Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

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

25 May 2026

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

This web publication constitutes a notice for the purposes of regulation 42ZCZS and regulation 42ZCZX of the *Therapeutic Goods Regulations, 1990* (the **Regulations**). In accordance with regulations 42ZCZS and 42ZCZX, this notice publishes:

- the decisions made by a delegate[1] of the Secretary of the Department of Health, Disability and Ageing (the **Delegate**) pursuant to regulations 42ZCZR and 42ZCZW
- the reasons for those final decisions and
- the date of effect of those decisions.

This web publication also contains decisions made by the Delegate pursuant to subsection 52D(2) of the *Therapeutic Goods Act, 1989* (the **Act**).

Defined terms

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

- 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 defined for individual decisions.

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

Final decisions on proposed amendments referred to the Advisory Committee on Chemicals Scheduling (ACCS #40, March 2025)

Final decision in relation to methyl ethyl ketone oxime (MEKO)

Proposal

The applicant proposed to amend the current Poisons (Schedule 6) entry for methyl ethyl ketone oxime (MEKO), such that preparations containing more than 0.1% MEKO are classified as Poisons (Schedule 6). These preparations will also be required to carry additional warning statements and safety directions regarding potential for inhalation carcinogenicity, ventilation, and the need to avoid breathing vapours of preparations containing MEKO. The application follows the recommendations of Australian Industrial Chemicals Introduction Scheme (AICIS) Evaluation Statement of 2-Butanone, oxime (MEKO) (the **Evaluation Statement**). Currently, MEKO is classified as a Poison (Schedule 6) except up to 2.5% in silicone adhesives or sealants and up to 1% in all other preparations. MEKO is also listed in Appendix E (first aid instructions) and Appendix F (warning statements and general safety directions) of the Poisons Standard.

Final decision

Pursuant to regulation 42ZCZR of the Regulations, the delegate has decided to confirm the interim decision and amend the current Poisons Standard in relation to MEKO as follows:[2]

Schedule 6 – Amend Entry

METHYL ETHYL KETONE OXIME **except**

(a) in viscous silicone adhesives or viscous silicone sealants for outdoor use containing 0.5~~2.5~~% or less of methyl ethyl ketone oxime; or

(b) in viscous silicone adhesives or viscous silicone sealants for indoor use containing 0.2% or less of methyl ethyl ketone oxime; or

(c) in other preparations containing 0.1% or less of methyl ethyl ketone oxime.

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METHYL ETHYL KETONE OXIME
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[2] 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 E, clause 3 – First aid instructions for poisons

Item	Poison	Statement code (and statement)
199	METHYL ETHYL KETONE OXIME	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.
		S1 – If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water.

Appendix F, clause 4 – Warning statements and safety directions

Item	Poison	Warning statement item number and statement	Safety direction item number and statement
213	METHYL ETHYL KETONE OXIME	5 – irritant 6 – May cause cancer. 12 – Vapour is harmful to health on prolonged exposure 28 – (Over) (Repeated) exposure may cause sensitisation	1 – Avoid contact with eyes 4 – Avoid contact with skin 8 – Avoid breathing vapour 10 – Ensure adequate ventilation when using

Materials considered

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

- the proposal to amend the current Poisons Standard with respect to MEKO (the **Proposal**)
- 8 public submissions with 5 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 Chemicals Scheduling (the **Committee**)[3]
- the interim decision and the materials considered as part of the interim decision, as published on 18 December 2025.
- 4 public submissions, all of which included a written component, received in response to the public consultation on the interim decision under regulation 42ZCZP of the Regulations.
- subsection 52E(1) of the Therapeutic Goods Act 1989, in particular (a) the 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 (e) the potential for abuse of a substance; and (f) any other matters considered necessary to protect public health
- pursuant to paragraph 52E(2)(a) of the Act, the SPF, and
- the Handbook.

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

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

I have made a final decision to confirm my interim decision to amend the current Poisons Standard with respect to MEKO.

My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have considered the materials in the interim decision and the 4 submissions received in response to the public consultation on the interim decision.

All the 4 submissions were generally in favour of the interim decision with 2 supporting it and 2 partially supporting it with caveats. All 4 submissions provided written justification for their preference. No response was submitted in opposition to the interim decision.

The applicant argued for a uniform Schedule 6 classification for all preparations containing more than 0.1% MEKO. However, risks from adhesives and sealants are distinct from risks from other MEKO products such as alkyd paints, lacquers and varnishes. Such distinction in presentations was the previous basis for allowing higher amounts of MEKO (up to 2.5%) in viscous silicone adhesives and sealants without requiring access control and warning statements through Schedule 6 classification.[4]

Two partially supportive submitters commented that introducing different thresholds for MEKO in different products and for different usage would create significant labelling challenges for the industry. Consumers may also inappropriately use adhesives and sealants meant for outdoors use for indoor purposes which would increase the risk.

I remain of the view that it is appropriate to differentiate MEKO contents based on indoor and outdoor applications as exposure by inhalation is substantially different in these two scenarios. Exposure by inhalation, and therefore the risk of carcinogenicity, will depend on both MEKO concentration in a product and the level of ventilation. Based on estimated exposures for various products, Health Canada has proposed a limit of 0.42% MEKO in exterior silicone sealants while for interior or dual use gasketing adhesives and silicone sealants the proposed limit is 0.2%.[5] The concentration limits that will be imposed on indoor and outdoor sealants and adhesives are consistent with the limits proposed in Canada. It is expected that professional users will adhere to the usage restrictions while for non-professionals the risk from inappropriate use will be less due to limited and infrequent use.

The applicant also recommended removing the warning statement relating to skin sensitisation for viscous silicone products containing up to 2.5% MEKO. The applicant argued that data supplied previously in relation to the application for exempting silicone adhesive sealants containing up to 2.5% MEKO from scheduling showed that such products are not skin sensitisers.

The ASEAN-Japan Chemical Safety Database lists MEKO as a skin-irritating and a skin-absorbing hazardous substance that must be handled with impermeable protective equipment under Japan's Industrial Safety and Health Act. Accordingly, in Japan, products containing more than 0.1% MEKO must have appropriate warning statements regarding skin irritation and workers are required to wear personal protective equipment while handling MEKO products. The AICIS Evaluation Statement noted MEKO at maximum concentrations of 5% and 2% in sealants and adhesives. Further, such preparations are highly likely to be in contact with the skin if handled without gloves. The requirement of a warning statement indictive of potential harm ((Over) (Repeated) exposure may cause sensitisation) for all preparations containing more than 0.1% MEKO is therefore justified.

The applicant also requested capture of MEKO-releasing silane-based preparations which have a similar risk profile under the entry for MEKO. I note that in the AICIS Evaluation Statement of 2-Butanone oxime (MEKO)-releasing silanes several MEKO releasing silanes could exhibit toxicological profiles similar to MEKO and may present comparable hazards when used as replacements for MEKO. However, the original proposal did not cover MEKO-releasing silanes and the public

[4] Final decisions and reasons for decisions by delegates of the Secretary to the Department of Health, 27 March 2015

[5] Health Canada, Consultation document on proposed new risk management actions for 2-butanone, oxime

consultations were limited to the scheduling of MEKO only. Therefore, I have decided to defer consideration of the scheduling of MEKO-releasing silanes to a later, separate consideration which may also require further expert advice and/or public consultation.

One submission proposed postponing the implementation date to 1 October 2028, while two others recommended earlier implementation in 2027. I am of the view that an implementation date of 1 February 2028 as proposed in my interim decision maintains a balance between the urgency for public health protection and the time required by the industry to implement the changes.

