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

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

18 December 2025

Confidentiality

All submissions received will be placed on the TGA's Internet site, unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked "IN CONFIDENCE". Reasons for a claim to confidentiality must be included in the space provided on the TGA submission form. For submission made by individuals, all personal details, other than your name, will be removed from your submission before it is published on the TGA's Internet site. In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission form.

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

This 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, Disability and Ageing 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 committee[2] under subdivision 3D.2 of the Regulations in March 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 23 January 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 Chemicals Scheduling (ACCS #40, March 2025)

Interim 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 recommendation from the Australian Industrial Chemicals Introduction Scheme (AICIS) evaluation of medium and long chain alkyl sulfates published in June 2024.[3] 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.

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 medium and long chain (C6-C15) alkyl sulfates and lauryl sulfate salts as follows:[4]

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.

[3] Medium and long chain alkyl sulfates - Evaluation Statement – 26 June 2024

[4] 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.

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.~~

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).

Schedule 6

Appendix E, clause 3

Materials considered

- In making this interim decision, the Delegate considered the following material:
- The proposal to amend the current Poisons Standard with respect to medium and long chain alkyl sulfates (the **Proposal**)
- The 9 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 40th meeting of the Advisory Committee on Chemicals 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; 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 medium and long chain (C6-C15) alkyl sulfates be entered in Schedule 6 and Appendix E in the Poisons Standard and that Schedule 6 and Appendix E, clause 3 entry for lauryl sulfate salts be deleted and cross-referenced under the new entry, as per the interim decision above.

The Committee also recommended an implementation date of 1 June 2026 for the purpose of allowing industry additional time to comply with the amendments, given the substantial quantity of products and volumes used in industrial processes that might be affected by the decision.

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:

– Eye damage – the majority of these chemicals are expected to cause serious eye damage at high concentrations.

– Skin irritation – alkyl sulfates are irritating to skin with varying degrees of severity. Skin irritation potential decreases with increasing chain length and the risks are reduced when products are formulated to be non-irritating.

– Ingestion of liquid laundry detergents and dishwashing products causing injury and death, whether accidental or intentional.

– There are risks of exposure of children to these chemicals from accidental ingestion of liquid laundry detergents and dishwashing products.

Benefits:

– Surfactants – used in a variety of consumer/commercial products including body wash, dishwashing liquid, laundry products, and shampoos.

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

– These chemicals have widespread use in cosmetic and household cleaning and laundry products.

– Consumer – widespread use in cosmetic and household cleaning and laundry products.

– Commercial/ Industrial – many commercial uses including in fire-fighting foams; chemical and polymer manufacture; coal seam extractions.

– Goods for human therapeutic use, including over the counter (OTC) preparations.

– Used in high volumes in Australia (>1,000 tonnes/year).

c) the toxicity of a substance

– Eye – “the majority of alkyl sulfates are expected to cause serious eye damage, warranting hazard classification.”[5] The eye irritating potential appears to decrease with increasing alkyl chain length. Alkyl sulfates with chain lengths C12-C15 caused irreversible eye damage in animal studies. While no reliable data are available for C6-C10 alkyl sulfates, corrosive chemicals are expected to cause eye damage.

– Eye – “for the unknown or variable composition, complex reaction products or biological (UVCB) materials, effects will depend on the composition. UVCB substances (except CAS No.

[5] Medium and long chain alkyl sulfates - Evaluation Statement – 26 June 2024

68955-20-4) are expected contain at least 3% of alkyl sulfates with chain lengths less than C15, warranting the same hazard classification. This is supported by the available data.

– Shorter chain length alkyl sulfates are more toxic than the longer chain length alkyl sulfates. The available data indicates that alkyl sulfates with carbon chains of C16 to C18 including the UVCB, CAS No. 68955-20-4, cause less severe effects, although severity of effects are still sufficient to warrant classification as an eye irritant.

– Skin – In humans, reported to be moderate to strong skin irritants at concentrations of 10% or greater and slightly irritating at 1%. Skin irritation potential decreases with increasing chain length, with moderate irritation or corrosion observed for alkyl sulfates with chain lengths less than C16.

– Dermal Toxicity – low acute dermal toxicity and are not considered to be skin sensitisers.

– Oral Toxicity – low to moderate acute oral toxicity. Generally, the median lethal dose (LD50) decreases with increasing chain lengths with LD50 values less than 2,000 mg/kg body weight reported for alkyl sulfates with chain lengths of C12 and below.

