



Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration

Notice of interim decisions to amend (or not amend) the current Poisons Standard

June 2026

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Notice of interim decisions made under Regulation 42ZCZN of the Therapeutic Goods Regulations 1990

This web publication constitutes a notice for the purposes of regulation 42ZCZP of the Therapeutic Goods Regulations 1990 (the Regulations). In accordance with regulation 42ZCZP, this notice sets out:

- the interim decisions made by a delegate of the Secretary of the Department of Health and Aged Care responsible for scheduling of medicines and chemicals (the Delegate)¹ under regulation 42ZCZN in relation to proposed amendments to the current Poisons Standard which were referred to an expert advisory committee² under subdivision 3D.2 of the Regulations in June 2025.
- the proposed date of effect of the proposed amendments (in circumstances where the interim decision proposes an amendment to the current Poisons Standard).

In accordance with regulation 42ZCZP, interested persons (including the applicant requesting the amendment) are invited to make submissions to the Secretary in relation to these interim decisions on or before **10 July 2026**.

Submissions should be provided through our [consultation hub](#). Submissions will be considered by the Delegate in making the final decision.

Please note that in accordance with subregulation 42ZCZQ(4) of the Regulations, the Secretary must publish all relevant submissions received, unless the Secretary considers the information to be confidential information.

Defined terms

In this notice the following defined terms are used in addition to those above:

- the *Therapeutic Goods Act 1989 (Cth)* (the **Act**)
- the Scheduling Policy Framework 2018 (the **SPF**)
- the Scheduling handbook: Guidance for amending the Poisons Standard (the **Handbook**), and
- the Therapeutic Goods Administration (the **TGA**).

Note: additional terms are also be defined for individual decisions.

¹ For the purposes of s 52D of the *Therapeutic Goods Act 1989 (Cth)*

² Established under sections 52B and 52C of the *Therapeutic Goods Act 1989 (Cth)*.

Interim decisions on proposed amendments referred to the Advisory Committee on Medicines Scheduling (ACMS #47, JUNE 2025)

Interim decision in relation to somatrogon, lonapegsomatropin and somapacitan

Proposal

The Department of Health, Disability and Ageing has proposed creating new Prescription only (Schedule 4) entries for somatrogon and lonapegsomatropin in the current Poisons Standard.

Somatrogon and lonapegsomatropin are human growth hormone analogues primarily used for the treatment of growth failure in paediatric patients, caused by inadequate endogenous growth hormone production. Somapacitan is a functional analogue of these two substances but is also used as replacement therapy in adults with growth hormone deficiency. While somapacitan is currently scheduled as a Prescription only (Schedule 4) medicine, somatrogon and lonapegsomatropin are currently not scheduled.

Additional controls on the possession and supply of somatrogon, lonapegsomatropin and somapacitan, inclusion of all 3 substances in Appendix D has also been proposed.

Interim decision

Pursuant to regulation 42ZCZN of the Regulations, the Delegate has, in relation to the proposed amendments, made an interim decision to amend the current Poisons Standard in relation to somatrogon, lonapegsomatropin and somapacitan as follows.³ Due the similarities in their function and therapeutic use, all 3 substances have been considered together.

Schedule 4 – New entry

SOMATROGON

Schedule 4 – New entry

LONAPEGSOMATROPIN

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SOMATROGON

Schedule 4

Appendix D, clause 5

LONAPEGSOMATROPIN

Schedule 4

Appendix D, clause 5

SOMAPACITAN

Schedule 4

Appendix D, clause 5

³ Proposed additions are shown in green underlined font, proposed deletions are shown in red strikethrough font, and text without this formatting represents the current text in the Poisons Standard.

Appendix D, clause 5 – Additional controls on possession or supply of poisons included in Schedule 4 or 8

Item	Poison
26	LONAPEGSOMATROPIN
34	SOMATROGON
35	SOMAPACITAN

Materials considered

In making this interim decision, the Delegate considered the following material:

- the application to amend the current Poisons Standard with respect to somatrogon, lonapegsomatropin and somapacitan (the **Application**)
- the 2 [public submissions](#) received in response to the [pre-meeting consultation](#) under regulation 42ZCZK of the Regulations (the **Submissions**)
- the advice received from the 47th meeting of the Advisory Committee on Medicines Scheduling
- subsection 52E(1) of the Act, in particular (a) risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; (e) the potential for abuse of a substance; and (f) any other matters that the Secretary considers necessary to protect public health
- the SPF, and
- the Handbook.

Summary of Committee advice to the Delegate

The Committee recommended that the Poisons Standard be amended in relation to somatrogon, lonapegsomatropin and somapacitan. They agreed on the creation of separate entries for somatrogon and lonapegsomatropin as this approach would avoid confusion and support law enforcement activities. They also agreed on the inclusion of all 3 substances in Appendix D due to their potential for misuse as lipolytic and anabolic agents and need for medical diagnosis of the indications and oversight during treatment.

The Committee recommended implementation in the first available Poisons Standard update after the Final Decision, as it would provide regulatory clarity and minimises risks of abuse or misuse while minimally impacting the industry.

Members agreed that the relevant matters under subsection 52E(1) of the Act included: (a) risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; (e) the potential for abuse of a substance; and (f) any other matters that the Secretary considers necessary to protect public health.

The reasons for the advice included:

a) the risks and benefits of the use of a substance

Risks:

- The risk profiles of all 3 substances are similar to that of somatropin, which is currently captured under Schedule 4 and Appendix D due to its abuse potential and requirement for medical oversight for the indication (treatment of stunted growth due to growth hormone deficiency in children and adolescents).

Benefits:

- An effective treatment for growth hormone deficiency in children and adolescents.

b) the purposes for which a substance is to be used and the extent of use of a substance

- Restricted growth due to growth hormone deficiency in children and adolescents. A relatively uncommon but serious condition.

c) the toxicity of a substance

- The safety profiles of all 3 drugs are similar to that of somatropin.

d) the dosage, formulation, labelling, packaging and presentation of a substance

- All 3 medications are available as pre-filled pens to be administered weekly via subcutaneous injection.

e) the potential for abuse of a substance

- There have been many reports of the misuse of growth hormones and their analogues by bodybuilders and in sports. The World Anti-Doping Agency has listed somatrogen, lonapegsomatropin and somapacitan as prohibited substances due to the potential misuse of their lipolytic and anabolic properties in sports.

f) any other matters that the Secretary considers necessary to protect public health

- Growth failure due to insufficient endogenous growth hormone is a condition requiring medical diagnosis and oversight during treatment.

