Government of Canada Gouvernement du Canada

Risk Management Scope

for

Terpenes and Terpenoids

Tricyclic Sesquiterpenes and Triterpenoids Group:

Cedarwood oil,

Texan cedarwood oil,

Enoxolone,

Mimosa oil, and

Ivy extract

Chemical Abstracts Service Registry Numbers (CAS RNs):

8000-27-9, 68990-83-0,

471-53-4, 8031-03-6, and 84082-54-2

Environment and Climate Change Canada

Health Canada

March 2025

Canada

Summary of Proposed Risk Management

This document outlines the risk management options under consideration for cedarwood oil, Texan cedarwood oil, enoxolone, mimosa oil, and ivy extract, which have been proposed to be harmful to human health. For the purposes of paragraph 77(1)(a) of the *Canadian Environmental Protection Act, 1999* (CEPA), the Government of Canada proposes to recommend that cedarwood oil, Texan cedarwood oil, enoxolone, mimosa oil, and ivy extract be added to Part 2 of Schedule 1 to CEPA. As a result, the Government of Canada is considering the following new risk management actions:

1. **Consumer products**, including essential oils or products sold directly to consumers in vials for use in do-it-yourself (DIY) applications:

    - Regulatory or non-regulatory actions to help reduce inhalation and/or dermal exposures to cedarwood oil, Texan cedarwood oil, mimosa oil, and ivy extract from certain consumer products.

2. **Food**:
    - Regulatory or non-regulatory actions to help reduce oral exposure to enoxolone from licorice teas and black licorice candy.

The Government of Canada is also considering other risk management actions as follows:

1. **Cosmetics**:
    - Listing cedarwood oil, Texan cedarwood oil, enoxolone, mimosa oil, and ivy extract as prohibited or restricted ingredients on Health Canada's Cosmetic Ingredient Hotlist (Hotlist)[1] to help reduce inhalation, dermal and/or oral exposures to these substances from certain cosmetics.

2. **Natural health products (NHPs) and non-prescription drugs (NPDs)**:
    - Listing cedarwood oil, enoxolone, and mimosa oil as restricted ingredients in Health Canada's Natural Health Products Ingredients

[1]The Cosmetic Ingredient Hotlist is an administrative tool that Health Canada uses to communicate to manufacturers and others that certain substances may contravene the general prohibition found in section 16 of the *Food and Drugs Act* or may contravene one or more provisions of the *Cosmetic Regulations*. Section 16 of the *Food and Drugs Act* states that "No person shall sell any cosmetic that has in or on it any substance that may cause injury to the health of the user." In addition, the Hotlist includes certain substances that may make it unlikely for a product to be classified as a cosmetic under the *Food and Drugs Act*. Compliance with the provisions of section 16 are monitored, in part, through the mandatory notification provisions of section 30 of the *Cosmetic Regulations* of the *Food and Drugs Act*, which requires that all manufacturers and importers provide a list of the cosmetic's ingredients to Health Canada. .

Database (NHPID)[2] to help reduce dermal exposure to these substances from certain topical NHPs or NPDs. Actions may aim to lower the concentration of these substances when used as non-medicinal ingredients (NMIs) in certain topical NHPs or NPDs to levels that are protective of human health.

3. **A public communications approach** for DIY consumer product essential oils of concern for human health.

Information on the following items should be provided (on or before April 30, 2025), to the contact details identified in section 8 of this document, to inform risk management decision-making:

- Potential alternative substances to cedarwood oil, Texan cedarwood oil, enoxolone, mimosa oil, and ivy extract for use in cosmetics;
- Current quantities and concentrations of cedarwood oil, enoxolone, and mimosa oil used as NMIs in NHPs or NPDs;
- Potential alternative substances to cedarwood oil, enoxolone, and mimosa oil for use as NMIs in NHPs or NPDs;
- Current quantities and concentrations of cedarwood oil, Texan cedarwood oil, mimosa oil, and ivy extract used in consumer product DIY applications identified as a concern;
- Potential alternative substances to cedarwood oil, Texan cedarwood oil, mimosa oil, and ivy extract for use in consumer product DIY applications identified as a concern; and
- Socio-economic and technical impacts and benefits associated with the proposed risk management for cedarwood oil, Texan cedarwood oil, enoxolone, mimosa oil, and ivy extract.

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

[2] The NHPID provides an electronic tool which enables members of the public to access information on the following topics:

- medicinal and non-medicinal ingredients used in Natural Health Products;
- standard terminology used by the Natural Health Products Online System, known as "Controlled Vocabulary", referring to quality test methods, dosage forms, non-medicinal ingredient purposes, and so on; and
- pre-cleared information such as single ingredient monographs and product monographs.

essential oils) to create homemade products, such as massage oils, body moisturizers, bath products, etc., as well as their 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 and section 7 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[3,4], and if so, to manage the associated risks.