– Inhalation – limited data is available. Given the irritant properties of these chemicals, inhalation could lead to irritation/corrosion of the mucous membranes of the respiratory tract.

– UVCBs contain varying amounts of C6-C15 alkyl sulfates (from at least 3% to 25%) and toxicity depends on their composition.

– Non-toxic for cosmetic topical application but can be a skin irritant at concentrations above 10%.

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

– Usually formulated as UVCBs (alkyl sulfates of unknown or variable composition) which contain varying amounts of C6-C15 alkyl sulfates (from at least 3% to 25%).

– Packaged and used in a range of cosmetic and cleaning products. Formulation and packaging vary based on the product application. Maximum reported concentrations for some alkyl sulfates are:

  - leave-on cosmetic products – 8%
  - rinse-off cosmetic products – 40%
  - diluted for bath use – 15%
  - cleaning products (including spray applications) – 5%
  - dishwashing liquid – 18%
  - laundry detergent (powder and liquid) – 30%.

e) the potential for abuse of a substance

– Nil.

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

– *Implementation considerations*

  - The proposed Schedule 6 entry for medium and long chain alkyl sulfates might capture many cosmetic and household cleaning and laundry products.

– *Implications for industrial uses*

  - The AICIS Evaluation Statement EVA00146 (June 2024) did not assess the use of these chemicals in oil or gas extraction and processing. Implications for these industries and workers is unclear.
  - There may be difficulties for some manufacturers in identifying the relative proportion of different chain length alkyl sulfates as their product may be made up of UVCBs.

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.

I have made an interim decision to create a Schedule 6 and Appendix E entry for medium and long chain (C6-C15) alkyl sulfates based on the current entries for lauryl sulfate salts. Additionally, I have decided to remove the Schedule 6 and Appendix E entries for lauryl sulfate salts. In making this decision I have balanced the potential regulatory burden of changing access to a broader range of alkyl sulfates against the health hazards posed by these substances.

I have considered the 3 written public submissions received during the pre-meeting consultation period. One written response received was fully supportive of the applicant's proposal and 2 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. Nine responses were received, with 7 supportive and 2 opposed. These respondents did not provide reasons for their support or opposition and as a result, the extent of my consideration is limited to noting that the submissions were generally in favour of the scheduling proposal.

The supportive submission was of the view that including medium and long chain alkyl sulfates in Schedule 6 and Appendix E would reduce the risk of both unintentional and intentional exposure to these chemicals.

The submissions opposed to the proposal highlighted that medium and long chain alkyl sulfates are used in many products in Australia with no significant adverse events reported. They argued that these substances are used globally in numerous products, and the proposed scheduling would be incongruent with international regulations. An opposed submission was also of the view that consumers are unlikely to purchase products that cause skin irritation, and that skin irritancy can be reduced through adapting the surfactant blend and with the addition of emollients to protect and hydrate the skin. Also, consumers are likely aware of the risks of eye contact for surfactant-based products. Several submissions raised concerns that the proposed scheduling does not specifically exclude goods for human therapeutic use and could have unintended consequences on therapeutic goods containing alkyl sulfates.

Finally, several submissions noted the regulatory burden for industry in complying with the proposed scheduling. These were two-fold; firstly, surfactant products typically contain a blend of several surfactants, each with variable carbon chain lengths; secondly, the proposed scheduling captures alkyl sulfuric acids which are very unstable and break down rapidly. Both issues would complicate compliance efforts by industry and manufacturers.

The interim decision proposes to include 26 substances in the Index as a cross-reference.

In relation to s 52E(1)(a) and (b) of the Act, I acknowledge the prevalence of medium and long chain alkyl sulfates in a variety of consumer and commercial products, especially cleaning agents, with high volumes of usage in Australia (greater than 1,000 tonnes/year). These substances are also used in human therapeutic goods including in over the counter (OTC) medicines. However, I am of the view that these chemicals pose a significant health hazard. The majority of these chemicals are expected to cause serious eye damage at higher concentrations. They are also irritating to the skin with varying degrees of severity. I note that skin irritancy decreases with increasing chain length, and the risks are reduced when products are formulated to be non-irritating. I am also concerned by the anecdotal reports of accidental (e.g. paediatric or elderly) and intentional ingestion of liquid laundry detergents and dishwashing products resulting in injury or death. However, these products also contain potentially

hazardous substances that are not the subject of this proposal. In considering SPF factors and balancing the risks and benefits, I am of the opinion that the substances have a moderate health hazard and that inclusion in Appendix E is necessary to inform consumers of appropriate first aid instructions in the event of eye or skin exposure.