Reasons for the interim decision (including findings on material questions of fact)

I agree with the Committee's findings on the relevant provisions of section 52E of the Act.

Two public submissions were received during the pre-meeting consultation period, both of which were supportive of the proposal. One submitter provided written justification for the support while the other did not.

Somatrogen, lonapegsomatropin and somapacitan function similarly as somatropin, a synthetic human growth hormone, but differ from somatropin in their primary structures and pharmacokinetics. Somapacitan varies from somatropin by one amino acid change which allows it to bind albumin. Somatrogen carries the same 191 amino acid sequence of somatropin but additionally contains 3 copies of the C-terminal peptide from the beta chain of human chorionic gonadotropin. Lonapegsomatropin consists of unmodified somatropin sequence attached covalently to an inert carrier molecule, methoxypolyethylene glycol, via a transient linker. These structural modifications allow for reduced clearance from the body (somatrogen and somapacitan) or sustained release (lonapegsomatropin), allowing for less frequent dosing than somatropin (section 52E(1)(a) of the Act).

Regarding section 52E(1)(b) of the Act, all 3 substances serve the purpose of treating growth hormone deficiency in children and adolescents. Whilst the condition is relatively uncommon, if left untreated growth hormone deficiency can lead to delayed puberty and permanent short stature⁴. However, diagnosis, management or monitoring of growth hormone deficiency requires medical intervention (Schedule 4, factor 1). Treatment typically involves dosage adjustment over time (Schedule 4,

⁴ Brod, M., S. L. Aolga, J. F. Beck, L. Wilkinson, L. Højbjerg, and M. H. Rasmussen. Understanding Burden of Illness for Child Growth Hormone Deficiency. *Quality of Life Research* 26, no. 2 (2017): 1673–1686. <https://doi.org/10.1007/s11136-017-1529-1>.

factor 2) and unmonitored and prolonged use of growth hormones runs the risk of the patient developing conditions such as diabetes or acromegaly, which can be permanent and/or life-threatening (Schedule 4, factor 4).

Regarding the risks and toxicity, sections 52E(1)(a) and (c) of the Act, all 3 substances have safety profiles comparable to the Schedule 4 substance, somatropin. As of January 2026, there were 218 reports of adverse events (AE) from somatropin on the TGA's [Database of Adverse Event Notifications](#). Three of these AEs resulted in death and in 185 cases, somatropin was the single suspected medicine. A large portion of the AEs were associated with dosing, such as missing doses or administering an incorrect dose (Schedule 4, factors 4 and 5). There were 9 AEs for products containing somatropin as an active ingredient, and no reports of AEs for lonapegsomatropin or somapacitan.

With consideration to section 52E (1)(d) of the Act, all 3 substances are long-acting derivatives of somatropin. At present, the [Australian Register of Therapeutic Goods](#) lists 2 products containing somatropin, 9 containing lonapegsomatropin and 3 containing somapacitan. Somatropin and somapacitan are available as pre-filled pens, whilst lonapegsomatropin is primarily sold in dual-chamber cartridges for reconstitution via an auto-injector. All 3 substances require once-weekly administration via subcutaneous injection (Schedule 4, factor 2).

With reference to section 52E(1)(e) of the Act, the inclusion of somatropin, lonapegsomatropin and somapacitan in Appendix D entries reflects their potential for misuse and abuse (Schedule 4, factor 3). Growth hormones have been reported to be used in sports and bodybuilding for their lipolytic and anabolic properties. The World Anti-Doping Agency includes each of the 3 substances on its International Standard Prohibited List under class S2. Illicit possession and use of human growth hormones and their analogues pose a concern for both the TGA and law enforcement agencies. I agree with the Committee's stance that separately listing each of these 3 substances will support enforcement activities against illicit possession, supply and use of these substances.

Inclusion of all 3 substances in Schedule 4 and Appendix D ensures that their use remains safe and professionally monitored. Noting the need for medical supervision in diagnosing and treating growth hormone deficiency, misuse potential of the 3 substances and limited number of products available in the market, I have decided that the decision should be implemented in the next Poisons Standard update.

Proposed implementation date

1 October 2026

Interim decision in relation to 6-methylnicotine

Proposal

The Department of Health, Disability and Ageing proposed the creation of a Dangerous Poison (Schedule 7) entry for 6-methylnicotine. 6-Methylnicotine has been reported to be present in several e-cigarette liquids being sold in Australia that are advertised as nicotine-free or a nicotine-alternative.⁵ There is evidence that 6-methylnicotine is also being added to preparations such as oral pouches. The proposal was initiated to mitigate the potential public health risks arising from 6-methylnicotine.

⁵ Jenkins C, Kelso C, Morgan J. 6-Methylnicotine: a new nicotine alternative identified in e-cigarette liquids sold in Australia. *Med J Aust.* 2024;221(7):333-335. <https://doi.org/10.5694/mja2.52423>.

Interim decision

Pursuant to regulation 42ZCZN of the Regulations, the Delegate has, in relation to the proposed amendment, made an interim decision to amend the current Poisons Standard as follows:⁶

Schedule 9 – New entry

6-METHYLNICOTINE

Index – New entry

6-METHYLNICOTINE

Cross-reference: CAS No. 13270-56-9

Schedule 9

Materials considered

In making this interim decision, the Delegate considered the following material:

- the application to amend the current Poisons Standard with respect to 6-methylnicotine (the **Application**)
- the 163 [public submissions](#), with 9 including a written component, received in response to the [pre-meeting consultation](#) under regulation 42ZCZK of the Regulations (the **Submissions**)
- the advice received from the 47th meeting of the Advisory Committee on Medicines Scheduling (the **Committee**)
- subsection 52E(1) of the Act, in particular (a) risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; (e) the potential for abuse of a substance; and (f) any other matters that the Secretary considers necessary to protect public health
- the SPF, and
- the Handbook.

Summary of Committee advice to the Delegate

The Committee recommended the creation of a new Prohibited substance (Schedule 9) entry for 6-methylnicotine in the Poisons Standard. This advice was based on the substance's high potency, acute toxicity, increased potential for addiction, and its emerging use in consumer products marketed as nicotine-free alternatives. The Committee expressed concerns about misleading safety claims and the appeal of such products to vulnerable populations, including younger users.

Members agreed that the relevant matters under subsection 52E(1) of the Act included: (a) risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; (e) the potential for abuse of a substance; and (f) any other matters that the Secretary considers necessary to protect public health.