The substances alpha-cedrene, thujopsene, alpha-gurjunene, beta-patchoulene, beta-cedrene, cedarwood oil, T&T cedarwood oil, Texan cedarwood oil, amboryl acetate, enoxolone, allantoin glycyrrhetinic acid, mimosa oil, ivy extract, and American ginseng extract, Chemical Abstracts Service Registry Numbers (CAS RNs)[5] 469-61-4, 470-40-6, 489-40-7, 514-51-2, 546-28-1, 8000-27-9, 68608-32-2, 68990-83-0, 59056-62-1, 471-53-4, 4572-09-2, 8031-03-6, 84082-54-2, and 90045-38-8, respectively (Annex A), are included in the draft assessment of Terpenes and Terpenoids: Tricyclic Sesquiterpenes and Triterpenoids Group of the Chemicals Management Plan (CMP) (Canada 2025).

2. Issue

2.1 Draft Assessment Conclusion

Health Canada and Environment and Climate Change Canada conducted a joint scientific assessment of the 14 substances that are part of the Terpenes and Terpenoids: Tricyclic Sesquiterpenes and Triterpenoids Group. A notice

[3] 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.

[4] 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.

[5] 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.

summarizing the scientific considerations of the draft assessment for these 14 substances was published in the *Canada Gazette*, Part I, on March 1, 2025 (Canada 2025). For further information, refer to the draft assessment for the Tricyclic Sesquiterpenes and Triterpenoids Group.

Based on the information available, the draft assessment proposes that cedarwood oil, Texan cedarwood oil, enoxolone, mimosa oil, and ivy extract are toxic under section 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 (ECCC, HC 2025).

It is proposed that all 14 substances in the Tricyclic Sesquiterpenes and Triterpenoids 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 (ECCC, HC 2025).

The draft assessment also proposes that alpha-cedrene, thujopsene, alpha-gurjunene, beta-patchoulene, beta-cedrene, T&T cedarwood oil, amboryl acetate, allantoin glycyrrhetinic acid, and American ginseng extract do not meet the criteria under section 64(*c*) of CEPA (ECCC, HC 2025).

The exposure sources of concern, identified in the draft assessment, are based on potential inhalation, dermal, and/or oral exposures to cedarwood oil, Texan cedarwood oil, enoxolone, mimosa oil, and ivy extract from the use of certain cosmetics; dermal exposures to cedarwood oil, enoxolone, and mimosa oil from the use of certain topical natural health products (NHPs); dermal exposures to enoxolone from the use of certain non-prescription drugs (NPDs); oral exposures to enoxolone from the consumption of certain foods; and inhalation and/or dermal exposures to cedarwood oil, Texan cedarwood oil, mimosa oil, and ivy extract from the use of certain consumer products. 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 cedarwood oil, Texan cedarwood oil, enoxolone, mimosa oil, and ivy extract be added to Part 2 of

Schedule 1 to CEPA[6]. Addition of a substance to Schedule 1 to CEPA enables the Government to propose certain risk management measures under CEPA to manage potential ecological and human health risks associated with the substance.

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, cedarwood oil, Texan cedarwood oil, enoxolone, mimosa oil, and ivy extract are proposed to be recommended for addition to Part 2 of Schedule 1. Following the availability of the aforementioned criteria, these substances 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 meets the criteria set out in paragraph (a), (b) or (c), to Part 1[7] 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.

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

The Ministers will take into consideration comments made 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 cedarwood oil, Texan cedarwood oil, enoxolone, mimosa oil, and ivy extract to Part 2 of Schedule 1, risk management instruments must, unless an exception in section 91 of CEPA applies, be proposed within 24 months from the date on which the Ministers recommended that cedarwood oil, Texan cedarwood oil, enoxolone, mimosa oil,

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[6] 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 Schedule 1 to CEPA (for substances that pose the highest risk) or recommend the addition of the substance to Part 2 of Schedule 1 to CEPA (for other CEPA-toxic substances).

[7] 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.

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and ivy extract 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 cedarwood oil, Texan cedarwood oil, enoxolone, mimosa oil, and ivy extract 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 5 proposed toxic substances in the Tricyclic Sesquiterpenes and Triterpenoids Group for the protection of human health are to:

- reduce inhalation, dermal, and/or oral exposures of the general public to cedarwood oil, Texan cedarwood oil, enoxolone, mimosa oil, and ivy extract from certain cosmetics (see detailed list below);
- reduce dermal exposure of the general population to cedarwood oil, enoxolone, and mimosa oil from certain topical NHPs (see detailed list below);
- reduce dermal exposure of the general population to enoxolone from certain topical NPDs (see details below);
- reduce inhalation and/or dermal exposures of the general population to cedarwood oil, Texan cedarwood oil, mimosa oil, and ivy extract from certain consumer products, including essential oils or products sold directly to consumers in vials for use in DIY applications (see detailed list below); and
- reduce oral exposure of the general population to enoxolone from certain food, such as licorice teas and black licorice candy.

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, risk management options are under consideration.