Implementation date

1 February 2028

Final decision in relation to acrylates and methacrylates based on bisphenol A (BPA)

Proposal

The Delegate has proposed the creation of new Poisons (Schedule 6) entries for two chemicals, BPA glycidyl dimethacrylate and BPA glycidyl diacrylate. Additional warning statement and safety directions relating to skin sensitisation are also proposed. The proposal is based on the recommendation from the Australian Industrial Chemicals Introduction Scheme (AICIS) Evaluation Statement on acrylates and methacrylates based on bisphenol A (BPA). BPA glycidyl dimethacrylate and BPA glycidyl diacrylate are not specifically scheduled in the current Poisons Standard.

Final decision

Pursuant to regulation 42ZCZR of the Regulations, the Delegate has made a final decision to confirm the interim decision and amend the current Poisons Standard in relation to acrylates and methacrylates BPA as follows:[6]

Schedule 6 – New entries

BPA GLYCIDYL DIMETHACRYLATE in preparations for cosmetic use.

BPA GLYCIDYL DIACRYLATE in preparations for cosmetic use.

[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.

Appendix E, clause 3 – First aid instructions for poisons

Item	Poison	Safety direction code number and statement
54	BPA GLYCIDYL DIMETHACRYLATE	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).
55	BPA GLYCIDYL DIACRYLATE	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).

Appendix F, clause 4 – Warning statements and safety directions

Item	Poison	Safety direction item number and statement
50	BPA GLYCIDYL DIMETHACRYLATE	4 – Avoid contact with skin 28 – (Over) (Repeated) exposure may cause sensitisation.
51	BPA GLYCIDYL DIACRYLATE	4 – Avoid contact with skin 28 – (Over) (Repeated) exposure may cause sensitisation.

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BPA GLYCIDYL DIMETHACRYLATE

Schedule 6

Appendix E, Clause 3

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BPA GLYCIDYL DIACRYLATE

Schedule 6

Appendix E, Clause 3

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Materials considered

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

- the application to amend the current Poisons Standard with respect to acrylates and methacrylates BPA (the **Application**)
- 6 public submissions, including 2 with 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 Chemicals Scheduling (the **Committee**)

- the interim decision and the materials considered as part of the interim decision, as published on 18 December 2025.
- 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
- pursuant to paragraph 52E(2)(a) of the Act, the SPF, and
- the Handbook.

No public submission was received in response to the public consultation on the interim decision taken under regulation 42ZCZP of the Regulations.

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

I have made a final decision to confirm my interim decision to amend the current Poisons Standard with respect to BPA glycidyl dimethacrylate and BPA glycidyl diacrylate. My reasons for making the final decision are those set out in the interim decision. No submission was received during the consultation of interim decision.

Currently, BPA glycidyl dimethacrylate and BPA glycidyl diacrylate are unscheduled. Creation of Schedule 6 entries would increase consumer awareness through the use of signal headings, thereby reducing the risk of unintentional consumer exposure to products containing BPA glycidyl dimethacrylate and BPA glycidyl diacrylate, particularly in cosmetic products. The inclusion of additional warning statements and safety directions related to skin sensitisation would further support effective risk management.

Given the range of cosmetic products that may be affected by the decision and the risks for the consumers, I maintain my previous view of an implementation date of 1 October 2026 to allow sufficient time for industry to comply with the changes.

Implementation date

1 October 2026.

Final decision in relation to medium and long chain alkyl sulfates

Proposal

The Delegate has proposed amendments to the current Poisons Standard to include medium and long chain (C6–C15) alkyl sulfates as Poisons (Schedule 6) with additional warning statements and first aid instructions. The proposal is based on the recommendations in the Australian Industrial Chemicals Introduction Scheme (AICIS) Evaluation Statement on Medium and Long Chain Alkyl Sulfates (the **Evaluation Statement**). Currently, only two long chain alkyl sulfates, sodium tetradecyl (C14) sulfate in preparations for injection and lauryl (C12) sulfate salts are listed in the Poisons Standard as Prescription only medicines (Schedule 4) and Poisons (Schedule 6), respectively.

Final decision

Pursuant to regulation 42ZCZR of the Regulations, the Delegate has made a final decision confirming the interim decision to amend the current Poisons Standard to create a new entry for medium and long chain (C6–C15) alkyl sulfates and delete the existing entry for lauryl sulfate salts. I have also decided to cross reference 7 additional alkyl sulfates not listed in the listed decision to the parent entry for medium and long chain (C6–C15) alkyl sulfates. The amendments are as follows.[7]

Schedule 6 – New entry

MEDIUM AND LONG CHAIN (C6–15) ALKYL SULFATES **except** when separately specified in these Schedules and

(a) in wash-off preparations containing, in total, 30% or less of medium and long chain alkyl sulfates and, if containing, in total, more than 5% of total medium and long chain alkyl sulfates, when labelled with a warning to the following effect:

IF IN EYES WASH OUT IMMEDIATELY WITH WATER; or

(b) in leave-on preparations containing, in total, 1.5% or less of medium and long chain alkyl sulfates; or

(c) in toothpaste and oral hygiene preparations containing, in total, 5% or less of medium and long chain alkyl sulfates; or

(d) in other preparations for animal use containing, in total, 2% or less of medium and long chain alkyl sulfates; or

(e) in other preparations containing, in total, 30% or less of medium and long chain alkyl sulfates and, if containing, in total, more than 5% of medium and long chain alkyl sulfates, when labelled with warnings to the following effect:

(i) IF IN EYES WASH OUT IMMEDIATELY WITH WATER; and

(ii) IF SKIN OR HAIR CONTACT OCCURS, REMOVE CONTAMINATED CLOTHING AND FLUSH SKIN AND HAIR WITH RUNNING WATER.

Schedule 6 – delete entry

~~LAURYL SULFATE SALTS (excluding their derivatives) except:~~

~~(a) in wash-off preparations containing 30% or less of lauryl sulfates and, if containing more than 5% of lauryl sulfates, when labelled with a warning to the following effect:~~

~~IF IN EYES WASH OUT IMMEDIATELY WITH WATER; or~~

~~(b) in leave-on preparations containing 1.5% or less of lauryl sulfates; or~~

~~(c) in toothpaste and oral hygiene preparations containing 5% or less of lauryl sulfates; or~~

~~(d) in other preparations for animal use containing 2% or less of lauryl sulfates; or~~

~~(e) in other preparations containing 30% or less of lauryl sulfates and, if containing more than 5% of lauryl sulfates, when labelled with warnings to the following effect:~~

~~(i) IF IN EYES WASH OUT IMMEDIATELY WITH WATER; and~~

~~(ii) IF SKIN OR HAIR CONTACT OCCURS, REMOVE CONTAMINATED CLOTHING AND FLUSH SKIN AND HAIR WITH RUNNING WATER.~~

[7] 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 E, Clause 3 – new entry

Poisons that must be labelled with first aid instructions		
Item	**Column 1 Poison**	**Column 2 Statement code**
179	MEDIUM AND LONG CHAIN (C6–15) ALKYL SULFATES — leave-on or wash-off preparations containing, in total, above 5% of alkyl sulfates	E1
180	MEDIUM AND LONG CHAIN (C6–15) ALKYL SULFATES — other preparations containing, in total, above 5% of alkyl sulfates	E1, S1

Standard statements for first aid instructions			
Item	**Column 1 Category**	**Column 2 Statement code**	**Column 3 Statement**
9	Eyes	E1	If in eyes wash out immediately with water.
13	Skin	S1	If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water.

