermal and inhalation exposures from one of its components, methyl eugenol, since the other main components of bay oil had no toxicological effects. The identified endpoint of concern for bay oil is genotoxic carcinogenicity related to the presence of methyl eugenol, based on the results of a multi-generational (2-year) National Toxicology Program (NTP) carcinogenicity study in rats (Suparmi et al. 2019). The draft assessment identified a health risk for dermal and inhalation exposure to bay oil from use in DIY aromatic diffusers and DIY body moisturizer. No other sources of exposure of concern were identified.

5.2 Tarragon oil

Similar to bay oil, as outlined in the draft assessment, the risks from exposure to tarragon oil are related to carcinogenicity, based on the presence of methyl eugenol, but also include estragole and elemicin. Risks to human health were identified from exposure to tarragon oil from its use in body moisturizer, body fragrance, and facial moisturizer, as well as its use in DIY aromatic diffusers, DIY

massage oil, DIY bath oil product, and DIY body moisturizer. No other sources of exposure of concern were identified.

5.3 Phenylpropanoids subgroup 1 (jasmine oil and perfumes and essences of jasmin)

The draft assessment considered the possible risks from exposure to substances in the Phenylpropanoids Subgroup 1 based on the critical oral health effect of female reproductive toxicity (oral exposure) and subsequent extrapolation for dermal exposure from jasmine extract in rats (Iqbal and Gosh 1993), since there was an absence of compositional information for perfumes and essences of jasmin. The identified endpoint of concern for the Phenylpropanoids Subgroup 1 is female reproductive toxicity for jasmine oil based on an increase of implantation loss, fetal mortality and resorption, and a decrease of fertility and progesterone level. For inhalation exposure, the risk was characterized for site-of-contact effects of phytol that induced inflammation in the lungs and a dose-responsive degeneration and necrosis of the respiratory tract (Schwotzer et al. 2021), respectively. The draft assessment identified a health risk for dermal exposure to jasmine oil and perfumes and essences of jasmin from sunscreen (NHP) (6-12 month-olds), and a health risk for dermal and inhalation exposures to jasmine oil and perfumes and essences of jasmin from body moisturizer, body fragrance, facial moisturizer/acne treatment (NHP), antiseptic skin cleanser (NHP), and use in DIY aromatic diffusers, DIY massage oil, DIY body moisturizer, or DIY facial steamers (as the user and as the bystander). No other sources of exposure of concern were identified.

5.4 Violet oil

In the draft assessment, the hazard information for violet oil was from 2,4-hexadienal. This substance was used as the read-across analogue for the main component of toxicological significance for violet oil, 2-trans-6-cis-nonadienal. Risk characterization for violet oil was subsequently based on critical health effects in laboratory animals of mild-to-moderate forestomach lesions (NTP 2003). The draft assessment identified risks for human health from inhalation exposure to violet oil from its use in massage oil (for 8-year-olds and younger) and in DIY aromatic diffusers or in DIY facial steamers during use of the device for all subpopulations and once the device is turned off after 20 minutes of use for children younger than 9 years of age. No other sources of exposure of concern were identified.

5.5 Aldehydes subgroup 2 (lilial)

The draft assessment considered the possible risks from exposure to substances in the Aldehydes Subgroup 2 based on a developmental toxicity study in rats exposed to lilial demonstrating adverse effects in the dams and fetuses at higher doses (SCCS 2016). This oral critical effect level is also supported by other

studies with similar endpoints (SCCS 2019) and was used for characterization of risk from oral exposure along with extrapolation for the Aldehydes Subgroup 2 to determine risk from dermal and inhalation routes of exposure since no hazard data was identified for the dermal and inhalation routes of exposure to lilial. The draft assessment identified health risks from dermal and inhalation exposures to lilial in cosmetics such as body fragrance, massage oil (for 8-year-olds and younger), body moisturizer, solid antiperspirant/deodorant, facial moisturizer, permanent hair colour product, and hair straightening, waving, and curling product. Health risks were also identified from inhalation exposure from use of solid gel air fresheners and liquid plug-in air fresheners (for children younger than two years of age). No other sources of exposure of concern were identified.

6. Risk management considerations

6.1 Alternatives and alternate technologies

Nympheal (CAS RN 1637294-12-2) may be used as a potential alternative for lilial by perfumers (Givaudan 2016). Available empirical data suggests that this substance could have harmful effects on human health (ECHA 2022). No publicly available information on alternatives to the other five proposed toxic substances in the Phenylpropanoids and Aldehydes Group were identified for cosmetics, NHPs, and consumer products. Follow-up information from stakeholders is requested, if known.