⁶ Proposed additions are shown in green underlined font, proposed deletions are shown in red strikethrough font, and text without this formatting represents the current text in the Poisons Standard.

The reasons for the advice included:

a) the risks and benefits of the use of a substance

Risks

- 6-methylnicotine is between 2 and 5 times more potent than nicotine and therefore may lead to increased risks of harm at lower doses.
- 6-methylnicotine poses toxicity risks including potential to increase the risk of damage to lung cells, including via cancer pathways.
- There is greater potential to damage from reactive oxygen species (ROS) generated during heating.

Benefits

- No identified benefits.

b) the purposes for which a substance is to be used and the extent of use of a substance

- There is no evidence for the therapeutic use or efficacy of 6-methylnicotine in smoking cessation
- No known use in industry.

c) the toxicity of a substance

- Human bronchial epithelial cells exposed to 6-methylnicotine, demonstrated a significant increase in cytotoxicity and intracellular ROS induction in a dose-specific manner compared to nicotine.
- The European Chemicals Agency considers 6-methyl nicotine to be acutely toxic.
- Concerns regarding psychotropic effects.

d) the dosage, formulation, labelling, packaging and presentation of a substance

- There are no substances containing 6-methylnicotine available on the ARTG.
- Present in unregulated pouches, vaping products and e-liquids. Often presented as nicotine free alternatives or safer alternatives to conventional nicotine.

e) the potential for abuse of a substance

- Evidence suggests 6-methylnicotine is potentially more addictive than nicotine, thereby has potential for misuse or abuse.

f) any other matters that the Secretary considers necessary to protect public health

- Consideration of how a class-based approach to scheduling nicotine analogues could occur.
- 6-methylnicotine is not permitted for use in vaping products as per TGO 110 order.
- Enforcement challenges need to be considered.
- Consider research uses.
- Use in younger people could be a gateway to use of tobacco and other nicotine products and their associated harms.

Reasons for the interim decision (including findings on material questions of fact)

I agree with the Committee's findings on the relevant provisions of section 52E of the Act and its recommendation to create a new Prohibited substance (Schedule 9) entry for 6-methylnicotine in the Poisons Standard.

I have considered the 163 public submissions received during the pre-meeting consultation period, 148 of which were fully supportive of the original proposal to classify the substance as a Dangerous Poison (Schedule 7), 14 partially supportive and 1 opposed. Nine public submissions provided written justifications citing concerns about toxicity, addictiveness, and lack of therapeutic benefit. Interested parties were also given the option to indicate support or opposition without providing written comments. These responses were counted toward overall support but did not include reasons, limiting the extent of my consideration to noting that the majority were in favour of the scheduling proposal. These submissions reinforced the Committee's advice that urgent regulatory action is necessary.

In assessing the matters under sections 52E(1)(a) and (c), I agree with the Committee that 6-methylnicotine is a synthetic analogue of nicotine rather than a derivative. Evidence supports that it poses a substantially greater health hazard than nicotine. Functional activity studies show stronger binding to nicotinic cholinergic receptors, with estimates of 2–5 times greater potency and significantly increased psychotropic effects.⁷ Toxicological research reveals elevated ROS, oxidative stress, and DNA damage, raising serious concerns about carcinogenic pathways.⁸ Thermal breakdown in e-cigarette liquids produces elevated levels of cytotoxic compounds and ROS, resulting in greater cellular damage compared to nicotine. The [European Chemicals Agency](#) classifies 6-methylnicotine as acutely toxic, and animal studies confirm lower median lethal doses than nicotine. There are no identified therapeutic benefits, and the risks outweigh any claims of safety.

With respect to section 52E(1)(b), I note that there is no evidence of approved therapeutic use or efficacy for 6-methylnicotine. Despite this, it has been detected in unapproved consumer products such as oral pouches and vaping liquids, often marketed as “nicotine-free” alternatives. These products are increasingly accessible and used recreationally, particularly among younger demographics, indicating a growing extent of use without any approved medical purpose.

In relation to section 52E(1)(d), I note that oral pouches sold overseas have been identified containing between 4 mg and 20 mg of 6-methylnicotine per pouch, which is similar to the amount found in regulated nicotine products. In Australia, some vaping liquids have been found with concentrations as high as 100 mg/mL. These products are sold without clear labelling, dosage guidance, or regulatory oversight, creating a high risk of accidental overexposure and misuse. Furthermore, claims that these products are safer than nicotine can mislead the public and undermine existing regulatory controls.

In considering sections 52E(1)(e) and (f), I am convinced that stronger regulatory controls are essential in light of the significant public health risks posed by 6-methylnicotine. Evidence suggests this substance may be more addictive than nicotine, increasing the risk of dependence, particularly among vulnerable populations. Its availability in unregulated products, often accompanied by misleading claims of reduced harm, raises serious concerns about uptake and potential gateway effects to tobacco use. Following the implementation of a new regulatory framework for vaping products in 2024, I am concerned that certain businesses and consumers may increasingly turn to oral pouches containing 6-methylnicotine. These products expose users to a substance that is both potent and addictive, without any approved medical benefit.

I agree with the Committee advice that classifying 6-methylnicotine as a Dangerous Poison (Schedule 7) does not provide sufficient regulatory controls to manage the risks. A Schedule 7 entry would limit the ability of authorities to take appropriate regulatory action, making enforcement difficult

⁷ Wang, D.X., Booth, H., Lerner-Marmarosh, N., Osdene, T.S. and Abood, L.G. (1998), Structure–activity relationships for nicotine analogs comparing competition for [3H]nicotine binding and psychotropic potency†. *Drug Dev. Res.*, 45: 10-16. Doi: [10.1002/\(SICI\)1098-2299\(199809\)45:1<10::AID-DDR2>3.0.CO;2-G](https://doi.org/10.1002/(SICI)1098-2299(199809)45:1<10::AID-DDR2>3.0.CO;2-G)

⁸ Effah, F., Sun, Y., Friedman, A. and Rahman, I. (2025) Emerging nicotine analogue 6-methyl nicotine increases reactive oxygen species in aerosols and cytotoxicity in human bronchial epithelial cells. *Toxicol. Lett.* 405: 9-15. Doi: [10.1016/j.toxlet.2025.01.007](https://doi.org/10.1016/j.toxlet.2025.01.007)

and is likely to enable 6-methylnicotine products to continue being accessible to the public. In contrast, Schedule 9 offers a stronger legal framework, enabling more effective enforcement through higher penalties for unlawful supply and possession under the Commonwealth and jurisdictional drug laws. This level of control will enable the states and territories to more effectively protect public health and prevent the spread of misleading claims that nicotine analogues are safer alternatives.