For the purposes of paragraph 77(1)(a) of CEPA, the Government of Canada, proposes to recommend that cedarwood oil, Texan cedarwood oil, enoxolone, mimosa oil, and ivy extract be added to Part 2 of Schedule 1 to CEPA. As a result, the Government of Canada is considering the following new risk management actions:

1. **Consumer products**, including essential oils or products sold directly to consumers in vials for use in DIY applications:

    - Regulatory or non-regulatory actions to help reduce inhalation and/or dermal exposures to cedarwood oil, Texan cedarwood oil, mimosa oil, and ivy extract from certain consumer products, listed below, to levels that are protective of human health, including:
        - Measures to reduce inhalation and dermal exposures to:
            - Cedarwood oil and Texan cedarwood oil in the following DIY applications: aromatic diffuser/air freshener (during use and refill for people older than 8 years of age), and facial steamer/mist (during use for people older than 3 years of age).
            - Mimosa oil in the following DIY application: aromatic diffuser/air freshener (during use and refill for people older than 8 years of age).
        - Measures to reduce inhalation exposure to:
            - Cedarwood oil and Texan cedarwood oil in the following DIY applications: aromatic diffuser/air freshener (for bystanders younger than 9 years of age) and facial steamer/mist (for 1-year old bystanders).
            - Mimosa oil in the following DIY application: aromatic diffuser/air freshener (bystanders younger than 9 years of age).
        - Measures to reduce dermal exposure to:
            - Cedarwood oil, Texan cedarwood oil, mimosa oil, and ivy extract in the following DIY applications: massage oil, and body moisturizer.
2. **Food**:
    - Regulatory or non-regulatory actions to help reduce oral exposure to enoxolone from licorice teas and black licorice candy.

The Government of Canada is also considering other risk management actions, as follows:

1. **Cosmetics**:

- Listing cedarwood oil, Texan cedarwood oil, enoxolone, mimosa oil, and ivy extract as prohibited or restricted ingredients on Health Canada's Cosmetic Ingredient Hotlist[8] (Hotlist) to help reduce inhalation, dermal, and/or oral exposures to these substances from certain cosmetics, listed below. 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* (Canada 2019).
    - List on Hotlist to reduce dermal exposure to:
        - Cedarwood oil in leave-on conditioner, body exfoliant, face aftershave, after body hair removal product.
        - Cedarwood oil and Texan cedarwood oil in massage oil, fragrance, solid deodorant/antiperspirant, body moisturizer, and face moisturizer.
        - Enoxolone in face moisturizer, lotion body moisturizer, and permanent hair dye.
        - Mimosa oil in body moisturizer, face moisturizer, massage oil (for children younger than 2 years of age), massage bar, sunless tanning product, and facial makeup (liquid foundation).
        - Ivy extract in massage oil, body moisturizer, face moisturizer, body exfoliant, and leave-on hair conditioner.
    - List on Hotlist to reduce inhalation exposure to:
        - Cedarwood oil in fragrance (for children 2 to 3 years of age).
    - List on Hotlist to reduce inhalation and dermal exposures to:
        - Enoxolone in spray body moisturizer.
        - Mimosa oil in roll on fragrance and spray fragrance.
        - Ivy extract in spray facial makeup fixer.
    - List on Hotlist to reduce oral exposure to:
        - Mimosa oil in lipstick (for children younger than 9 years of age).

[8] The Cosmetic Ingredient Hotlist is an administrative tool that Health Canada uses to communicate to manufacturers and others that certain substances may contravene the general prohibition found in section 16 of the *Food and Drugs Act* or may contravene one or more provisions of the *Cosmetic Regulations*. Section 16 of the *Food and Drugs Act* states that "No person shall sell any cosmetic that has in or on it any substance that may cause injury to the health of the user." In addition, the Hotlist includes certain substances that may make it unlikely for a product to be classified as a cosmetic under the *Food and Drugs Act*. Compliance with the provisions of section 16 are monitored, in part, through the mandatory notification provisions of section 30 of the *Cosmetic Regulations* of the *Food and Drugs Act*, which requires that all manufacturers and importers provide a list of the cosmetic's ingredients to Health Canada.

2. **NHPs and NPDs**:

    - Listing cedarwood oil, enoxolone, and mimosa oil as restricted ingredients in Health Canada's Natural Health Products Ingredients Database (NHPID)[9] to help reduce dermal exposures to these substances from certain topical NHPs or NPDs, listed below. Actions may aim to lower the concentration of these substances when used as non-medicinal ingredients (NMIs) in certain topical NHPs or NPDs to levels that are protective of human health, including:
        - List in NHPID to reduce dermal exposure to:
            - Cedarwood oil when used as an NMI in the following NHPs: antiseptic skin cleanser spray (for children 2 to 8 years of age for situations of public health concern resulting in increased use), counterirritant spray (for children and adolescents 9 to 18 years of age), and irritation relief balm.
            - Enoxolone when used as an NMI in the following NHPs: sunscreen cream, analgesic patch (for children 13 years and under), acne therapy cream, and medicated skin care product cream.
            - Enoxolone when used as an NMI in the following NPDs: sunscreen cream.
            - Mimosa oil when used as an NMI in the following NHPs: sunscreen lotion (for children 3 years and under and adolescents 14 to 18 years of age).