Appendix E, clause 3 – delete entry

Poisons that must be labelled with first aid instructions		
Item	**Column 1 Poison**	**Column 2 Statement code**
~~297~~	~~LAURYL SULFATE SALTS—leave-on or wash-off preparations above 5%~~	~~E1~~
~~298~~	~~LAURYL SULFATE SALTS—other preparations above 5%~~	~~E1, S1~~

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~~**LAURYL SULFATE SALTS**~~

~~cross reference: SODIUM LAURYL SULPHATE, DODECYL SULFATES~~

~~Schedule 6~~

~~Appendix E, clause 3~~

MEDIUM AND LONG CHAIN (C6–15) ALKYL SULFATES

cross reference: Sulfuric acid, monooctyl ester, sodium salt (CAS No. 142-31-4), Sulfuric acid, monodecyl ester, sodium salt (CAS No. 142-87-0), 1-Tetradecanol, hydrogen sulfate, sodium salt (CAS No. 1191-50-0), Sulfuric acid, monohexyl ester, sodium salt (CAS No. 2207-98-9), 1-Tridecanol, hydrogen sulfate, sodium salt (CAS No. 3026-63-9), 1-Tetradecanol, hydrogen sulfate, compound with 2,2',2''-nitrilotris[ethanol] (1:1) (CAS No. 4492-78-8), Sulfuric acid, monodecyl ester, ammonium salt (CAS No. 13177-52-1), 1-Tetradecanol, hydrogen sulfate, magnesium salt (CAS No. 25446-91-7), Sulfuric acid, monoisononyl ester, sodium salt (CAS No. 26856-96-2), Sulfuric acid, monooctyl ester, compound with 2,2',2''-nitrilotris[ethanol] (1:1) (CAS No. 30862-34-1), Sulfuric acid, monodecyl ester, compound with 2,2',2''-nitrilotris[ethanol] (1:1) (CAS No. 39943-70-9), Sulfuric acid, mono-C6-10-alkyl esters, ammonium salts (CAS No. 68187-17-7), Isodecanol, hydrogen sulfate, sodium salt (CAS No. 68299-17-2), Sulfuric acid, mono-C12-15-alkyl esters, compounds with triethanolamine (CAS No. 68815-25-8), Sulfuric acid, mono-C12-15-alkyl esters, sodium salt (CAS No. 68890-70-0), Sulfuric acid, mono-C9-13-alkyl esters, sodium salts (CAS No. 72906-11-7), Sulfuric acid, mono-C9-11-alkyl esters,

sodium salts (CAS No. 84501-49-5), Sulfuric acid, mono-C12-14-alkyl esters, sodium salts (CAS No. 85586-07-8), Sulfuric acid, mono-C8-14-alkyl esters, compounds with triethanolamine (CAS No. 85665-45-8), Sulfuric acid, mono-C12-14-alkyl esters, compounds with isopropanolamine (CAS No. 85681-66-9), Sulfuric acid, mono-C8-14-alkyl esters, ammonium salts (CAS No. 90583-10-1), Sulfuric acid, mono-C12-14-alkyl esters, compounds with ethanolamine (CAS No. 90583-16-7), Sulfuric acid, mono-C12-14-alkyl esters, compounds with triethanolamine (CAS No. 90583-18-9), Sulfuric acid, mono-C12-14-alkyl esters, magnesium salts (CAS No. 90583-23-6), Sulfuric acid, mono-C6-12-alkyl esters, sodium salts (CAS No. 90583-25-8), sodium lauryl sulfate (CAS No. 151-21-3), dodecyl sulfate (CAS No. 151-21-3), sulfuric acid, monododecyl ester, compound with 2,2',2''-nitrilotris[ethanol] (1:1) (CAS No. 139-96-8), sulfuric acid, monododecyl ester, compound with 2,2'-iminobis[ethanol] (1:1) (CAS No. 143-00-0), sulfuric acid, monododecyl ester (CAS No. 151-41-7), sulfuric acid, monododecyl ester, compound with 2-aminoethanol (1:1) (CAS No. 4722-98-9), sulfuric acid, monododecyl ester, compound with 1-amino-2-propanol (1:1) (CAS No. 21142-28-9), sulfuric acid, monododecyl ester, compound with 2-(diethylamino) ethanol (1:1) (CAS No. 65104-49-6), sulfuric acid, monododecyl ester, compound with 1,1',1''-nitrilotris[2-propanol] (CAS No. 66161-60-2).

Schedule 6

Appendix E, clause 3

Materials considered

In making this final decision, the Delegate considered the following materials:

- 9 public submissions, with 3 including a written component, received in response to pre-meeting consultation under regulation 42ZCZK of the Regulations
- the advice received from the 40th meeting of the Advisory Committee on Chemicals Scheduling (the **Committee**)
- the interim decision and the materials considered as part of the interim decision, as published on 18 December 2025.
- the 2 public submissions, both of which included a written component, received in response to the public consultation on the interim decision under regulation 42ZCZP of the Regulations.
- subsection 52E(1) of *the Therapeutic Goods Act 1989*, in particular (a) the 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 (e) the potential for abuse of a substance; and (f) any other matters considered necessary to protect public health
- pursuant to paragraph 52E(2)(a) of the Act, the SPF, and
- the Handbook.

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

I have made a final decision to confirm my interim decision to create a Schedule 6 and Appendix E entries for medium and long chain (C6-C15) alkyl sulfates and to delete the current entries for lauryl sulfate salts. My reasons for making the final decision are those set out in the interim decision. I have also decided to include 7 additional substances in the list of alkyl sulfates cross referenced to the parent entry for medium and long chain (C6-C15) alkyl sulfates for reasons detailed below.

In making my final decision, I have considered the material in the interim decision and the 2 submissions received in response to the public consultation on the interim decision.

Both the submissions opposed the interim decision and provided written justifications. Both considered the broad grouping of the alkyl sulfates outlined in the interim decision to be disproportionate to the risk especially at concentrations typically used in consumer products and would create unnecessary regulatory burden without improving public health outcomes. They were also of the view that the scheduling on alkyl sulfate in isolation is misaligned with the recommendations in the Evaluation Statement and instead suggested a broader, holistic review of surfactants.

The Evaluation Statement specifically recommended:

a review of the current scheduling of lauryl sulfate salts to more broadly capture alkyl sulfates

a consideration of applying the similar labelling requirements currently in place for lauryl sulfates to alkyl sulfates with chain lengths less than C16 to manage the potential risk associated with the use of these chemicals.

The Evaluation Statement suggested consideration of the identified use of these chemicals, their potential for eye damage and skin irritation, unscheduled status of UVCBs and contemplation of any risk management measure as part of any broader review of the management of surfactants. My decision to schedule the range of medium and long chain (C6–C15) alkyl sulfates is based on similar usage patterns and health risks as lauryl sulfate salts and aligns with the recommendations in the Evaluation Statement. Scheduling of medium and long chain (C6–C15) alkyl sulfates can be reviewed in the context of managing similar risks from surfactants, should a broader review of the surfactants be undertaken in future.

Other views raised in the submission regarding compliance burden on industry and consumer awareness of risk and treatments were also raised during the pre-meeting consultation and considered in making the interim decision. In my view, products containing these alkyl sulfates, including UVCBs or varying alkyl chain lengths, at concentrations above these exemptions pose sufficient public health risk to warrant inclusion in Schedule 6.

I have decided to include the 7 alkyl sulfates listed below to the list of substances cross-referenced to the parent entry for medium and long chain (C6–C15) alkyl sulfates.

- Sulfuric acid, monododecyl ester, compound with 2,2',2''-nitrilotris[ethanol] (1:1) (CAS No. 139-96-8)
- Sulfuric acid, monododecyl ester, compound with 2,2'-iminobis[ethanol] (1:1) (CAS No. 143-00-0)
- Sulfuric acid, monododecyl ester (CAS No. 151-41-7)
- Sulfuric acid, monododecyl ester, compound with 2-aminoethanol (1:1) (CAS No. 4722-98-9)
- Sulfuric acid, monododecyl ester, compound with 1-amino-2-propanol (1:1) (CAS No. 21142-28-9)
- Sulfuric acid, monododecyl ester, compound with 2-(diethylamino) ethanol (1:1) (CAS No. 65104-49-6)
- Sulfuric acid, monododecyl ester, compound with 1,1',1''-nitrilotris[2-propanol] (CAS No. 66161-60-2).