6.2 Socio-economic and technical considerations

The International Fragrance Association has established recommended limits for lilial of 0.1 and 0.63% for household care excluding aerosol products and household aerosol/spray products, respectively (IFRA 2020). No other information on socio-economic or technical considerations was identified. We ask that stakeholders submit information on these considerations, if known.

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. Socio-economic factors will also be considered in the development of regulation(s), instrument(s) and/or tool(s) as identified in the *Cabinet Directive on Regulation* (TBS 2018a) 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

Bay oil, tarragon oil, jasmine oil, and violet oil were reported to be used as food flavouring agents in Canada. The safety of food flavouring agents is subject to the provisions of section 4(1)(a) of the *Food and Drugs Act*.

7.1.1 Bay oil

Pimenta racemosa (source of bay oil) is listed in the NHPID with a medicinal role as classified as an NHP substance falling under Schedule 1, item 1 (a plant or a plant material) of the *Natural Health Products Regulations* (NHPR). Bay oil is listed in the NHPID with a non-medicinal role for use as flavour enhancer or fragrance ingredient. *Pimenta racemosa* and its preparations are listed in the Licensed Natural Health Products Database (LNHPD) as being present as medicinal or non-medicinal ingredient in NHPs (LNHPD 2023; personal communication, email from the Natural and Non-prescription Health Products Directorate, Health Canada, to the Risk Management Bureau, Health Canada, 2023; unreferenced). The NHPID listing does not include any concentration limits for the substance.

Domestically, bay oil is listed on Schedule 2 of the *Denatured and Specially Denatured Alcohol Regulations*. This regulation specifies that denatured alcohol or specially denatured alcohol may not be sold, provided for use in, or used in or as a beverage (Canada 2005).

Bay oil is listed as a 4B formulant on the Pest Management Regulatory Agency's (PMRA's) list of formulants. List 4B-formulants are of minimal concern under specific conditions of use and include formulants, some of which may be hazardous to human health, but for which there are sufficient data to reasonably conclude that the specific use pattern of the pest control product will not adversely affect public health or the environment (PMRA 2010). Although not an exposure of concern, the use of this substance in pest control products is subject to the provisions of the *Pest Control Products Act* (PCPA).

As mentioned above, its use as a food flavouring agent is subject to the provisions of section 4(1)(a) of the *Food and Drugs Act*.

7.1.2 Tarragon oil

Artemisia dracunculus (source of tarragon oil) is listed in the NHPID with a medicinal role as classified as an NHP substance falling under Schedule 1, item 1 (a plant or a plant material) of the NHPR. Tarragon essential oil is listed in the

NHPID with a medicinal role as classified as an NHP substance falling under Schedule 1, item 2 (an extract) of the NHPR. It is also listed with a non-medicinal role for oral use as flavour enhancer up to 0.05 mg/kg bw/day or for topical use as fragrance ingredient or skin-conditioning agent at concentrations equal to or less than 0.12%. Both *Artemisia dracunculus* and Tarragon essential oil are also associated with the following medicinal role restrictions: *Artemisia species contain thujone. For adults, the upper limit for total daily intake of thujone from health products is 6 mg.* Pharmacopée française (PhF)_Artemisia dracunculus, from the fresh flowering whole plant, is listed in the NHPID with a homeopathic role. *Artemisia dracunculus* and its preparations are listed in the LNHPD as being present as medicinal or non-medicinal ingredient in NHPs (LNHPD 2023; personal communication, email from the Natural and Non-prescription Health Products Directorate, Health Canada, to the Risk Management Bureau, Health Canada, 2023; unreferenced).

Tarragon oil is listed as a List 3 formulant on PMRA's list of formulants. List 3 contains the formulants, in use in registered pest control products that do not meet the criteria of any of the other lists (that is, List 1-Formulants of Toxicological Concern, List 2-Potentially Toxic Formulants with a High Priority for Testing, List 4A-Formulants of Minimal Toxicological Concern, and List 4B-Formulants of Minimal Concern under Specific Conditions of Use). If new information becomes available on any List 3 formulant that raises concern, the formulant will immediately be subject to the appropriate data requirement to support continued use (PMRA 2010). Although not an exposure of concern, the use of these substances in pest control products is subject to the provisions of the PCPA.

As mentioned above, its use as a food flavouring agent is subject to the provisions of section 4(1)(a) of the *Food and Drugs Act*.