The Committee has identified a global trend in the development of nicotine analogues like 6-methylnicotine, which are designed to exploit controls in existing regulations. Suppliers are making “nicotine-free” claims in an attempt to avoid regulation, and Australia must take strong action to prevent similar practices. There are currently no lawful products in Australia that would be affected by this decision, which supports immediate implementation and will not disrupt legitimate markets.

For these reasons, I am satisfied that listing 6-methylnicotine in Schedule 9 of the Poisons Standard is the most appropriate course of action. This classification addresses serious health risks and enables stricter regulation required for 6-methylnicotine which is a high-risk substance with no therapeutic value.

Proposed implementation date

1 October 2026

Interim decisions on proposed amendments referred to the Advisory Committees on Medicines and Chemicals Scheduling in joint session (ACMS-ACCS #40, JUNE 2025)

Interim decision in relation to azelaic acid

Proposal

The applicant proposed to amend the current Pharmacy medicine (Schedule 2) entry for azelaic acid in the Poisons Standard as below.

Schedule 2 – Amend Entry

AZELAIC ACID in dermal preparations for human ~~therapeutic~~ use except in preparations for cosmetic use containing 10% or less of azelaic acid.

Under the proposal cosmetic preparations containing 10% or less azelaic acid will be captured as Caution (Schedule 5) and will require cautionary labelling which is same as the current requirement applied to all non-therapeutic preparations of azelaic acid. All other preparations for human use containing more than 10% of azelaic acid will be captured under Schedule 2 and will be required to be assessed by the TGA for quality, safety and efficacy prior to being available in the Australian market.

Interim decision

Pursuant to regulation 42ZCZN of the Regulations, the Delegate has, in relation to the proposed amendment, made an interim decision to amend the current Poisons Standard in relation to azelaic acid as follows.⁹

Schedule 2

AZELAIC ACID in dermal preparations for human therapeutic use.

Schedule 3

AZELAIC ACID for therapeutic use except when included in Schedule 2.

Schedule 4

AZELAIC ACID except when included in Schedule 2 or 4.

Appendix E, Clause 3 - Poisons that must be labelled with first aid instructions

Item	Poison	Standard statement for first aid instruction
32	AZELAIC ACID	A – For advice, contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor (at once).
		E1 – If in eyes wash out immediately with water.

⁹ Proposed additions are shown in green underlined font, proposed deletions are shown in red strikethrough font, and text without this formatting represents the current text in the Poisons Standard.

Appendix F, Clause 4 - Poisons that must be labelled with warning statements and safety directions – Amend Entry

Item	Poison	Safety directions
33	AZELAIC ACID	1 – Avoid contact with eyes.
		4 – Avoid contact with skin. 31 - Do not use on broken skin.

Materials considered

In making this interim decision, the Delegate considered the following material:

- the application to amend the current Poisons Standard with respect to azelaic acid (the **Application**)
- the 161 [public submissions](#), with 10 including a written component, received in response to the [pre-meeting consultation](#) under regulation 42ZCZK of the Regulations (the **Submissions**)
- the advice received from the 40th meeting of the Advisory Committee on Medicines and Chemicals Scheduling in joint session (the **Committee**)
- subsection 52E(1) of the Act, in particular (a) risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; (e) the potential for abuse of a substance; and (f) any other matters that the Secretary considers necessary to protect public health
- the SPF, and
- the Handbook.

Summary of Committee advice to the Delegate

The Committee recommended that the current Poisons Standard in relation to azelaic acid be amended as below, such that cosmetic preparations containing 10% or less azelaic acid are exempted from the current Schedule 5 classification provided they are labelled with appropriate warning statements and safety directions. Human therapeutic preparations will continue to be captured as Pharmacy only (Schedule 2) and Prescription only (Schedule 4) medicines.

The amendments are different from the ones proposed by the applicant and are as below.¹⁰

Schedule 5 – Amend Entry

AZELAIC ACID **except**

- a) when included in Schedule 2 or 4; or
- b) in cosmetic preparations containing 10% or less azelaic acid when labelled with the statements:
 - (i) Avoid contact with eyes
 - (ii) Avoid contact with broken skin.
 - (iii) If in eyes wash out immediately with water.

¹⁰ Proposed amendments to the Poisons Standard in relation to azelaic acid referred to the Joint ACMS-ACCS #40 in June 2025 available at: www.consultations.tga.gov.au/tga/scheduling-pre-meeting-june-2025/user_uploads/pre-meeting-public-notice---june-2025-1.pdf (published 17 April 2025).

- (iv) For advice, contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor (at once).

Schedule 4

AZELAIC ACID for therapeutic use **except** when included in Schedule 2.

Schedule 2

AZELAIC ACID in dermal preparations for human therapeutic use

Azelaic acid preparations captured under the Schedule 5 entry will also require the following first aid instructions (Appendix E, clause 3), and warning statements and safety directions (Appendix F, clause 4).

Appendix E, Clause 3 - Poisons that must be labelled with first aid instructions

Item	Poison	Standard statement for first aid instruction
32	AZELAIC ACID	A – For advice, contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor (at once).
		E1 – If in eyes wash out immediately with water.

Appendix F, Clause 4 - Poisons that must be labelled with warning statements and safety directions

Item	Poison	Safety directions
33	AZELAIC ACID	1 – Avoid contact with eyes.
		4 – Avoid contact with skin.
		31 - Do not use on broken skin.

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AZELAIC ACID

Schedule 6

Schedule 5

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Appendix E, Clause 3

Appendix F, Clause 4

The Committee considered the current safety direction 'avoid contact with skin' is not suitable for dermal cosmetic products and recommended the direction be revised to 'do not use on broken or peeling skin'.

The Committee also recommended an immediate implementation as the changes will facilitate market access for cosmetics with azelaic acid and will impose less stringent measures for manufacturers.

Members agreed that the relevant matters under subsection 52E(1) of the Act included: (a) risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; and (f) any other matters that the Secretary considers necessary to protect public health.

The reasons for the advice included:

a) the risks and benefits of the use of a substance

Risks:

- Newer formulations such as oil-in-water microemulsions of azelaic acid can significantly increase exposure, skin penetration and risk of irritation
- Self-diagnosis and treatment for dermatological conditions which require medical assessment.