These substances were listed in the Evaluation Statement but not included in the interim decision as they can be covered under another cross-referenced substance, dodecyl sulfate. However, upon reflection, I have decided to specifically cross reference these 7 substances for clarity and avoidance of doubt.

Given the substantial number and quantity of consumer products and industrial materials affected by the decision and noting the industry request for an extended implementation period to enable compliance with the amendments, I have decided on an implementation date of 1 October 2027.

Implementation date

1 October 2027

Final decision in relation to sodium hydroxide and potassium hydroxide

Proposal

The applicant proposed a new Dangerous Poisons (Schedule 7) entry and amendments to the Caution (Schedule 5) and Poisons (Schedule 6) entries for sodium hydroxide and potassium hydroxide. The proposed amendments would classify:

- high concentrations (greater than 5%) and high pH (greater than 12.5) preparations of sodium hydroxide and potassium hydroxide as Dangerous poisons (Schedule 7).
- preparations containing 5% or less of these substances and greater than pH 12.5 or preparations containing greater than 5% of these substances with a pH of 12.5 or less as Poisons (Schedule 6)
- preparations containing 5% or less of the substances that are greater than pH 11.5, but less than or equal to pH 12.5 as Caution (Schedule 5).

All preparations containing sodium hydroxide or potassium hydroxide in liquid or semi-solid food additive preparations for domestic use, with a pH greater than 11.5, will continue to be considered as Schedule 10 substances.

The applicant also proposed to create an Appendix J entry for both the substances requiring that Schedule 7 preparations only be supplied to a person who is appropriately authorised or licensed under the law of the jurisdiction where the person will receive the poison.

Final decision

Pursuant to regulation 42ZCZR of the Regulations, the delegate has decided to confirm the interim decision and not amend the current Poisons Standard in relation to sodium hydroxide and potassium hydroxide.

Materials considered

In making this final decision, the Delegate considered the following materials:

- the application to amend the current Poisons Standard with respect to sodium hydroxide and potassium hydroxide (the **Application**)
- 26 public submissions, with 22 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 Chemicals Scheduling (the **Committee**)

- the interim decision and the materials considered as part of the interim decision, as published on 18 December 2025.
- 7 public submissions, 5 of which included a written component, received in response to the public consultation on the interim decision under regulation 42ZCZP of the Regulations.
- subsection 52E(1) of the Therapeutic Goods Act 1989, in particular (a) the 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 (e) the potential for abuse of a substance; and (f) any other matters considered necessary to protect public health
- pursuant to paragraph 52E(2)(a) of the Act, the SPF, and
- the Handbook.

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

I have made a final decision to confirm my interim decision to not amend the current Poisons Standard with respect to sodium hydroxide and potassium hydroxide. My reasons for making the final decision are those set out in the interim decision.

In making my final decision, I have considered the material in the interim decision and the 7 submissions received in response to the public consultation on the interim decision. All the submissions were in favour of the interim decision with 5 providing written justifications. However, none provided any information not considered in making the interim decision. No responses were submitted in opposition or partial support of the interim decision.

While I acknowledge the severity of accidental ingestion of high pH products containing these substances, particularly in children and the impact on affected families, I remain of the view that amending the scheduling of these substances is unlikely to significantly reduce the frequency of accidental ingestion by children. The substantial regulatory burden of the proposed up-scheduling on domestic and commercial consumers, as well as the industrial, manufacturing, and educational sectors is not justified based on the current evidence of the risk.

Preventing poisoning in the home relies on a small number of consistent, practical behaviours that reduce exposure to hazardous substances before harm occurs. As most poisonings occur in the home, first-line prevention should focus on safe storage, appropriate use and handling, and active supervision.

Together, embedding these practices in everyday household routines can substantially reduce the likelihood of accidental poisoning and support safer home environments.

Final decision in relation to cyanoacrylate esters

Proposal

The Delegate proposed amendments to the current Poisons Standard to amend the current scheduling of cyanoacrylate esters and create a new Dangerous poisons (Schedule 7) entry for eyelash adhesives containing cyanoacrylate esters to restrict their usage to professional settings. The proposal was based on the recommendation from the Australian Industrial Chemicals Introduction Scheme (AICIS) evaluation of cyanoacrylate esters published in June 2024.[8]

[8] Cyanoacrylates - Evaluation Statement - 26 June 2024

Final decision

Pursuant to regulation 42ZCZR of the Regulations, the Delegate has made a final decision to amend the current Poisons Standard in relation to cyanoacrylate esters as follows:[9]

Schedule 5 – Amend Entry

CYANOACRYLATE ESTERS in contact adhesives **except**:

when labelled with the warning:

KEEP OUT OF REACH OF CHILDREN. Avoid contact with skin and eyes and avoid breathing vapour. Bonds on contact. Should fingers stick together apply a solvent such as acetone to contact areas then wash off with water. Do not use solvents near eyes or open wounds. In case of eye contact immediately flush with water; and

WARNING – This product contains ingredients which may cause skin sensitisation in certain individuals; or

when packed in sealed measure packs each containing 0.5 g or less of cyanoacrylate esters:

(i) labelled with the approved name or trade name of the poison, the quantity and the warning:

Can cause eye injury. Instantly bonds skin; and

(ii) enclosed in a primary pack labelled with the warning:

KEEP OUT OF REACH OF CHILDREN. Avoid contact with skin and eyes and avoid breathing vapour. Bonds on contact. Should fingers stick together apply a solvent such as acetone to contact areas then wash off with water. Do not use solvents near eyes or open wounds. In case of eye contact immediately flush with water; and

WARNING – This product contains ingredients which may cause skin sensitisation in certain individuals.

Index

CYANOACRYLATE ESTERS

Schedule 5

Appendix F, Clause 4

Appendix F, clause 4 – Warning statements and safety directions

Item	Poison	Safety direction item number and statement
87	CYANOACRYLATE ESTERS	28 – (Over) (Repeated) exposure may cause sensitisation.

Materials considered

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

- the application to amend the current Poisons Standard with respect to cyanoacrylate esters (the **Application**)

[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.

- 11 public submissions, with 7 including the pre-meeting consultation under regulation 42ZCZK of the Regulations
- the advice received from the 40th meeting of the Advisory Committee on Chemicals Scheduling (the **Committee**)
- the interim decision relating to cyanoacrylate esters and the materials considered as part of the interim decision, as published on 18 December 2025
- 2 public submissions, both with written components, received in response to public consultation on the interim decision under regulation 42ZCZP
- subsection 52E(1) of the Therapeutic Goods Act 1989, in particular (a) the 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 (e) the potential for abuse of a substance; and (f) any other matters considered necessary to protect public health.
- pursuant to paragraph 52E(2)(a) of the Act, the SPF, and
- the Handbook.

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

I have made a final decision to confirm the interim decision to not include a Dangerous Poisons (Schedule 7) entry for eyelash adhesives containing cyanoacrylate esters. The existing Caution (Schedule 5) classification remains appropriate for these substances. However, I have decided that contact adhesives containing cyanoacrylate esters must carry an additional warning about skin sensitisation in order to be exempted from Schedule 5 classification. My reasons for making the final decision are set out in the interim decision.

In making this decision, I have considered the information set out in the interim decision, as well as 2 public submissions from organisations received during the interim consultation period. Both submissions included written components and supported amending Schedule 5 to include the warning label regarding skin sensitisation.