3. **DIY use of essential oil** that are consumer products for which health concerns are identified:

    - A public communications approach for DIY essential oil consumer products as a complementary tool to reduce inhalation and/or dermal exposures to cedarwood oil, Texan cedarwood oil, mimosa oil, and ivy extract in the DIY applications listed under consumer products above.

Note that these proposed risk management options are preliminary and subject to change. 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

[9] The NHPID provides an electronic tool which enables members of the public to access information on the following topics:

- medicinal and non-medicinal ingredients used in Natural Health Products;
- standard terminology used by the Natural Health Products Online System, known as "Controlled Vocabulary", referring to quality test methods, dosage forms, non-medicinal ingredient purposes, and so on; and
- pre-cleared information such as single ingredient monographs and product monographs.

instrument selection and development process[10]. 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 needed on the following:

- Potential alternative substances to cedarwood oil, Texan cedarwood oil, enoxolone, mimosa oil, and ivy extract for use in cosmetics;
- Current quantities and concentrations of cedarwood oil, enoxolone, and mimosa oil used as NMIs in NHPs or NPDs.
- Potential alternative substances to cedarwood oil, enoxolone, and mimosa oil for use as NMIs in NHPs or NPDs;
- Current quantities and concentrations of cedarwood oil, Texan cedarwood oil, mimosa oil, and ivy extract used in consumer product DIY applications identified as a concern;
- Potential alternative substances to cedarwood oil, Texan cedarwood oil, mimosa oil, and ivy extract for use in consumer product DIY applications identified as a concern; and
- Socio-economic and technical impacts and benefits associated with the proposed risk management for cedarwood oil, Texan cedarwood oil, enoxolone, mimosa oil, and ivy extract.

3.5 Performance Measurement and Evaluation

Performance measurement evaluates the ongoing effectiveness and relevance of the actions taken to manage risks from toxic substances[11]. Environment and Climate Change Canada and Health Canada have developed a Performance Measurement Evaluation Strategy that sets out the approach to evaluate the

[10] 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 Regulatory Management (TBS 2012a), Red Tape Reduction Action Plan (TBS 2012b) and the *Red Tape Reduction Act* (Canada, 2015).

[11] 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 is needed (that is, 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 (that is, evaluate whether human health and/or environmental objectives have been met).

For more information on performance measurement evaluation (including Health Canada and Environment and Climate Change Canada's Performance Measurement Evaluation Strategy) please visit Performance measurement for toxic substances - Canada.ca.

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 5 proposed toxic substances in the Tricyclic Sesquiterpenes and Triterpenoids 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

Terpenes are simple hydrocarbons consisting of repeating 5 carbon isoprene units, having the empirical formula $C_{10}H_{16}$. Terpenoids are modified terpenes that usually have additional oxygen-containing functional groups, in which methyl groups have been moved or removed, or oxygen atoms added. Terpenes and terpenoids are classified according to the number of isoprene units they contain (Caputi and Aprea 2011; Perveen 2018). Sesquiterpenes (for example, alpha-cedrene) contain 3 isoprene units whereas triterpenoids (for example, enoxolone) contain 6 isoprene units, with chemical formulas $C_{15}H_{24}$ and $C_{30}H_{46}O_4$, respectively.

All of the substances in the Tricyclic Sesquiterpenes and Triterpenoids Group were included in a survey issued pursuant to section 71 of CEPA (Canada 2012). Based on information submitted in response to the section 71 survey, there were no reports of import or manufacture of enoxolone, mimosa oil and ivy extract in Canada above the reporting threshold of 100 kg in 2011 (Environment Canada 2013). Cedarwood oil was reported as being imported into Canada at quantities between 100 and 1000 kg and there were no reports of manufacture in Canada above the reporting threshold of 100 kg in the same calendar year (Environment Canada 2013). Texan cedarwood oil was reported as being manufactured and imported into Canada in 2011 at quantities of 277 and 200 kg, respectively (Environment Canada 2013).

The 14 substances in the Tricyclic Sesquiterpenes and Triterpenoids Group consist of discrete substances (for example, enoxolone) as well as representative structures for unknown or variable composition, complex reaction products, or

biological materials (UVCB) substances (for example, cedarwood oil, Texan cedarwood oil, mimosa oil, and ivy extract). These representative structures are components of UVCB essential oils found in a wide variety of plants and are generally used as fragrances in cosmetics, NHPs, NPDs, cleaning products, and air fresheners. Some of them are also present in pest control products as formulants (PMRA 2010), and cedarwood oil is an active ingredient used only to manufacture pest control products intended for export out of Canada. Some of them occur naturally in food and may be used as food flavouring agents.