Benefits:

- Effective for treatment of mild-to-moderate acne and rosacea
- Confirmed keratolytic, antibacterial, and antioxidant properties
- Low oral and dermal toxicity with good safety profile for cosmetic use formulations (<10%).

b) the purposes for which a substance is to be used and the extent of use of a substance

- Cosmetic uses: Products containing azelaic acid derivatives also used as buffer in fragrances.
- Therapeutic uses: Several topical formulations used to treat rosacea and acne.
- Emerging veterinarian use of azelaic acid derivatives for seborrheic dermatitis in animals (registered international products) e.g. adelmidrol.
- Industrial uses: wide ranging uses, including in adhesives, lubricants, cleaning products, inks and toners.

c) the toxicity of a substance

- Low acute oral and dermal toxicity
- Azelaic acid is not a skin sensitiser; not genotoxic or carcinogenic, and not expected to be carcinogenic in humans (US EPA Report)
- Moderate to severe skin and eye irritation is well documented in higher strength formulations (with products containing 15–20% azelaic acid)
- Recent studies indicate oil in water microemulsion formulations of azelaic acid have increased dermal permeability and activity.¹¹

d) the dosage, formulation, labelling, packaging and presentation of a substance

- Therapeutic use: Primarily cream and gel products for topical use
- Cosmetic use: Over 40 different cosmetic products and formulations reported on EWG database ranging from facial cleansers to serums, exfoliants, face masks and antiperspirants
- For therapeutic or cosmetic use: cream and gel products available in Australia for topical application
- Despite the wide range of possible uses, limited information on current industrial/domestic use in Australia

¹¹ Hung WH, Chen PK, Fang CW, Lin YC, Wu PC. Preparation and Evaluation of Azelaic Acid Topical Microemulsion Formulation: In Vitro and In Vivo Study. *Pharmaceutics*. 2021 Mar 19;13(3):410. doi: 10.3390/pharmaceutics13030410. PMID: 3380883

- Safety directions to be appropriate for cosmetic use (e.g. do not use on broken skin).

e) the potential for abuse of a substance

- Nil.

f) any other matters that the Secretary considers necessary to protect public health

- Azelaic acid is banned in some Asian countries under current regulations for cosmetic use (as a skin whitening agent), although products containing less than 10% azelaic acid as an active ingredient seem to be available.
- Overseas cosmetic use includes topical formulation indicated for rosacea, acne and these products have significant potential to be imported into Australia.

Reasons for the interim decision (including findings on material questions of fact)

I have made an interim decision to amend the current scheduling of azelaic acid to revise the Appendix F Safety Directions from “Avoid contact with skin” to “Do not use on broken skin.”

In making this interim decision, I have decided not to exempt cosmetic preparations containing 10% or less azelaic acid from Schedule 5 or included in Schedule 2.

I broadly agree with the Committee's findings on the relevant provisions of section 52E of the Act except for their considerations of the safety of cosmetic preparations containing less than 10% azelaic acid. Previously, exempting cosmetic preparations containing less than 10% azelaic acid from Schedule 5 classification was considered, but was not agreed due to lack of data demonstrating safety at concentrations of 10% or less of azelaic acid.^{12,13} I remain concerned by the continued lack of evidence that can adequately demonstrate that cosmetic preparations containing 10% or less azelaic acid pose no or very low risks to the users. I agree with the Committee advice that based on the risks from use of azelaic acid in cosmetic products, “Do not use on broken skin” is a more appropriate safety direction than “Avoid contact with skin”.

I have considered the 161 public submissions received during the pre-meeting consultation period. Interested parties were given the choice to select from options to indicate their support or opposition to the proposed amendment without providing a written component.

Of the 161 submissions, 140 were supportive of the proposal with 6 providing written responses and 19 submissions were partially supportive with 2 providing written justification. Two submissions opposed the proposal and both provided written components.

The Australian College of Dermatologists noted that dermatologists use 15% azelaic acid for acne, rosacea, and melasma and strongly supported therapeutic use to be captured as Pharmacy medicines (Schedule 2) or Prescription-only medicines (Schedule 4) because of the known potential of 15–20% azelaic acid preparations to lead to moderate to severe skin and eye reactions. Several supporting submissions were in favour of the proposal which will ensure health professional oversight of products containing more than 10% azelaic acid while cosmetic preparations with less than 10% azelaic acid will require cautionary labelling under Schedule 5.

One written submission in partial support stated that azelaic acid does not require cautionary labelling due to its antioxidant properties at low concentrations while the other recommended a 5% limit in cosmetics as a safer threshold.

¹² Notice of interim decision to amend (or not amend) the current Poisons Standard in relation to azelaic acid available at: www.tga.gov.au/sites/default/files/2023-07/public-notice-of-interim-decisions-acms-41-accs-36-joint-acms-accs-33-march-2023.pdf (published 12 July 2023).

¹³ Notice of final decision to amend (or not amend) the current Poisons Standard in relation to azelaic acid available at: www.tga.gov.au/sites/default/files/2024-11/notice-final-decision-amend-or-not-amend-current-poisons-standard-acms-44-accs-38-joint-acms-accs-36-marh-2024.pdf (published 27 September 2024).

One opposing submission questioned the rationale of the 10% cut-off for exemption from Schedule 2 and suggested removal of the warning statement to avoid contact with skin from the current requirements for all cosmetics. Noting the moderate to severe skin and eye reactions at 15–20% azelaic acid, this submitter proposed cosmetics containing less than 14% azelaic acid be exempted from the current Caution (Schedule 5) entry provided they carry warning statements and safety directions regarding contact with the eye.

Regarding sections 52E(1)(a), (b) and (d) of the Act, azelaic acid is widely used across cosmetic, therapeutic, and industrial applications. Dermal preparations containing 15–20% azelaic acid are approved and recommended for the treatment of rosacea, acne vulgaris, melasma and post-inflammatory hyperpigmentation, particularly when associated with acne and in people with darker skin.¹⁴ Currently, there are 3 azelaic acid gels indicated for acne vulgaris and/or papulopustular rosacea listed on the Australian Register of Therapeutic Goods. In New Zealand, azelaic acid preparations for dermal use are pharmacy only medicines.¹⁵

Cosmetic formulations of azelaic acid are available internationally as antimicrobial, anti-acne and skin-whitening/brightening agents and personal care products such as skin serums, lotions, gel masks, creams, exfoliants and shampoos.¹⁶ However, they typically contain less than 10% azelaic acid and lack therapeutic efficacy as monotherapy for acne and rosacea, and are primarily used for skin brightening and antioxidant benefits. Health Canada has restricted azelaic acid and its salts in cosmetics to a maximum concentration of 14% due to risk of skin irritation above 14%.¹⁷