One submission indicated full support for the interim decision, while the other expressed partial support. The partially supportive submission recommended extending the transition period to at least 18 months to accommodate the broad impact on cosmetic and non-cosmetic product industry.

I acknowledge that the primary concern associated with cyanoacrylate esters is the risk of skin sensitisation, particularly where products are applied directly to the skin. This risk is well recognised and may be exacerbated by repeated or prolonged skin contact. A review of 893 single-substance cyanoacrylate exposure cases from 2005-2015 found that most exposures were in children, with a median age of 11 years and resulted in no or only minor clinical effects, with no major effects reported. Most cases were managed on-site without the need for medical intervention, and the identified effects were predominantly local in nature, involving skin or eye contact rather than systemic toxicity.[10] This would support the conclusion that, while cyanoacrylate esters present a recognised hazard, particularly in relation to direct contact and repeated exposure, the severity and outcomes of reported exposures do not demonstrate a level of risk that would justify classification in Schedule 7. Retention

[10] Carstairs, S. D., Koh, C., Qian, L., Qozi, M., Seivard, G., & Cantrell, F. L. (2017). Sticky situations: cyanoacrylate exposures reported to a poison control system. *Clinical toxicology (Philadelphia, Pa.)*, *55*(9), 1001–1003. https://doi.org/10.1080/15563650.2017.1327067.

of the Schedule 5 classification, with the addition of a warning statement addressing skin sensitisation, provides an appropriate, proportionate, and effective regulatory response to the risks identified.

Finally, I acknowledge that the amendment to the Schedule 5 entry will affect a wide range of cosmetic and non-cosmetic products currently in the market. In response to the public submission, particularly the recommendation for a longer transition period, I agree that an extended transition period is appropriate to allow industry sufficient time to update product labelling in accordance with the new requirements.

Implementation date

1 February 2028

Final decisions on proposed amendments referred to the Advisory Committee on Medicines and Chemicals Scheduling in joint session (Joint ACMS-ACCS #39, March 2025)

Final decision in relation to chromium-DL methionine

Proposal

The Delegate received an application to amend the current Poisons Standard to include chromium-DL-methionine in Schedule 6 (Poison) of the Poisons Standard under a new generic entry, chromium organic chelates, with specific exceptions for certain preparations for human internal use and animal feed premixes. Chromium-DL-methionine is not currently included in the current Poisons Standard and is not covered by other entries for chromium compounds.

Final decision

Pursuant to regulation 42ZCZR of the Regulations, the Delegate has made a final decision to not amend the current Poisons Standard in relation to Chromium-DL-methionine (CHROMIUM ORGANIC CHELATES).

Materials considered

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

- the application to amend the current Poisons Standard with respect to chromium-DL methionine (the **Application**)
- 6 public submissions, with 3 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 39th meeting of the Advisory Committee on Medicines and the Advisory Committee on Chemicals Scheduling in a joint session (the **Committee**)
- the interim decision and the materials considered as part of the interim decision, as published on 18 December 2025
- 2 public submissions received in response to the public consultation on the interim decision under regulation 42ZCZP of the Regulations
- subsection 52E(1) of the Therapeutic Goods Act 1989, in particular (a) the 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 (e) the potential for abuse of a substance; and (f) any other matters considered necessary to protect public health
- pursuant to paragraph 52E(2)(a) of the Act, the SPF, and
- the Handbook.

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

I have made a final decision not to amend the current Poisons Standard with respect to chromium-DL-methionine. My reasons for making the final decision are set out in the interim decision. In making my final decision, I have considered the information previously considered in the interim decision, as well as the 2 public submissions from professional peak bodies that were received via public consultation on the interim decision. No written components were provided with these submissions.

The submissions supported the interim decision not to amend the current Poisons Standard in relation to chromium-DL-methionine (CHROMIUM ORGANIC CHELATES).

Furthermore, I note that European Food Safety Authority, in 2020, concluded that the product containing chelated chromium was safe for consumers of products derived from the animals fed this additive. The Panel concluded that the additive should be considered a skin sensitiser, however, I consider the risk to farmers to be minimal.[11]

I maintain that the limited data available does not align with the criteria for chromium-DL-methionine to be included in Schedule 6 (Poison), under the Scheduling Policy Framework. Consequently, I have decided that maintaining the current status is appropriate and will ensure that regulatory measures continue to adequately protect public health without inadvertently impacting existing therapeutic goods.

[11] EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), Bampidis, V., Azimonti, G., Bastos, M. L., Christensen, H., Durjava, M., Dusemund, B., Kouba, M., López-Alonso, M., López Puente, S., Marcon, F., Mayo, B., Pechová, A., Petkova, M., Ramos, F., Villa, R. E., Woutersen, R., Galobart, J., Innocenti, M. L., Ortuño, J., … Navarro-Villa, A. (2023). Efficacy of Availa®Cr (chromium chelate of dl-methionine) as a feed additive for dairy cows (Zinpro Animal Nutrition (Europe), Inc). EFSA journal. European Food Safety Authority, 21(12), e8455. https://doi.org/10.2903/j.efsa.2023.8455

Final decisions on proposed amendments to the current Poisons Standard under regulation 42ZCZW

Final decision in relation to bromoxynil

Final Decision

Pursuant to r 42ZCZW of the Regulations, the Delegate has made a final decision not to amend the current Poisons Standard in relation to bromoxynil.

Materials considered

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

- the application to amend the current Poisons Standard with respect to bromoxynil (the **Application**)
- the interim decision notified in writing to the applicant on 27 February 2026
- subsection 52E(1) of the *Therapeutic Goods Act 1989* (Cth) (the **Act**), in particular (a) the 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 considered necessary to protect public health
- pursuant to paragraph 52E(2)(a) of the Act, the SPF, and
- the Handbook.

The applicant did not make a submission on the interim decision.

Proposal

Bromoxynil is listed in the current Poisons Standard as Dangerous poison (Schedule 7) except for preparations containing 1.5% or less of bromoxynil that are considered Poison (Schedule 6). The Application proposes to down schedule all bromoxynil preparations for agricultural or industrial use in containers with a nominal capacity of 20 L or more from Schedule 7 to Schedule 6 irrespective of bromoxynil content. The purpose is to make these high-volume preparations intended for agricultural or industrial use available without the additional restrictions on the availability, possession, storage or use applicable to Schedule 7 substances.

Reasons for the final decision

The proposal was not referred to an advisory committee for advice. Pursuant to r 42ZCZW of the Regulations, I made a final decision to not amend the current Poisons Standard in relation to bromoxynil. My reasons for making the final decision are those set out in the interim decision sent to the applicant. In accordance with r 42ZCZV of the Regulations, the interim decision was communicated to the applicant on 27 February 2026 and written submissions on the interim decision was invited. No submission on the interim decision was received from the applicant. The reasons for my decision follow.

Bromoxynil is an herbicide used to control broad-leaf weeds in domestic (particularly useful in Buffalo lawns), agricultural (crops including wheat, oats, barley, rye, linseed and lucerne) and commercial (turf) settings and for environmental management of invasive weeds. It disrupts energy production and respiration via uncoupling oxidative phosphorylation in mitochondria in plants, animals and humans. To date, there is no specific antidote available for use in bromoxynil poisonings. Fatalities from the ingestion of bromoxynil containing products have been reported to the jurisdictional Poison Information Centres (PICs) and in the literature. Considering the serious harm including death from intentional ingestion of high concertation bromoxynil products, preparations containing more than 1.5% bromoxynil were placed in Schedule 7.