With regards to s 52E(1)(c) of the Act, these substances can result in acute eye toxicity and skin irritation. Alkyl sulfates with chain lengths C12-C15 caused irreversible eye damage in animal studies and have been shown in humans to be moderate to strong skin irritants. Whilst there is no reliable data available for C6-C10 alkyl sulfates, based on the AICIS Evaluation Statement they are expected to be corrosive chemicals and are therefore likely to cause eye damage. Whilst these are the primary toxicity concerns, these substances also have low to moderate oral toxicity and may present with inhalation toxicity owing to its irritant properties, though there is limited empirical data showing this. Generally, shorter chain length alkyl sulfates are more toxic and irritable than longer chain length alkyl sulfates, although severity of effects of longer chain length alkyl sulfates are still sufficient to warrant classification as an eye irritant.

The Committee and numerous submissions noted that the hazards posed by unknown or variable composition, complex reaction products or biological materials (UVCBs) alkyl sulfates will depend on their composition. UVCBs typically comprise at least 3% of alkyl sulfates with chain lengths less than C15, warranting the same hazard classification. I acknowledge concerns that UVCBs may pose a challenge for industry compliance, particularly for manufacturers in identifying the relative proportion of different chain length alkyl sulfates in products made up of UVCBs. Turning my mind to s 52E(1)(d) of the Act, I note that medium and long chain alkyl sulfates are present in a wide variety of cosmetic and cleaning products with a maximum concentration ranging from 5% (cleaning products) to 40% (rinse-off cosmetic products). The proposed scheduling contains a range of exemptions that should cover the majority of products currently on the market as they contain alkyl sulfate concentrations below the proposed cutoffs and/or are labelled with the required first aid instructions. Products which would be affected by the scheduling changes contain a higher total concentration of alkyl sulfate substances for which creates a higher risk for adverse effects from exposure.

I acknowledge that numerous public submissions raised concerns that surfactant products may incorporate a blend of medium and long chain alkyl sulfates which may complicate industry compliance efforts. However, in considering the SPF factors, I remain of the view that medium and long chain alkyl sulfates pose a moderate health hazard and warrant inclusion in Schedule 6.

In considering s52E(1)(f) of the Act, I note that the AICIS Evaluation Statement did not assess the use of these chemicals in oil or gas extraction and processing. The Interim Decision is not expected to create a substantial impact on these industries as risks are managed under relevant work health and safety laws.

The Interim Decision is intended to ensure that the risks of these substances which have similar hazards are managed by considering their total concentrations in preparations. Therefore, I have also removed the Schedule 6 and Appendix E entries for lauryl sulfate salts as recommended by the Committee. The removal of these entries will prevent ambiguity in the scheduling of substances that could be captured under both entries.

Given the substantial quantity of products and volumes used in industrial processes likely affected by the decision, I have decided on an implementation date of 1 June 2027 to allow industry additional time to comply with the amendments.

Proposed implementation date

1 June 2027

Interim 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.

Interim decision

Pursuant to regulation 42ZCZN of the Regulations, the Delegate has, in relation to the proposed amendment, made an interim decision to not amend the current Poisons Standard in relation to sodium hydroxide and potassium hydroxide.

Materials considered

- In making this interim decision, the Delegate considered the following material:
- The application to amend the current Poisons Standard with respect to sodium hydroxide and potassium hydroxide (the **Application**)
- The 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**)
- 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 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 entries for sodium hydroxide and potassium hydroxide remains appropriate.

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:

– Can cause severe caustic injury, particularly if ingested.

– Some reports of self-poisoning.

Benefits:

– Effective cleaning agents, particularly for drains and ovens (in domestic settings).

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

– Very wide use in manufacturing, other industrial, commercial and educational settings – considered to be ‘high volume’ chemicals. Also widely used in the domestic setting as cleaning agents. Some reports of self-poisoning.

c) the toxicity of a substance

– Caustic injury, severity of which is pH dependent. Higher pH results in liquefaction necrosis.