7.1.3 Phenylpropanoids subgroup 1 (jasmine oil and perfumes and essences of jasmin)

Jasminum officinale (Jasmine) oil is listed in the NHPID with a non-medicinal role for topical use only as fragrance ingredient. Jasmine absolute is listed in the NHPID with a medicinal role as classified as an NHP substance falling under Schedule 1, item 2 (an extract) of the NHPR. Flos Jasmini is listed in the NHPID with a medicinal role as classified as an NHP substance falling under Schedule 1, item 1 (a plant or a plant material) of the NHPR. *Jasminum officinale* (Jasmine) flower extract is listed in the NHPID with a non-medicinal role for topical use as fragrance ingredient. *Jasminum officinale* (Jasmine) flower/leaf extract is listed in the NHPID with a non-medicinal role for topical use only as skin-conditioning agent or skin-conditioning agent – occlusive. Encyclopedia of Homeopathic Pharmacopoeia (EHP)_Jasminum officinale and Homeopathic Pharmacopoeia of the United States (HPUS)_Jasminum officinale, from the ripe berries, are listed in the NHPID with a homeopathic role. *Jasminum officinale* and its preparations are

listed in the LNHPD as being present as medicinal or non-medicinal ingredient in NHPs (LNHPD 2023; personal communication, email from the Natural and Non-prescription Health Products Directorate, Health Canada, to the Risk Management Bureau, Health Canada, 2023; unreferenced).

As mentioned above, jasmine oil's use as a food flavouring agent is subject to the provisions of section 4(1)(a) of the *Food and Drugs Act*.

7.1.4 Violet oil

Viola odorata (source of violet oil) is listed in the NHPID with a medicinal role as classified as an NHP substance falling under Schedule 1, item 1 (a plant or a plant material) of the NHPR. *Viola odorata* flower/leaf extract is listed in the NHPID with a non-medicinal role for topical use only as fragrance ingredient or skin-conditioning agent. EHP_Viola odorata and HPUS_Viola odorata, from the whole plant, are listed in the NHPID with a homeopathic role. *Viola odorata* and its preparations are listed in the LNHPD as being present as medicinal or non-medicinal ingredient in NHPs (LNHPD 2023; personal communication, email from the Natural and Non-prescription Health Products Directorate, Health Canada, to the Risk Management Bureau, Health Canada, 2023; unreferenced).

As mentioned above, its use as a food flavouring agent is subject to the provisions of section 4(1)(a) of the *Food and Drugs Act*.

7.1.5 Aldehydes subgroup 2 (lilial)

Butylphenyl methylpropional, a synonym for lilial, is listed in the NHPID with a non-medicinal role for topical use only as fragrance ingredient. It is also listed in the LNHPD as being present as a NMI in NHPs (LNHPD 2023; personal communication, email from the Natural and Non-prescription Health Products Directorate, Health Canada, to the Risk Management Bureau, Health Canada, 2023; unreferenced).

Lilial is listed as a 4B formulant on the PMRA's list of formulants. As indicated above, List 4B includes formulants, some of which may be hazardous to human health, but for which there are sufficient data to reasonably conclude that the specific use pattern of the pest control product will not adversely affect public health or the environment (PMRA 2010). Although not an exposure of concern, the use of this substance in pest control products is subject to the provisions of the PCPA.

7.2 Pertinent international risk management context

7.2.1 Bay oil

In the United States (US), bay oil is approved for use as a fragrance in pesticides by the United States Environmental Protection Agency (US EPA; 2018).

Bay oil is listed as a substance generally recognized as safe by the United States Food and Drug Administration (US FDA; 2022).

In the US' *Code of Federal Regulations*, title 27, - Alcohol, Tobacco Products and Firearms, bay oil is listed as a denaturant authorized for denatured alcohol (US eCFR 2022).

7.2.2 Tarragon oil

In the US, tarragon oil is approved for fragrance use in pesticides by the US EPA (2018).

Tarragon oil is listed as a substance generally recognized as safe by the US FDA (2022).

In the European Union (EU), tarragon oil has been withdrawn from the market for certain feed additives belonging to the group of flavouring and appetizing substances (EC 2013). It was removed because notification of tarragon oil in feed additives was not received by the EC from persons first placing the feed additive containing the substance on the market or any interested parties, as per Article 10(5) of EC 1831/2003.

7.2.3 Phenylpropanoids subgroup 1 (jasmine oil and perfumes and essences of jasmin)

In the US, jasmine oil is approved for use as a fragrance in pesticides by the US EPA (2018).

Jasmine oil is also listed as a substance generally recognized as safe by the US FDA (2022).

Jasmine oil was withdrawn from the market for feed additives belonging to the group of flavouring and appetizing substances by the EC (2013). It was removed because notification of jasmine oil use in feed additives was not received by the EC from persons first placing the feed additive containing the substance on the market or any interested parties, as per Article 10(5) of EC 1831/2003.

Jasmine oil must also be listed on a toy, on an affixed label, on the packaging or in an accompanying leaflet, if added to a toy or any of its components in

concentrations exceeding 100 mg/kg based on evidence of jasmine oil as an allergenic fragrance (EC 2020).