Due to the associated high risk, Schedule 7 substances should be available only to specialised or authorised users who have the skills necessary to handle them safely. Further, products containing Schedule 7 substances must be stored in an area and a manner, that does not allow access by the public. No such restrictions apply to products containing Schedule 6 substances. The applicant argues that exempting bromoxynil products in containers with more than 20 L from Schedule 7 will reduce the high compliance burden on agricultural and industrial end users by removing the additional regulatory requirements relating to transport, logistics and storage of Schedule 7 substances.

The applicant further stated that their proposed changes would maintain controls on access for the domestic user at the same level as achieved by the current scheduling of bromoxynil. The applicant considers that in domestic settings, herbicides are not used in large volumes and therefore, domestic user access to large volume products containing more than 1.5% bromoxynil will be limited. Smaller volumes of products containing more than 1.5% bromoxynil will remain in Schedule 7 and would not be accessible to domestic users, while lower concentration Schedule 6 bromoxynil products in appropriate container sizes will continue to be available for domestic use.

As of April 2026, there are 125 herbicide products registered in the Australian Pesticides and Veterinary Medicines Authority (APVMA) Public Chemical Registration Information System that contain bromoxynil, of which 108 are marketed for commercial operators. Almost all are available in containers of more than 20 L, with the majority (87 products) containing 20-25% bromoxynil. It is important to note, that there is no regulatory mechanism that can prohibit a domestic user from buying ≥ 20 L herbicide products containing more than 1.5% bromoxynil, should it be classified as a Schedule 6 substance. The applicant has not proposed any mechanism to ensure that high volume-high concentration bromoxynil preparations are only available to commercial or broad acre agricultural operators, should the proposed down-scheduling of bromoxynil be implemented. I am not convinced that existing general arrangements for preparations containing Schedule 6 substances will be effective in limiting general consumer access to 20 L or larger bromoxynil products which typically contains 14-40% bromoxynil. Ingestion of products containing high concentrations of bromoxynil can be fatal.

The applicant, based on their emergency response and adverse incident records, claimed their products intended for agricultural and industrial use have been widely and safely used for many years. Access control through scheduling applies to substances rather than individual products. However, jurisdictional PICs reported 11 cases of bromoxynil self-poisonings between April 2023 and February 2025. Four of these incidents resulted in deaths while 4 were severely life-threating, and at least 5 of these incidents involved preparations containing 20% bromoxynil.

The applicant, with reference to my earlier decision to classify products containing more than 1.5% bromoxynil as Schedule 7 substances, noted that intentional ingestion of concentrated bromoxynil products resulting in serious harm have occurred in urban or domestic settings. My reasoning did not exclude incidents from regional or rural areas. Further, analysis of the April 2023–February 2025 data from PICs indicate that incidents of intentional self-poisoning with bromoxynil were not limited to city or urban areas. Therefore, I am not satisfied that restricting domestic user access to smaller volumes of high concentration bromoxynil products as the sole regulatory measure will mitigate the risk of self-harm in rural or agricultural settings.

The applicant also referred to the classification of methylcyclopentadienyl manganese tricarbonyl (MMT), which is exempted from its Schedule 7 classification when packed for industrial use in

containers with a nominal capacity of 100 L or more. MMT is an additive in automotive lead replacement petrol (LRP) which is either pre-blended at the refinery or added to unleaded petrol by the consumer. Preparations containing more than 10% MMT were considered to be a Schedule 7 poison because of its acute toxic effects in animals and possible lethal effect in children in case of accidental ingestion. Unlike the reports of self-harm from bromoxynil, I have not received any reports of accidental or intentional poisoning from MMT. I do not consider that the risks for bromoxynil are directly comparable to that of MMT.

I also note that the container volumes of commercial bromoxynil products vary form 1-1000 L and 122 of them have a nominal volume of 20 L or less as well as more than 20 L (April 2026 data). Exempting containers of more than 20 L of bromoxynil poses the challenge of having single products with different scheduling based on volumes and will impact all businesses producing different pack sizes as it would not be possible to market products with the different signal headings and access controls. It is not clear whether broader consultation within the industry was undertaken in preparing this application.

My earlier decision dated 4 September 2023 to change the scheduling of bromoxynil was made following the consideration of advice from the Advisory Committee on Chemicals Scheduling (ACCS 36, March 2023), poisoning and self-harm data provided by the PICS, and submissions received through two public consultations conducted in January 2023 and July–August 2023.[12] My decision to up-schedule bromoxynil aligned with the ACCS advice. In my interim decision, I set an implementation date of 1 June 2024 to allow the industry sufficient time to make necessary arrangements to comply with the changed regulatory requirements. I did not receive any submissions opposing the proposal or opposing my interim decision including the implementation date.

However, in February 2024, I received an application to defer the implementation date to 1 January 2025. The applicant raised concerns about the logistical challenges of complying with the additional restrictions placed on Schedule 7 bromoxynil products that could disrupt supply chain during peak usage period. Approximately 80–90% of bromoxynil products are supplied, purchased and used between May and July. In recognition of the significant potential impact of the disruptive changes on broad acre agriculture, I deferred the implementation date to 1 February 2025 allowing more time than requested.[13] In making this decision I consulted the applicant, one major supplier/manufacturer and the industry peak body, none of whom raised any concern about the decision on scheduling of bromoxynil.

Final decision in relation to *Mitragyna speciosa* (kratom)

Final Decision

Pursuant to r 42ZCZW of the Regulations, the Delegate has made a final decision not to amend the current Poisons Standard in relation to *Mitragyna speciosa* (kratom).

Materials considered

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

- the application to amend the current Poisons Standard with respect to *Mitragyna speciosa* (kratom) (the **Application**)
- the interim decision notified in writing to the applicant on 12 February 2026

[12] Notice of final decisions to amend (or not amend) the current Poisons Standard, published 4 September 2023

[13] Notice of final decision to amend the current Poisons Standard in relation to bromoxynil, published 17 April 2024

- subsection 52E(1) of the *Therapeutic Goods Act 1989* (Cth) (the **Act**), in particular (a) the 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 considered necessary to protect public health
- pursuant to paragraph 52E(2)(a) of the Act, the SPF
- the Handbook, and
- applicant's written submission on the interim decision.

Proposal

The applicant proposed to amend the current Poisons Standard in relation to *Mitragyna speciosa* (kratom) to create a Prescription only medicine (Schedule 4) or a Controlled drug (Schedule 8) entry for human therapeutic use of kratom for pain relief, mental health, and opioid withdrawal support. Kratom is currently classified as a Prohibited substance (Schedule 9).

Reasons for the final decision

The proposal was not referred to an advisory committee for advice. Pursuant to r 42ZCZW of the Regulations, I have made a final decision to not amend the current Poisons Standard in relation to *Mitragyna speciosa* (kratom). My reasons for making the final decision are those set out in the interim decision sent to the applicant.

In accordance with r 42ZCZV of the Regulations, the interim decision was communicated to the applicant on 12 February 2026 and written submission on the interim decision was invited on or before 27 February 2026. The applicant provided a late response on 19 March 2026.

Although not required to consider any submission made after the time specified in the written notice on the interim decision, I have considered the late submission by the applicant in arriving at my final decision.

The applicant provided limited information to support their application and therefore in making my decision, I also relied on assessments from comparable overseas regulatory bodies and organisations and broader peer-reviewed scientific literature. The detailed reasons for my decision follow.