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

– Used in a variety of dosage forms including granular and liquid preparations

– Available in formulations that require reconstituting and ready to use formulations

e) the potential for abuse of a substance

– Nil.

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

– Frequency of accidental paediatric ingestion could be reduced through consumer education campaigns, as the number of childhood poisonings summarised in the application mentioned poor storage and dilution behaviours by adults.

– Moving higher pH preparations to Schedule 6 would mandate stronger warnings on products.

– Child resistant closures (CRCs) should be considered for all domestic products, regardless of form, as there are reports of injury from aerosol products.

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.

I have made an interim decision to not amend the Poisons Standard regarding sodium hydroxide and potassium hydroxide. In making this decision I have considered the health hazards posed by the substances, particularly with respect to concerning incidents of accidental paediatric ingestion and balanced the risks against the need for maintaining consumer access to these products. Chiefly, these substances are used in high volumes across a wide variety of products in domestic, commercial, industrial, and educational settings. Numerous domestic products are routinely used for common cleaning tasks such as toilet and drain cleaning (currently in Schedule 5 or Schedule 6). All these products carry strong warnings and safety directions and are generally available in child-resistant packs. Applying more restrictive scheduling (Schedule 7) will severely restrict consumer access to these domestic cleaning products without significantly impacting accidental paediatric exposure resulting from improper handling or storage of these products. In this context, increasing consumer education for appropriate handling and storage of such cleaning products should be a focus for reducing consumer harm from accidental exposure particularly in children.

I have considered the 22 written public submissions received during the pre-meeting consultation period. Twelve written responses received were fully supportive of the applicant’s proposal, 2 partially supportive and 8 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. Twenty-six responses were received, with 16 supportive, 2 partially supportive and 8 opposed. These respondents did not provide reasons for their support or opposition and as a result, the extent of my consideration is limited to noting that the submissions were generally in favour of the scheduling proposal.

Submissions in support of the proposed scheduling expressed concern for the significant risk of corrosive injury posed by the substances. Both sodium hydroxide and potassium hydroxide, with their extremely high pH levels, can cause severe chemical burns and injuries, particularly when used without proper precautions. These risks are of greatest concern in the context of accidental paediatric exposure, though there are also reports of their use in intentional self-harm. Reports of accidental paediatric ingestion in Australia occur primarily in the domestic setting and have resulted in serious short- and long-term health consequences and also deaths. Over the last 20 years, there have been 4 fatalities reported in Queensland. These occurred in children aged 1, 2, 3, and 10 years of age in both the domestic and work settings. Exposure was to drain or oven cleaners, or other caustic cleaning agents. These submissions generally expressed a view that these incidents are avoidable by restricting access to high pH products in domestic settings. One jurisdictional Poisons Information Centre pointed to the past success of up-scheduling caustic agents in dishwasher detergents and food additives. They considered passive protective strategies (such as product reformulation) are more effective than ones that require continual behavioural vigilance (such as child resistant closures (CRCs) and keeping products out of reach of children). With no safe and comparably efficacious substitutes currently available for these substances, the up-scheduling would impact a wide range of products used in substantial volumes by consumers on a regular basis.

I agree with these submissions that there are concerning reports of accidental paediatric ingestion resulting in serious injuries or death. Having considered each of the case studies provided by the submissions, I am in agreement with the Committee that increasing access restrictions to these products through scheduling is unlikely to reduce the frequency of accidental paediatric exposure. Whilst reducing the maximum pH of cleaning products may reduce the severity of injuries, the proposed scheduling changes would have a profound impact on the availability of these products across domestic settings and the industrial sector. Furthermore, I am of the view that based on the accidental nature of these cases additional labelling requirements are unlikely to reduce the likelihood of accidental paediatric ingestion.

The submissions in partial support of the proposal agreed with the risks posed by sodium hydroxide and potassium hydroxide, though raised concerns that the proposed scheduling would have unintended impacts outside of the domestic and commercial settings. One submission noted that these substances are commonly used in research and educational settings without viable alternative

substances. Another submission noted that potassium hydroxide is still used at a 20% concentration by dermatologists and pathologists for dermatopathology needs, such as to prepare microscope slides to examine scrapings. As the risk of ingestion in this context is negligible, they were supportive of a Schedule 7 entry provided it excluded professional use in a laboratory setting. It was also noted that sodium hydroxide and potassium hydroxide are included in the Permissible Ingredients Determination (PID) for use as excipient ingredients in listed medicines. Any amendments to scheduling were supported providing they do not affect listed medicines that are compliant with the requirements of the PID or registered medicines. Submissions noted that the proposed Schedule 7 entry might result in a greater administrative burden and will impact use of solid preparations in teaching and research practice. Supervision by qualified staff and appropriate Work Health and Safety (WHS) measures are sufficient to ensure safe usage by staff and students.