For the human health risk assessment, 10 of the 14 substances in this group were addressed under 2 subgroups, due to similarities in chemical structure, properties and/or toxicity. Tricyclic Sesquiterpenes Subgroup 1 included alpha-cedrene, thujopsene, alpha-gurjunene, beta-patchoulene, beta-cedrene, cedarwood oil, T&T cedarwood oil, and Texan cedarwood oil. Triterpenoids Subgroup 2 is comprised of the substances enoxolone and allantoin glycyrrhetinic acid. The remaining 4 substances (that is, amboryl acetate, mimosa oil, ivy extract, and American ginseng extract) 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.

5. Exposure Sources and Identified Risks

Overall, the primary area of concern for the 5 proposed toxic substances in the Tricyclic Sesquiterpenes and Triterpenoids Group is the use of these substances in cosmetics, NHPs, NPDs, food, and certain consumer products, including essential oils or products sold directly to consumers in vials for 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.

5.1 Tricyclic Sesquiterpenes Subgroup 1 (cedarwood oil and Texan cedarwood oil)

The draft assessment considered the possible risks from dermal exposure to cedarwood oil and Texan cedarwood oil based on systemic effects (decreased thymus weights). For the oral route and inhalation, an adverse health effect of cedarwood oil was used to characterize risk based on thyroid hormone changes. The draft assessment identified a health risk for daily dermal exposure to cedarwood oil from use in massage oil, fragrance, deodorant/antiperspirant

(solid), moisturizer (body and face), conditioner (leave-on), body exfoliant (14-18 years), aftershave (face), after hair removal product (body), antiseptic skin cleanser (spray) (NHP) (for children 2 to 8 years of age for situations of public health concern resulting in increased use), counterirritant (spray) (NHP) (for children and adolescents 9 to 18 years of age), irritation relief balm (NHP), use in DIY aromatic diffuser/air freshener (during use and refill for people older than 8 years of age), DIY massage oil, DIY body moisturizer, and DIY facial steamer/mist (during use for people older than 3 years of age). A health risk was also determined for inhalation exposure to cedarwood oil in fragrance (for children 2 to 3 years of age), use in DIY aromatic diffuser/air freshener (during use for people over 8 years of age and for bystanders younger than 9 years of age), DIY massage oil (all except adults), and DIY facial steamer/mist (during use for people older than 3 years of age and for 1-year old bystanders).

A health risk was also identified for dermal exposure to Texan cedarwood oil in massage oil, fragrance, deodorant/antiperspirant (solid), and moisturizer (body and face), as well as the use of Texan cedarwood oil in DIY aromatic diffuser/air freshener (for people older than 8 years of age), DIY massage oil, DIY body moisturizer, and DIY facial steamer/mist (for people older than 3 years of age).

A health risk was determined for inhalation exposure to Texan cedarwood oil use in DIY aromatic diffuser/air freshener (for people older than 8 years of age and for bystanders younger than 9 years of age), and DIY facial steamer/mist (use for people older than 3 years of age and for 1-year old bystanders).

5.2 Triterpenoids Subgroup 2 (enoxolone)

In the draft assessment, the risks from exposure to enoxolone were based on developmental neurotoxicity. In addition, there is a risk of increased blood pressure, blood potassium levels thereby resulting in potential maternal arrythmias and increased life-threatening effects for the fetus. In consideration of the severity of the developmental effects and the uncertainty on the neurological developmental and endocrine disruptor effects of enoxolone in fetuses and children, these risks were considered relevant for people of childbearing age, pregnant and breastfeeding people, fetuses and children. Risks to human health were identified from dermal, inhalation, and/or oral exposures to enoxolone from its use in face moisturizer, body moisturizer (spray and lotion), permanent hair dye, sunscreen (cream) (NHP and NPD), analgesic patch (NHP) (for children 13 years and under), acne therapy cream (NHP), medicated skin care product (cream) (NHP), regular consumption of licorice tea and short-term, high exposure of black licorice candy.

5.3 Mimosa Oil

The draft assessment characterized the risks to human health from exposure to mimosa oil based on the adverse health effects identified for the read-across

analogue enoxolone, since there was limited hazard data available on mimosa oil and its main components (lupenone and lupeol). Specifically, the adverse health effect was developmental neurotoxicity. Risks to human health were identified from daily dermal, inhalation, and/or oral exposures to mimosa oil in fragrance (roll on and spray), body moisturizer, face moisturizer, massage oil (for children younger than 2 years of age), massage bar, sunless tanning product, facial makeup (liquid foundation), lipstick (for children younger than 9 years of age), and sunscreen (lotion) (NHP) (for children 3 years and under and adolescents 14 to 18 years of age), as well as its use in the following DIY applications: DIY aromatic diffuser/air freshener, DIY massage oil, and DIY body moisturizer.

5.4 Ivy Extract

In the draft assessment, the health effects information for ivy extract and its main components, hederacoside C, hederagenin, and alpha-hederin, was from enoxolone. This substance was used as the read-across analogue to characterize the risk to ivy extract and its components. As mentioned above, risk characterization was based on developmental neurotoxicity. The draft assessment identified risks for human health from inhalation and/or dermal exposures to ivy extract from its use in massage oil, body moisturizer, face moisturizer, facial makeup fixer (spray), body exfoliant, and hair conditioner (leave on), as well as its use in the following DIY applications: DIY massage oil and DIY body moisturizer.