In relation to section 52E(1)(c) of the Act, I note that the majority of the adverse effects of azelaic acid regarding skin and eye irritations have been reported at concentrations of 15–20%. The most common adverse effects include burning, stinging, pruritus, erythema, dryness, and scaling, particularly during the initial weeks of therapy. These effects are generally mild to moderate, local and transient.¹⁸ However, therapeutic products are applied topically twice a day and while improvement is typically seen within 1–2 months, treatment can be continued for up to 6 months. No significant systemic adverse reactions or photosensitivity have been observed with these products and 15–20% azelaic acid is generally considered to be well tolerated for short to mid-term therapeutic use.¹⁹ Further, all the therapeutics products available in Australia warn consumers about avoiding contact with eyes and advising them to discontinue use or consult a pharmacist or doctor if irritation persists or if the condition does not improve within 8 weeks. However, cosmetic products containing azelaic acid can be expected to be applied once to twice daily and for continuous ongoing use.

One study comparing 10% and 20% azelaic acid creams for the treatment of mild to moderate acne reported that the 10% azelaic acid cream demonstrated better safety compared with a lower incidence of adverse events, most of which were mild.²⁰ I note that the Committees' advice is consistent with the submission of the Australasian College of Dermatologists that 10% could be a reasonable maximum permissible level for azelaic acid in cosmetics, if products are labelled with suitable safety statements. However, the aforementioned results do not exclude the occurrence of adverse events or establish the safety of azelaic acid formulations at concentrations below 10% beyond doubt.

Furthermore, 2 other small scale clinical studies reported local cutaneous adverse effects in women following 12 weeks of treatment with 5% azelaic acid preparations. The first one reported scaling, dry skin, erythema, oiliness and pruritus in half of the participants treated with preparations containing

¹⁴ King S, Campbell J, Rowe R, Daly ML, Moncrieff G, Maybury C. A systematic review to evaluate the efficacy of azelaic acid in the management of acne, rosacea, melasma and skin aging. *J Cosmet Dermatol*. 2023 Oct;22(10):2650-2662. DOI: <https://doi.org/10.1111/jocd.15923>.

¹⁵ New Zealand Medicines and Medical Devices Safety Authority - [MEDSAFE - Database of Medicine Classifications](#)

¹⁶ Australian Industrial Chemicals Introduction Scheme (2021). [Evaluation statement: Nonanedioic acid \(azelaic acid\)](#)

¹⁷ [Health Canada - August 2022 Changes to the Cosmetic Ingredient Hotlist](#)

¹⁸ Petrovici AG, Spennato M, Bîtcan I, Péter F, Cotarcă L, Todea A, Ordodi VL. A Comprehensive Review of Azelaic Acid Pharmacological Properties, Clinical Applications, and Innovative Topical Formulations. *Pharmaceutics*. 2025; 18(9):1273. DOI: <https://doi.org/10.3390/ph18091273>.

¹⁹ Feng X, Shang J, Gu Z, Gong J, Chen Y, Liu Y. Azelaic Acid: Mechanisms of Action and Clinical Applications. *Clin Cosmet Investig Dermatol*. 2024 Oct 22;17:2359-2371. DOI: <https://doi.org/10.2147/ccid.s485237>.

²⁰ Tomić I, Miočić S, Pepić I, Šimić D, Filipović-Grčić J. Efficacy and Safety of Azelaic Acid Nanocrystal-Loaded In Situ Hydrogel in the Treatment of Acne Vulgaris. *Pharmaceutics*. 2021;13(4):567. DOI: <https://doi.org/10.3390/pharmaceutics13040567>.

either 5% azelaic acid or 5% azelaic acid with 2% clindamycin.²¹ In the other study, treatment with 5% azelaic acid (with 2% erythromycin) resulted in at least one adverse effect (scaling, dry skin, erythema, oiliness and pruritus) in 27.5% of the participants.²² While the incidence of adverse events at 5% azelaic acid was significantly lower than treatment with 20% azelaic acid alone (45%), based on these two reports the potential for skin or eye irritation for cosmetics containing 10% or less azelaic acid cannot be ruled out.

Cosmetic products, intended for daily use for reducing redness, hyperpigmentation, even skin tones etc., generally contain 10% azelaic acid but 20% formulations are available internationally. Ongoing, unsupervised use of such cosmetics, can therefore pose considerable risk from long-term exposure exacerbated by lack of consumer knowledge. Azelaic acid is listed in the latest [ASEAN Cosmetic Directive](#) (Annex II Part 1) which specifies substances that must not be present in cosmetic products.

Because of the current uncertainty in establishing a safe exemption concentration limit for azelaic acid in cosmetics, and the lack of robust evidence on its safety at lower concentrations, I have made an interim decision that the current scheduling of azelaic acid remains appropriate, except for the change to the Appendix F Safety Directions identified above. That is, human therapeutic preparations containing azelaic acid remain in Schedule 2 (dermal preparations) or Schedule 4 (other than dermal preparations) while all other preparations including cosmetics are captured under Schedule 5. To mitigate the risk from all uses of azelaic acid, human therapeutics containing azelaic acid will continue to be assessed for safety and efficacy while all cosmetics will require first aid instructions and safety directions as Schedule 5 preparations.

Interim decision in relation to extracts and essential oils primarily composed of methyl salicylate

Proposal

The Delegate proposed an amendment to the current Poisons Standard in relation to various extracts and essential oils primarily composed of methyl salicylate, including sweet birch oils (CAS No. 68917-50-0), wintergreen oils (CAS No. 68917-75-9), birch (*Betula lenta*) extract (CAS No. 85251-66-7), and wintergreen (*Gaultheria procumbens*) extract (CAS No. 90045-28-6).

Currently, methyl salicylate is listed as a Prescription only (Schedule 4) medicine in preparations for internal therapeutic use and as a Caution (Schedule 5) and Poison (Schedule 6) substance for all other usage. However, the various extracts and essential oils primarily composed of methyl salicylate are not separately scheduled.

This proposal was initiated following a recommendation in the Australian Industrial Chemical Introduction Scheme (AICIS) [evaluation of extracts and essential oils primarily composed of methyl salicylate](#) (December 2024) and presented two options for the amendments.

Option 1: cross-reference each extract and essential oil specified above to the current methyl salicylate entry

Option 2: creating separate entries for each extract and essential oil specified above.

Additional warning statements related to pregnancy and skin sensitisation due to sunlight also have been proposed to align the risk mitigation measures with methyl salicylate.