Kratom is a tree native to south-east Asia that has long been used by labourers and farmers as a stimulant and to reduce fatigue.[14] It is typically consumed by chewing the leaves, smoking, or preparations as tea. In traditional medicine, kratom is used to relieve chronic pain, insomnia, anxiety and diarrhoea, boost energy and stamina, and assist with opium substitution or withdrawal. While kratom contain over 40 structurally related alkaloids, 2 major alkaloids, mitragynine (CAS 4098-40-2) and 7-hydroxymitragynine (CAS 174418-82-7) are known to be pharmacologically active. These 2 compounds are potent μ-opioid receptor agonists and exhibit psychotropic and opioid-like effects.[15]

In relation to s 52E(1)(a), and (b) of the Act, the applicant claimed that kratom has potential therapeutic benefits for pain relief and opioid withdrawal. However, the applicant did not provide credible evidence for its efficacy or therapeutic benefit. While the articles cited by the applicant support

[14] Veltri C, Grundmann O. Current perspectives on the impact of Kratom use. Subst. Abuse Rehabil. 2019;10:23-31. DOI: https://doi.org/10.2147/SAR.S164261.

[15] Sokup B, Pippin MM. Kratom. [Updated 2023 Aug 28]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK585120

potential therapeutic benefits of kratom based on its traditional use, they also conclude that further research is required to establish the safety and efficacy of kratom.[16,17,18,19]

A recent systematic review identified 18 clinical studies, all of which were conducted in south-east Asian populations.[20] Of these, only one randomised, double-blind, placebo-controlled trial found that kratom leaf extract, prepared as a decoction, increased pain tolerance an hour after use.[21] However, the sample size was small (36), and the participants were chronic kratom users. Both the randomised trial and the systemic review emphasised the need for rigorous research on kratom's therapeutic use and safety profile.

Regarding s 52E(1)(c) and (e) of the Act, I note that the physiological effects of kratom are dose dependent where stimulant-like effects are often seen at lower doses and opioid-like effects are observed at higher doses. Toxicities typically occur when the ingested dose exceeds 8 grams.[22] Adverse effects of kratom intoxication include neuropsychiatric (agitation, confusion, sedation, hallucinations, tremor, seizure, coma), cardiovascular (tachycardia, hypertension) and gastrointestinal (abdominal pain, nausea, vomiting) effects as well as respiratory depression.[23,24]

Chronic recreational use of kratom, in rare cases, has been associated with acute liver injury and may also cause complications such as acute renal failure and bone marrow toxicity.[25] In animal studies, repeated dosing with mitragynine led to dependence as shown by naloxone-induced withdrawal. Based on limited epidemiological data, opioid-like withdrawal symptoms that are typically mild have been reported in humans after cessation of kratom use. A few cases of neonatal withdrawal have also been documented in infants born to mothers who regularly used kratom.[26]

Notably, from 2017 to 2020, 127 deaths were associated with kratom and recorded by the United Nations Office on Drugs and Crime (UNODC) Early Warning Advisory Tox-Portal, with 63.8% from the United States (US, mainly California), 30.7% from Thailand, and smaller percentages from Sweden, Australia, and Finland.[27] The World Health Organisation Expert Committee on Drug Dependence Pre-Review Report: Kratom (*Mitragyna speciosa*), mitragynine, and 7-hydroxymitragynine (ECDD Report) conceded attributing causality in kratom-associated deaths is complex due to challenges in detecting its active compounds, limited toxicological testing, and frequent polysubstance involvement. While

[16] Brown PN, Lund JA, Murch SJ. A botanical, phytochemical and ethnomedicinal review of the genus Mitragyna korth: Implications for products sold as kratom. *J Ethnopharmacol*. 2017;202:302-325. doi:10.1016/j.jep.2017.03.020

[17] Smith KE, Sharma A, Grundmann O, McCurdy CR. Kratom Alkaloids: A Blueprint?. ACS Chem Neurosci. 2023;14(2):195-197. doi:10.1021/acschemneuro.2c00704

[18] Singh D, Narayanan S, Vicknasingam B, et al. The Use of Kratom (Mitragyna speciosa Korth.) Among People Who Co-use Heroin and Methamphetamine in Malaysia. *J Addict Med*. 2022;16(2):223-228. doi:10.1097/ADM.0000000000000876

[19] Henningfield JE, Wang DW, Huestis MA. Kratom Abuse Potential 2021: An Updated Eight Factor Analysis. *Front Pharmacol*. 2022;12:775073. Published 2022 Jan 28. doi:10.3389/fphar.2021.775073

[20] Prevete E, Kuypers KPC, Theunissen EL, Corazza O, Bersani G, Ramaekers JG. A systematic review of (pre)clinical studies on the therapeutic potential and safety profile of kratom in humans. *Hum Psychopharmacol*. 2022;37(1):e2805. doi:10.1002/hup.2805

[21] Vicknasingam B, Chooi WT, Rahim AA, et al. Kratom and Pain Tolerance: A Randomized, Placebo-Controlled, Double-Blind Study. Yale J Biol Med. 2020;93(2):229-238. Published 2020 Jun 29. PMID: 32607084

[22] Sokup B, Pippin MM. Kratom. [Updated 2023 Aug 28]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan. Available from: https://www.ncbi.nlm.nih.gov/books/NBK585120

[23] Papadi G, Bakhiya N, Ildico Hirsch-Ernst K. Assessment of the possible health risks associated with the consumption of botanical preparations of *Mitragyna speciosa* (kratom). *EFSA J*. 2022;20(Suppl 1):e200415. Published 2022 May 25. doi:10.2903/j.efsa.2022.e200415

[24] World Health Organization. (2022). Meeting report of the 44th Expert Committee on Drug Dependence. In *WHO Expert Committee on Drug Dependence* (pp. 1–15). http://www.jstor.org/stable/resrep44196.7

[25] LiverTox: Clinical and Research Information on Drug-Induced Liver Injury [Internet]. Bethesda (MD): National Institute of Diabetes and Digestive and Kidney Diseases; 2012-. Kratom. [Updated 2020 Apr 3].

[26] World Health Organization. (2022). Meeting report of the 44th Expert Committee on Drug Dependence. In *WHO Expert Committee on Drug Dependence* (pp. 1–15). http://www.jstor.org/stable/resrep44196.7

[27] 44th ECDD (2021): Kratom (Mitragyna speciosa), mitragynine, and 7-hydroxymitragynine

kratom has been implicated in some deaths, multiple studies indicate mitragynine is most often detected alongside other drugs such as opioids, stimulants and sedatives. However, the ECDD Report also included information on individuals presenting for drug dependence treatment related to the use of kratom, mitragynine or 7-hydroxymitragynine. The ECDD Report further indicated that kratom consumption generally can impair quality of life, particularly in cases of severe dependence, which may deteriorate physical health. Reports of kratom being mixed with substances like Coca-Cola and cough syrup suggest misuse and possibly abuse, raising significant public health concerns due to its potential for dependence.

Internationally, kratom use is prohibited in many countries (including some US states) due to concerns about its safety and potential for abuse. Currently, neither kratom nor any kratom-derived substances are lawful as ingredients in any US Food and Drug Administration approved drug or as dietary supplements in conventional foods.[28] Canada bans the marketing of kratom for human consumption.[29] In Europe, the regulation of kratom varies from county to country and ranges from complete prohibition (the United Kingdom, Ireland, France, Italy) to unregulated (Spain, Germany and the Netherlands) through controlled (psychoactive or narcotic substance; Finland, Norway, Sweden) or regulated (psychomodulatory substance requiring licence for sale and age verification; Czech Republic).[30] In New Zealand, mitragynine is classified as a prescription medicine, and its use in herbal remedies is prohibited under section 2 of the *Medicines Act 1981*.[31] Kratom was removed from Thailand's list of prohibited substances, effectively decriminalising its consumption and possession in 2021.[32] However, the Association of Southeast Asian Nations banned its inclusion in traditional medicine and health supplements in 2013 categorising them as "harmful to human health".[33]

Turning my mind to s 52E(1)(d) of the Act, neither a cutoff limit nor any justification was proposed for the inclusion of kratom in Schedule 4 or Schedule 8. The applicant proposed various forms of kratom (i.e. powder, capsule, liquid extract, dry leaves) without any information regarding the dosage, labelling, or packaging to enable any assessment against the scheduling framework criteria.