7.2.4 Violet oil

In the US, violet oil is approved for use as a fragrance in pesticides by the US EPA (2018).

Violet oil is listed as a substance generally recognized as safe by the US FDA (2020).

Violet oil has also been withdrawn from the market for certain feed additives belonging to the group of flavouring and appetizing substances by the EC (2013).

7.2.5 Aldehydes subgroup 2 (lilial)

In the US, lilial is approved for fragrance and nonfood use in pesticides by the US EPA (2018).

In the EU, lilial must be listed on a toy, on an affixed label, on the packaging or in an accompanying leaflet, if added to a toy or any of its components in concentrations exceeding 100 mg/kg based on evidence of lilial as an allergenic fragrance (EC 2009).

Lilial is also banned from use in any cosmetic products marketed for sale or use in the EU (2021/1902) as it is classified as a CMR substance based on evidence of reproductive toxicity.

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 sections 3.2 or 3.3). Please submit additional information and comments prior to April 3rd, 2024.

If the final assessment confirms that bay oil, tarragon oil, jasmine oil, perfumes and essences of jasmin, violet oil, and lilial are toxic, a risk management approach document, outlining and seeking input on the proposed risk management instrument(s), would be published concurrently with the final 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:

Substances Management Information Line
Chemicals Management Plan
Environment and Climate Change Canada
Gatineau Quebec K1A 0H3
Tel: 1-800-567-1999 | 819-938-3232
Email: substances@ec.gc.ca

Companies who have a business interest in bay oil, tarragon oil, jasmine oil, perfumes and essences of jasmin, violet oil, and lilial are encouraged to identify themselves as stakeholders. Stakeholders will be informed of future decisions regarding bay oil, tarragon oil, jasmine oil, perfumes and essences of jasmin, violet oil, and lilial and may be contacted for further information.

8.2 Timing of actions

Electronic consultation on the draft assessment and risk management scope: February 3rd, 2024 to April 3rd, 2024. This should include the submission of public comments, additional studies, and/or information on bay oil, tarragon oil, jasmine oil, perfumes and essences of jasmin, violet oil, and lilial.

Publication of responses to public comments on the draft assessment and risk management scope: concurrent to the publication of the final assessment and, if required, the risk management approach.

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 bay oil, tarragon oil, jasmine oil, perfumes and essences of jasmin, violet oil, and lilial be added to Schedule 1 of CEPA.

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

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

These are planned timelines, and are subject to change.

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ANNEX A. Substances in the phenylpropanoids and aldehydes group

CAS RN	Subgroup	*Domestic Substances List* name	Common name used in the draft assessment
8006-78-8[a]	Individual (Phenylpropanoids)	Oils, bay	Bay oil
8016-88-4[a]	Individual (Phenylpropanoids)	Oils, tarragon	Tarragon oil
8022-96-6[a]	Phenylpropanoids subgroup 1 (Phenylpropanoids)	Oils, jasmine	Jasmine oil
8024-43-9[a]	Phenylpropanoids subgroup 1 (Phenylpropanoids)	Perfumes and essences, jasmin	Perfumes and essences of jasmin
8024-08-6[a]	Individual (Aldehydes)	Oils, violet	Violet oil
80-54-6	Aldehydes subgroup 2 (Aldehydes)	Benzenepropanol, 4-(1,1-dimethylethyl)-α-methyl-	Lilial
91-51-0	Aldehydes subgroup 2 (Aldehydes)	Benzoic acid, 2-[[3-[4-(1,1-dimethylethyl)phenyl]-2-methylpropylidene]amino]-, methyl ester	Verdantiol
37677-14-8	Aldehydes subgroup 2 (Aldehydes)	3-Cyclohexene-1-carboxaldehyde, 4-(4-methyl-3-pentenyl)-	Myrac-aldehyde
52474-60-9	Aldehydes subgroup 2 (Aldehydes)	3-Cyclohexene-1-carboxaldehyde, 1-methyl-3-(4-methyl-3-pentenyl)-	Myrmac-aldehyde
52475-86-2	Aldehydes subgroup 2 (Aldehydes)	3-Cyclohexene-1-carboxaldehyde, 1-methyl-4-(4-methyl-3-pentenyl)-	Myrmac-carboxaldehyde

CAS RN	Subgroup	*Domestic Substances List* name	Common name used in the draft assessment
65405-84-7	Aldehydes subgroup 2 (Aldehydes)	Cyclohexenebutanal, α,2,2,6-tetramethyl-	Cetonal
66327-54-6	Aldehydes subgroup 2 (Aldehydes)	3-Cyclohexene-1-carboxaldehyde, 1-methyl-4-(4-methylpentyl)-	Vernaldehyde

[a] This substance is a UVCB (substance of unknown or variable composition, complex reaction products, or biological materials).