²¹ Pazoki-Toroudi, H., Nilforoushadeh, M. A., Ajami, M., Jaffary, F., Aboutaleb, N., Nassiri-Kashani, M., & Firooz, A. (2011). Combination of azelaic acid 5% and clindamycin 2% for the treatment of acne vulgaris. *Cutaneous and Ocular Toxicology*, 30(4), 286–291. DOI: <https://doi.org/10.3109/15569527.2011.581257>

²² Pazoki-Toroudi, H., Nassiri-Kashani, M., Tabatabaie, H., Ajami, M., Habibey, R., Shizarpour, M. Firooz, A. (2010). Combination of azelaic acid 5% and erythromycin 2% in the treatment of acne vulgaris. *Journal of Dermatological Treatment*, 21(3), 212–216. DOI: <https://doi.org/10.3109/09546630903440064>

Interim decision

Pursuant to regulation 42ZCZN of the Regulations, the Delegate has, in relation to the proposed amendment, made an interim decision to amend the current Poison Standard to include:

- cross reference for each extract and essential oil mentioned above to the current methyl salicylate entry
- additional warning statements for methyl salicylate under Appendix F.

The amendments are as follows.²³

Schedule 6

METHYL SALICYLATE **except**:

- when included in Schedule 5; or
- in preparations for therapeutic use; or
- in preparations containing 5% or less of methyl salicylate.

Schedule 5

METHYL SALICYLATE in preparations containing 25% or less of methyl salicylate **except**:

- in preparations for therapeutic use; or
- in preparations containing 5% or less of methyl salicylate.

Schedule 4

METHYL SALICYLATE in preparations for internal therapeutic use.

Appendix E, Clause 3 - Poisons that must be labelled with first aid instructions

Item	Poison	Standard statements of first aid instruction
207	METHYL SALICYLATE LIQUID when included in Schedule 5 or 6	A – For advice, contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor (at once).
		G3 – If swallowed, do NOT induce vomiting.
		E1 – If in eyes wash out immediately with water.

Appendix F, Clause 4 - Poisons that must be labelled with warning statements and safety directions

Item	Poison	Warning statement
212	METHYL SALICYLATE LIQUID when included in Schedule 5 or 6	67 – Do not use if pregnant or likely to become pregnant.
		89 – Application to skin may increase sensitivity to sunlight

²³ Proposed additions are shown in green underlined font, proposed deletions are shown in red strikethrough font, and text without this formatting represents the current text in the Poisons Standard.

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METHYL SALICYLATE

Cross reference: sweet birch oil (CAS No. 68917-50-0), wintergreen oil (CAS No. 68917-75-9), birch (*Betula lenta*) extract (CAS No. 85251-66-7) and wintergreen (*Gaultheria procumbens*) extract (CAS No. 90045-28-6)

Schedule 6

Schedule 5

Schedule 4

Appendix E, Clause 3

[Appendix F, Clause 4](#)

Methyl salicylate and preparations containing more than 50% of methyl salicylate are also required to be in containers with child-resistant closure (s 49 of the Poisons Standard). No changes will be made to that requirement.

Materials considered

In making this interim decision, the Delegate considered the following material:

- the application to amend the current Poisons Standard with respect to methyl salicylate (the **Application**)
- the 153 [public submissions](#), with 6 including a written component, received in response to the [pre-meeting consultation](#) under regulation 42ZCZK of the Regulations (the **Submissions**)
- the advice received from the 40th meeting of the Advisory Committee on Medicines and Chemicals Scheduling in joint session (the **Committee**)
- subsection 52E(1) of the Act, in particular (a) risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; (e) the potential for abuse of a substance; and (f) any other matters that the Secretary considers necessary to protect public health
- the SPF, and
- the Handbook
- AICIS [evaluation of methyl salicylate](#) (June 2024)
- AICIS [evaluation of extracts and essential oils primarily composed of methyl salicylate](#) (December 2024).

Summary of Committee advice to the Delegate

The Committee recommended that the current Poisons Standard be amended to cross reference the METHYL SALICYLATE entry to sweet birch oil (CAS No. 68917-50-0), wintergreen oil (CAS No. 68917-75-9), birch (*Betula lenta*) extract (CAS No. 85251-66-7) and wintergreen (*Gaultheria procumbens*) extract (CAS No. 90045-28-6). The current Schedule 4, 5 and 6 entries for METHYL SALICYLATE remain unaltered otherwise.

The Committee also recommended creating a new Appendix F entry for methyl salicylate in the Poisons Standard for requiring the warnings statements regarding:

- use during pregnancy or planned pregnancy
- increased sensitivity to sunlight.

The Committee also recommended an implementation period of at least 6 months to allow industry sufficient time to implement the changes.

Members agreed that the relevant matters under subsection 52E(1) of the Act included: (a) risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; (e) the potential for abuse of a substance; and (f) any other matters that the Secretary considers necessary to protect public health.

The reasons for the advice included:

a) the risks and benefits of the use of a substance

Risks

- Acute oral toxicity: deaths from methyl salicylate poisoning have been reported with as little as 4 mL of methyl salicylate
- Dermal toxicity
- Potential risks during pregnancy
- Can cause serious eye damage
- Weak dermal sensitisers
- Low acute dermal and inhalation toxicity
- Possible risk of drug interactions with commonly used drugs like blood thinners and anti-platelet agents.

Benefits

- Used in a wide range of personal care and domestic use products
- Used in therapeutic goods for anti-inflammatory effects or topical pain preparations (analgesic effect)
- Mild antiseptic properties
- Antioxidant
- Reduces photo damage
- Used in fragrances and food flavourings.

b) the purposes for which a substance is to be used and the extent of use of a substance

- Natural health products including topical analgesics at concentrations up to 20%
- Aromatherapy: massage oils, oils in room diffusers
- Cosmetics and personal care products including skin care products, hair care products, perfumes, body sprays and oral care products (mouthwashes, oral and nasal health products)
- Domestic use: cleaning and furniture care products, air care products
- Non-industrial uses: food flavouring, insect repellents, pet care products and animal feeds.

c) the toxicity of a substance

- As methyl salicylate is the major constituent of these extracts and essential oils (>90%), toxicity is based on the consideration of methyl salicylate