Following communication of the interim decision, the applicant submitted that a Schedule 8 classification can provide an appropriate framework for substances with potential therapeutic utility that require controlled access due to their opioid-like properties. The applicant argued that the proposed Schedule 8 kratom preparations would be used for short-term adjunct treatment for opioid withdrawal syndrome in adults where first-line opioid substitution therapy (methadone, buprenorphine) is contraindicated, refused, or inaccessible. The proposed presentations are oral tablets or liquid formulations containing 1-5 mg mitragynine per unit dose with a daily maximum dosage of 15 mg mitragynine.

The applicant has proposed that the prescription of kratom as a Schedule 8 medicine will be limited to addiction medicine specialists and general physicians with relevant authorisation. However, it is unclear who such prescribers will be or how the process will be regulated. Similarly, the applicant's proposals to include kratom prescriptions in real-time prescription monitoring systems, mandatory enrolment in a national kratom pharmacovigilance registry, mandatory co-prescription of an opioid antagonist do not provide any details regarding implementation. Lastly, the applicant proposed listing kratom in Schedule 8 conditional on a formal review by the Advisory Committee on Medicines Scheduling within 36 months of commencement, based on pharmacovigilance data is not a mechanism available under the current legislation.

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[28] FDA Center for Drug Evaluation and Research, 2025, 7-Hydroxymitragynin (7-OH): An Assessment of the Scientific Data and Toxicological Concerns Around an Emerging Opioid Threat (Accessed 22 Oct 2025)

[29] 44th ECDD (2021): Kratom (Mitragyna speciosa), mitragynine, and 7-hydroxymitragynine

[30] European Kratom Alliance; www.eka.eu/legality; accessed 15 May, 2025.

[31] MedSafe, 2021, Kratom – not such a nice cup of tea. (Accessed 2 Oct 2025)

[32] Australian – Thai Chamber of Commerce, 2025, Thailand's Updated Guidelines on Kratom in Food and Herbal Products (Accessed 22 Oct 2025)

[33] Association of South East Asian Nations (ASEAN) - Guiding principles for inclusion into or exclusion from the negative list of substances for Traditional Medicines and Health Supplements (Accessed 2 Oct 2025)

The applicant also argued that classifying kratom as a Schedule 9 substance prevents all legitimate research and therefore gathering of information on safety and efficacy. Schedule 9 classification does *not* prevent any medical or scientific research or use for analytical, teaching or training purposes with prohibited substances, but requires approval by Commonwealth and/or state or territory health authorities.[34]

To be included in Schedule 8, a substance must have an established therapeutic value but its use, at established therapeutic dosage levels, is recognised to produce dependency with a high propensity for misuse, abuse or illicit use (Schedule 8, factor 2). The applicant has not provided any data demonstrating safety or efficacy for the proposed presentations, dosage or indication. The 5 additional review articles cited by the applicant in support of kratom's efficacy appraised animal studies, case reports, traditional usage or self-reports that are at best suggestive of potential medicinal use.[35, 36, 37, 38, 39] All 5 reviews highlighted the need for additional controlled clinical trials to establish the safety and efficacy of kratom and cautioned against kratom use in a therapeutic setting in view of its high abuse liability, potential for drug interactions and adverse events, and inadequate research into the balance of benefits to harm.

While mitragyine is a Schedule 4 medicine in New Zealand, there are currently no products containing mitragyine available for sale in New Zealand. There are no products containing kratom or its alkaloids approved by the US FDA, although some US states permit sale of kratom products with additional restrictions and requirements.

Overall, I maintain my view that the potential for misuse, abuse and dependence of kratom is well documented while its therapeutic value has not been established. Therefore, kratom must remain listed as a Prohibited substance (Schedule 9, factor 2).

Based on the above considerations, and in particular, the unsubstantiated claims about therapeutic benefits compared with risks and potential for misuse, abuse and dependence, I am not convinced kratom can be moved from Schedule 9 to Schedule 4 or Schedule 8. Therefore, I have decided not to amend the current Poisons Standard in relation to kratom.

[34] https://www.tga.gov.au/products/unapproved-therapeutic-goods/access-pathways/clinical-trials

[35] Prozialeck WC, Avery BA, Boyer EW, et al. (2019). Kratom policy: The challenge of balancing therapeutic potential with public safety. International Journal on Drug Policy, 70, 70-77. DOI: 10.1016/j.drugpo.2019.05.003

[36] Grundmann O, Hendrickson RG, Greenberg MI (2022). Kratom: History, pharmacology, current user trends, adverse health effects and potential benefits. Disease-a-Month, 69(6), 101442. DOI: 10.1016/j.disamonth.2022.101442

[37] White CM (2019). Pharmacologic and clinical assessment of kratom: An update. American Journal of Health-System Pharmacy, 76(23), 1915-1925. DOI: 10.1093/ajhp/zxz221

[38] Singh D, Narayanan S, Vicknasingam B, et al. (2017). Changing trends in the use of kratom (Mitragyna speciosa) in Southeast Asia. Human Psychopharmacology, 32(3). DOI: 10.1002/hup.2582

[39] Heywood J, Smallets S, Paustenbach D (2024). Beneficial and adverse health effects of kratom (Mitragyna speciosa): A critical review of the literature. Food and Chemical Toxicology, 192, 114913. DOI: 10.1016/j.fct.2024.114913

Decision to amend the current Poisons Standard under section 52D(2) of the Act

Decision in relation to WIN 55,212-2

Decision

Pursuant to regulation 52D (2) of the Regulations, a Delegate of the Secretary has made a final decision to amend the current Poisons Standard in relation to WIN 55,212-2 as below.[40] This decision does not change the scheduling of naphthoylindoles which remain listed as Prohibited substances (Schedule 9) and only clarifies that WIN 55,212-2 is captured under the entry for naphthoylindoles.

Index – Amend entry

NAPHTHOYLINDOLES

cross reference: WIN 55,212-2 (CAS 137795-17-6)

Schedule 9

Materials considered

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

subsection 52E(1) of the Act, in particular (a) the 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 (e) the potential for abuse of a substance; and (f) any other matters considered necessary to protect public health

pursuant to paragraph 52E(2)(a) of the Act, the SPF, and

the Handbook.

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

In exercising my power under section 52D(2) of the Act, I have taken into account the information provided in the materials listed above. My reasons for making the final decision are as follows.

WIN 55,212-2, is an aminoalkylindole (family of cannabinergic compounds that act as a cannabinoid receptor agonist) derivative. It is not specifically scheduled but can be captured under the class entries for naphthoylindole or synthetic cannabinomimetics both of which are Prohibited substances (Schedule 9). WIN 55,212-2 was discussed at the October 2011 meeting of the Advisory Committee of Medicines Scheduling where it was ascertained that WIN 55,212 should be included in the group entry for napthoylindoles. Therefore, to improve clarity, I have decided to include WIN 55,212-2 in the Poisons Standard as a cross reference to naphthoylindoles. The proposed amendment was not referred to an expert advisory committee.

[40] 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.

Implementation date

1 June 2026

Amendments to the Poison Standard in relation to New Chemical Entities (NCEs)

The NCEs listed below will be included in the new Poisons Standard that will come into effect on 1 June 2026.

ANACAULASE-BCDB

Schedule 4 – New Entry

ANACAULASE-BCDB

Index – New Entry

ANACAULASE-BCDB

Schedule 4

APADAMTASE ALFA

Schedule 4 – New Entry

APADAMTASE ALFA

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APADAMTASE ALFA

Schedule 4

AVACINCAPTAD PEGOL

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Schedule 4

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Schedule 4

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