6. Risk Management Considerations

6.1 Alternatives and Alternate Technologies

No publicly available information on alternatives to the five proposed toxic substances in the Tricyclic Sesquiterpenes and Triterpenoids Group were identified for cosmetics, NHPs, NPDs, food, and consumer products. Follow-up information from stakeholders is requested, if known.

6.2 Socio-economic and Technical Considerations

No information on socio-economic or technical considerations was identified. We ask that stakeholders submit information on these considerations, if known (refer to section 8 for how to submit information).

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 as per the guidance provided in the Treasury Board document Assessing, Selecting, and Implementing Instruments

for Government Action (TBS 2007). 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 2018), Red Tape Reduction Action Plan (TBS 2012), and the *Red Tape Reduction Act* (Canada 2015).

7. Overview of Existing Risk Management

7.1 Related Canadian Risk Management Context

In general, cosmetics, NHPs, and NPDs are regulated under the *Food and Drugs Act* and its regulations as follows.

Cosmetics:
The human health risks of substances in cosmetics are primarily managed under the *Food and Drugs Act* and the *Cosmetic Regulations*. The addition or modification of the entries in the Cosmetic Ingredient Hotlist (Hotlist) inform stakeholders and the public about substances that, according to Health Canada, may contravene section 16 of the *Food and Drugs Act* or may contravene one or more provisions of the *Cosmetic Regulations* when they are present in a cosmetic. Section 16 of the *Food and Drugs Act* states among other things, that "No person shall sell any cosmetic that has in or on it any substance that may cause injury to the health of the user."

NHPs:
NHPs are regulated under the *Food and Drugs Act* and the *Natural Health Products Regulations* (NHPR) and undergo pre-market review in accordance with the NHPR. The risks to human health from substances in NHPs are primarily managed under section 7 of the NHPR, which provides for issuance or amendments to a product licence if the licence is not likely to result in injury to the health of a purchaser or consumer. The NHPID provides information on substances used as medicinal ingredients (MIs) and/or NMIs in NHPs. The NHPID entries for substances can be revised to describe limits on the quantity and recommended uses of substances in NHPs to inform the public and stakeholders on potential health concerns. Natural health product applicants may access the information when completing a product licence application. Health Canada may access the information in the NHPID when reviewing a product licence application which may inform how a product is managed under the provisions of the NHPR, such as section 7.

NPDs:
NPDs are regulated under the *Food and Drugs Act* and the *Food and Drug Regulations* and undergo pre-market review in accordance with the *Food and*

Drug Regulations. The risks to human health from substances in NPDs is primarily managed under section C.01.014.2 of the *Food and Drug Regulations*, which provides for refusal of issuance of a drug identification number if the sale of the NPD may cause injury to the health of the purchaser or consumer. The NHPID provides information on substances used as NMIs in NPDs. The NHPID entries for substances can be revised to describe limits on the quantity and recommended uses of substances in NPDs to inform the public and stakeholders on potential health concerns. A manufacturer of a drug may access the information in the NHPID when making an application for a drug identification number. Health Canada may access the information in the NHPID when reviewing a drug application which may inform how a NPD is managed under provisions of the *Food and Drugs Regulations*, such as section C.01.014.2.

7.1.1 Tricyclic Sesquiterpene Subgroup 1 (cedarwood oil and Texan cedarwood oil)

Atlas cedarwood essential oil, which is extracted from the wood of *Cedrus atlantica* (atlas cedar), 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. This substance is also listed for topical or inhalation use as medicinal ingredient (MI) in the Natural and Non-prescription Health Products Directorate's Aromatherapy – Essential Oils monograph. *Cedrus atlantica* wood oil is listed in the NHPID with a non-medicinal role for topical use only, at concentrations below 1%, as a fragrance ingredient. The composition of oils extracted from *Cedrus atlantica* may vary from the composition of oils extracted from *Juniperus virginiana* (eastern red cedar); however, both types of substances may be referred to as cedarwood essential oil and share the same CAS RN. *Juniperus virginiana* essential oil (from the fruit and leaf of *Juniperus virginiana*) is listed in the NHPID with a non-medicinal role for topical use only as masking agent. Other preparations of *Juniperus virginiana* listed in the NHPID include homeopathic substances (NHPID 2024).

Cedarwood oil and Texan cedarwood oil are List 3 formulants on the Pest Management Regulatory Agency 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 comes to light on any List 3 formulant that raises concern, the formulant will immediately be subject to the appropriate data requirement to support continued use. Cedarwood oil is also used as an active ingredient under the PMRA's Importation for Manufacturing and Export Program. As such, it is currently used only in the manufacture of pest control products intended for export from Canada. Although not an exposure of concern, the use of these substances in pest control products is subject to the provisions of the *Pest Control Products Act*.