- High potential for acute oral toxicity with concentrated products; can also cause chronic toxicity
- Acute animal toxicity (methyl salicylate):
 - LD₅₀ value ranges from 580 mg/kg bw (mice) to higher than 2,000 mg/kg bw (rats, rabbits and dogs)
 - Human exposure data available, classified as Acute Tox. 4; H302 (Harmful if swallowed)
- Chronic animal toxicity (methyl salicylate):
 - Oral exposure: a NOAEL of 50 mg/kg bw/day
 - Dermal exposure: a LOAEL of 585 mg/kg bw/day
 - Exposure by inhalation: a NOAEL of 700 mg/m³ (120 ppm)
- Can cause severe eye damage
- Low acute dermal and inhalational toxicity
- Methyl salicylate is a weak skin sensitiser in humans, classification as a 1B skin sensitiser.
- Salicylate toxicity causes tinnitus, dizziness, nausea, vomiting, respiratory alkalosis, metabolic acidosis, multiorgan dysfunction, coma, seizures
- Potential risks during pregnancy particularly in the third trimester but also at earlier stages.

d) the dosage, formulation, labelling, packaging and presentation of a substance

- Methyl salicylate concentration of extracts/oils depends on the part of the plant used, methods of extraction, environmental conditions
- Concentration of the oils/methyl salicylate available varies widely depending on application
 - Pure essential oils are available containing up to 100% methyl salicylate
 - Massage oils contain up to 20% essential oils
 - Mouthwashes contain 0.06%–1.0% essential oils while toothpastes contain 0.1–1.5% essential oils
 - Chewing gum typically contains 0.04% and under essential oils as flavouring agents
 - Skin and hair products typically have low concentrations (<1%) of the oils/extracts
 - Topical pain preparations often contain 25% essential oils/extracts
 - Listed medicines contain ~0.1–0.15% depending on modality (e.g. ointment, vapour inhaler)
- Packaging is in child proof containers as per Poisons Standard
- Products require additional labelling (warning and safety).

e) the potential for abuse of a substance

- Nil.

f) any other matters that the Secretary considers necessary to protect public health

- Pregnancy warning labels are needed

- Industrial exposure of workers involved in formulation and packaging of these essential oils should be considered. These oils are not listed in the Hazardous Chemical Information System.

Reasons for the interim decision (including findings on material questions of fact)

I agree with the Committee's findings on the relevant provisions of section 52E of the Act and have made an interim decision to create cross references for sweet birch oil (CAS No. 68917-50-0), wintergreen oil (CAS No. 68917-75-9), birch (*Betula lenta*) extract (CAS No. 85251-66-7) and wintergreen (*Gaultheria procumbens*) extract (CAS No. 90045-28-6) to the existing entry for methyl salicylate, and create additional warning statements in relation to pregnancy and skin sensitisation.

In total, 153 responses were received during the pre-meeting consultation period, with 128 supportive, 22 partially supportive (including support either Option 1 or 2 with caveats) and 3 opposed. Interested parties were also given the choice to select from options to indicate their support or opposition to the proposed amendment without providing a written component. The majority of the respondents did not provide written reasons for their preference.

Of the 6 submissions with written component, one supported Option 1 preferring its simplicity and advocating for clearer labelling and secure packaging. In contrast, another submitter supported Option 2 for clearer, separate entries and better alignment with international and EU regulatory standards. One submitter opposed Option 1 and only partially supported Option 2, arguing cross-referencing is misleading as oils and extracts may not contain 100% methyl salicylate. This submitter also raised that for individual entries, the cut-off levels for Schedule 5 and Schedule 6 should be based on the concentration of methyl salicylate, rather than the extracts.

With regards to sections 52E(1)(a) and (b) of the Act, I have considered the benefits and wide usages of extracts and essential oils primarily composed of methyl salicylate across various domains, such as personal use including aromatherapy, massage oils, aroma diffusers, cosmetics for dermal application, hair care products, perfumes, mouthwash, toothpaste, body sprays and insect repellents. Preparations are also used in domestic settings such as cleaning and furniture care, as food flavouring and in pet care products.

Regarding the risks and toxicity (sections 52E(1)(a) and (c)), I noted that methyl salicylate has high potential for acute and chronic toxicity in humans and animals. It exhibits acute toxicity in animals, with LD₅₀ values ranging from 580 mg/kg in mice to over 2,000 mg/kg in other species and is classified under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) as Acute Toxicity. 4; H302 (harmful if swallowed). The acute toxicity data aligns with Schedule 5, scheduling factor 1. Chronic animal toxicity data include an oral NOAEL of 50 mg/kg/day, a dermal LOAEL of 585 mg/kg/day, and an inhalation NOAEL of 700 mg/m³. Methyl salicylate can also cause severe eye damage, poses pregnancy risks (especially in the third trimester), and is considered a weak skin sensitiser (Schedule 5, factors 1 and 2). Other toxic effects of salicylate include tinnitus, dizziness, nausea, vomiting, acid-base disturbances, organ dysfunction, coma, and seizures.

Turning my mind to sections 52E(1)(d) and (f), the concentration of methyl salicylate in oils and extracts varies depending on the plant part used, extraction method, and environmental conditions. Pure essential oils can contain up to 100% methyl salicylate, while topical pain preparations usually contain 25–50% methyl salicylate. Concentrations in personal care and domestic use products vary widely such as 0.04% on chewing gums, less than 1% in skin and hair products, up to 1.5% in toothpaste and up to 20% in massage oils.

The toxicity of sweet birch oil, wintergreen oil, birch extract and wintergreen extract are due to their methyl salicylate content (often >90%) and the toxicity end points for methyl salicylate applies to these extracts and essential oils. I agree with the Committee advice that, overall, there isn't a substantially higher benefit by listing these oils and extracts separately in the Poisons Standard when the primary concern is managing the risk from methyl salicylate exposure. I note the Committee's advice that separate listings may also create confusion as these names, albeit incorrectly, are often used interchangeably. For example, in British Pharmacopoeia, the alternative name of methyl salicylate is winter green oil. Therefore, I have decided to cross-reference each of these extracts and essential oils

to the existing entry for methyl salicylate as the most practical mechanism to highlight the scheduling controls on these substances.

Considering the potential risk for skin sensitisation, I agree with the Committee's recommendation on the inclusion of a precautionary warning statement regarding increased sensitivity to sunlight. Further, adverse effects on foetal development including increased foetal mortality, increased incidences of neural tube defects and foetal growth retardation have been reported in animal studies. Therefore, I have decided to include an additional warning statement advising against use during pregnancy. Both the warning statements are required for listed medicines containing methyl salicylate and aim to enhance consumer safety.

Proposed implementation date

1 October 2026

Therapeutic Goods Administration

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