7.1.2 Triterpenoid Subgroup 2 (enoxolone)

Enoxolone is listed, as glycyrrhetinic acid, in the NHPID with a medicinal role as classified as an NHP substance falling under Schedule 1, item 2 (an isolate) of the NHPR, as well as with a non-medicinal role for use as skin-conditioning agent (NHPID).

7.1.3 Individual Triterpenoid (mimosa oil)

Mimosa oil is obtained from the *Acacia decurrens* plant (Burdock 2010). In the NHPID, preparations of *Acacia decurrens* (black wattle) that are listed with a non-medicinal role include *Acacia dealbata* flower/stem extract, *Acacia decurrens* flower extract, *Acacia decurrens* flower wax, and *Acacia decurrens*/jojoba/sunflower seed wax/polyglyceryl-3 esters (NHPID 2024).

Mimosa oil was reported to be used as a food flavouring agent in Canada. The safety of food flavouring agents is subject to the provisions of section 4(1)(a) of the *Food and Drugs Act*.

7.1.4 Individual Triterpenoid (ivy extract)

In the NHPID, *Hedera helix* (Ivy) extract is listed with a non-medicinal role for topical use as astringent, hair-conditioning agent, or preservative antioxidant. Other preparations of *Hedera helix* listed in the NHPID include homeopathic substances (NHPID 2024).

7.2 Pertinent International Risk Management Context

7.2.1 Tricyclic Sesquiterpene Subgroup 1 (cedarwood oil and Texan cedarwood oil)

In the United States (US), cedarwood oil alcohols and terpenes are permitted for use as flavouring agents under the US Food and Drug Regulations (US eCFR 2022). Cedarwood oil and Texan cedarwood oil are listed as inert ingredients which are safe for fragrance use in pest control products (US EPA 2022). Cedarwood oil is also approved for non-food use and is undergoing registration review as an active ingredient in pesticides by the United States Environmental Protection Agency (US EPA) (2022).

The European Commission (EC) permits cedarwood oil for fragrance and tonic use and Texan cedarwood oil for fragrance use (CosIng 2022). The European Union (EU) lists cedarwood oil and Texan cedarwood oil for removal as feed additives used in animal agriculture (EC 2013) since notification of use of these substances in feed additives was not received by the EC from persons first

placing the feed additives containing these substances on the market or any interested parties, as per Article 10(1) of EC 1831/2003. These substances in feed additives were authorized without a time limit by Directive 70/524/EEC and were subsequently entered in the Community register for Feed Additives as existing products.

In addition, cedarwood 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 its components in excess of 100 mg/kg based on evidence of cedarwood oil as an allergenic fragrance (EC 2020).

7.2.2 Triterpenoid Subgroup 2 (enoxolone)

There are no restrictions in place for enoxolone in the US. The United States Food and Drug Administration (US FDA), however, warned consumers that black licorice contains glycyrrhizin, the precursor for enoxolone, which can cause potassium levels in the body to fall, abnormal heart rhythms, high blood pressure, edema (swelling), lethargy, and congestive heart failure (US FDA 2017). The US FDA advised against eating large amounts of black licorice at one time and to refrain from further ingestions should symptoms cited previously appear.

The European Medicines Agency (EMA) determined a safety dose of 80-100 mg/day of glycyrrhizic acid for short-term use only based on hypokalemia and hypertension following chronic use of highest doses (EMA 2013). The EMA stated that the safety dose was not recommended for pregnant and breastfeeding people, children, and adolescents (<18 years) since adverse effects may occur at lower doses.

The Joint Food and Agriculture Organization of the United Nations and the World Health Organization Expert Committee on Food Additives (JECFA) confirmed that the consumption of glycyrrhizinic acid should not exceed 100 mg/day (about 2 mg/kg bw/day) and recognized that adverse effects may occur below this limit for vulnerable populations (for example, pregnant and breastfeeding people and children). The JECFA was not able to establish an adequate daily intake for vulnerable populations because of the uncertainty of the database (WHO 2005, WHO 2009).

The French Agency for Food, Environmental and Occupational Health & Safety recommends consuming no more than 10 mg of glycyrrhizin per day, taking care not to multiply the sources of intake through food, medication, and tobacco products and that the continuous consumption of products containing liquorice should be avoided (ANSES 2022a, 2022b, 2023).

The EC has enoxolone listed as an ingredient with the function of skin conditioning (CosIng 2022).

7.2.3 Individual Triterpenoid (mimosa oil)

In the US, mimosa oil is approved for use as a fragrance in pest control products by the US EPA (2022).

The EC has listed mimosa oil as an ingredient with skin conditioning, astringent, and tonic uses in cosmetics (CosIng 2022).

7.2.4 Individual Triterpenoid (ivy extract)

There are no risk management measures identified for ivy extract in the US.

In the EU, ivy extract has been withdrawn from the market for certain feed additives belonging to the group of flavouring and appetizing substances by the EC for the same reason as the Tricyclic Sesquiterpene Subgroup 1 (EC 2013).

Ivy extract is listed as an ingredient with skin conditioning, astringent, soothing, antimicrobial, anticaking, and tonic uses in cosmetics (CosIng 2022).

The Committee on Herbal Medicinal Products has also recognized ivy leaf extract for medicinal use. It is approved as an expectorant; however, the use of ivy extract by pregnant and breastfeeding people is not recommended by the EMA due to a lack of data and the presence of alpha-hederin as a main component. Alpha-hederin has been shown to disturb maternal zinc distribution and induce adverse developmental outcomes in rats (EMA 2017).

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 30, 2025.

If the final assessment confirms that cedarwood oil, Texan cedarwood oil, enoxolone, mimosa oil, and ivy extract are toxic, a risk management approach document, outlining and seeking input on the proposed risk management instruments, 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 cedarwood oil, Texan cedarwood oil, enoxolone, mimosa oil, and ivy extract are encouraged to identify themselves as stakeholders. Stakeholders will be informed of future decisions regarding cedarwood oil, Texan cedarwood oil, enoxolone, mimosa oil, and ivy extract and may be contacted for further information.

Following the public comment period on the risk management approach, the Government of Canada will initiate the development of the specific risk management instrument(s), where necessary. Comments received on the risk management approach will be taken into consideration in the selection or development of the instrument(s). Consultation will also take place as instruments are developed.

8.2 Timing of Actions

Electronic consultation on the draft assessment and risk management scope: March 1, 2025 to April 30, 2025. This should include the submission of public comments, additional studies, and/or information on cedarwood oil, Texan cedarwood oil, enoxolone, mimosa oil, and ivy extract.

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 cedarwood oil, Texan cedarwood oil, enoxolone, mimosa oil, and ivy extract 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 Tricyclic Sesquiterpenes and Triterpenoids Group

CAS RN	Subgroup	*Domestic Substances List* name	Common name
469-61-4	Tricyclic Sesquiterpene Subgroup 1	1H-3a,7-Methanoazulene, 2,3,4,7,8,8a-hexahydro-3,6,8,8-tetramethyl-, [3R-(3α,3aβ,7β,8aα)]-	Alpha-cedrene
470-40-6	Tricyclic Sesquiterpene Subgroup 1	Cyclopropa[d]naphthalene, 1,1a,4,4a,5,6,7,8-octahydro-2,4a,8,8-tetramethyl-, [1aS-(1aα,4aβ,8aR)]-	Thujopsene
489-40-7	Tricyclic Sesquiterpene Subgroup 1	1H-Cycloprop[e]azulene, 1a,2,3,4,4a,5,6,7b-octahydro-1,1,4,7-tetramethyl-, [1aR-(1aα,4α,4aβ,7bα)]-	Alpha-gurjunene
514-51-2	Tricyclic Sesquiterpene Subgroup 1	4,7-Methanoazulene, 1,2,3,4,5,6,7,8-octahydro-1,4,9,9-tetramethyl-, [1S-(1α,4α,7α)]-	Beta-patchoulene
546-28-1	Tricyclic Sesquiterpene Subgroup 1	1H-3a,7-Methanoazulene, octahydro-3,8,8-trimethyl-6-methylene-, [3R-(3α,3aβ,7β,8aα)]-	Beta-cedrene
8000-27-9[a]	Tricyclic Sesquiterpene Subgroup 1	Oils, cedarwood	Cedarwood oil
68608-32-2[a]	Tricyclic Sesquiterpene Subgroup 1	Terpenes and Terpenoids, cedarwood-oil	T&T cedarwood oil
68990-83-0[a]	Tricyclic Sesquiterpene Subgroup 1	Oils, cedarwood, Texan	Texan cedarwood oil
59056-62-1	Individual (Tricyclic Sesquiterpene)	2,3b-Methano-3bH-cyclopenta[1,3]cyclopropa[1,2]benzene-4-methanol, octahydro-7,7,8,8-tetramethyl-, acetate	Amboryl acetate
471-53-4	Triterpenoid Subgroup 2	Olean-12-en-29-oic acid, 3-hydroxy-11-oxo-, (3β,20β)-	Enoxolone

4572-09-2[a]	Triterpenoid Subgroup 2	Olean-12-en-29-oic acid, 3-hydroxy-11-oxo-, (3β,20β)-, compd. with (2,5-dioxo-4-imidazolidinyl)urea (1:1)	Allantoin glycyrrhetinic acid
8031-03-6[a,b]	Individual (Triterpenoid)	Oils, mimosa	Mimosa oil
84082-54-2[a]	Individual (Triterpenoid)	Ivy, Hedera helix, ext.	Ivy extract
90045-38-8[a]	Individual (Triterpenoid)	Ginseng, Panax quinquefolium, ext.	American ginseng extract

[a] This CAS RN is a UVCB (substance of unknown or variable composition, complex reaction products, or biological materials).
[b] This substance was not identified under subsection 73(1) of CEPA but was included in the draft assessment as it was considered a priority through other mechanisms.