Submissions in opposition to the proposal noted that sodium hydroxide and potassium hydroxide are used in high quantities across consumer, commercial and industrial sectors. These hydroxides are essential components in cleaning and degreasing agents, including toilet and drain cleaning products. In 2001-02 the reported use volume for sodium hydroxide was greater than 1,000,000 tonnes per year, and potassium hydroxide between 1,000-10,000 tonnes per year. Sodium hydroxide is broadly used across industry in water treatment, ingredient synthesis for industry, hydrolysis process, saponification, laboratory testing, construction materials, tanning agents, food processing, printing inks, and manufacturing of paints. The proposed scheduling would place a disproportionate burden on numerous industrial sectors due to the licencing requirements of Dangerous Poisons (Schedule 7) and lead to reduced availability of effective cleaning and other products on the market.

The requirements and licensing of Schedule 7 substances also vary across states and territories and would add to the burden on industrial sectors. Furthermore, substitution of these substances is not possible in most products, and therefore the impact of inclusion in Schedule 7 would be unavoidable. In domestic products, non-sodium hydroxide and non-potassium hydroxide products, including enzymatic products, although used for general pipe maintenance, lack effectiveness in cleaning heavily carbonised equipment. In paint products, sodium hydroxide is formulated to have lower chronic health risks as an active ingredient and is generally safer than alternative products. One submission raised concerns that the proposal does not specifically exclude goods for human therapeutic use. Additionally, products containing less than a 5% concentration will be inadvertently impacted; however, the applicant did not provide any evidence that products containing less than 5% sodium or potassium hydroxide are of concern.

Regarding international regulation of sodium hydroxide and potassium hydroxide containing products, countries such as New Zealand, the EU, US and UK currently do not prohibit domestic access to high pH products. With respect to UK regulations, sodium hydroxide and potassium hydroxide products (with at least 12% total caustic alkalinity) are classified as ‘Reportable Poisons.’ Although these products cannot be sold to people under 18 years of age, high pH products can still be sold to adults for domestic use. The inclusion of some products containing these substances as Reportable Poisons was due to an increase in street attacks on people using strongly alkaline substances, not incidences of paediatric poisoning. Sodium hydroxide and potassium hydroxide are not included in the UK equivalent of Schedule 7, ‘Regulated Poisons,’ which requires an explosives precursors and poisons (EPP) licence to acquire, possess or use these chemicals.

Numerous submissions in opposition felt that the evidence of harm associated with these products was not sufficient to justify the wide-reaching regulatory burden that would be caused by the proposed scheduling. They argued these substances do not meet the hazard profile of a Schedule 7 substance and similarly hazardous poisons, such as phosphoric acid, sulphuric acid, sodium metasilicate, and sodium hypochlorite are not included in Schedule 7. They also argued that this would be inconsistent with international regulations for these substances. Numerous submissions felt that with the current requirements around labelling and packaging, incidents of accidental ingestion can only arise from misuse or improper storage. They also highlighted that current labelling and packaging requirements, including child-resistant closures are designed to prevent misuse and accidental ingestion.

I acknowledge that even with these safeguards, accidental exposure is still occurring, and the consequences for children and their families can be devastating. However, additional restrictions through scheduling may not significantly enhance safety but will certainly impose significant burdens on consumers, businesses, and industry.

Turning my mind to s 52E(1)(a) and (c) of the Act, I am in agreement with numerous public submissions that sodium hydroxide and potassium hydroxide are used as effective cleaning agents, particularly in drains and ovens (in domestic settings), often with few efficacious alternatives. I have weighed the benefits of these substances against the potential for harm. These substances can cause severe caustic injury, particularly when ingested. The severity of caustic injury is largely dependent on the product pH, with a higher pH resulting in severe health consequences through liquefactive necrosis. I remain concerned by the reports of self-poisoning, particularly in cases of accidental paediatric ingestion. However, as discussed below, I remain of the view that amending scheduling is unlikely to reduce the frequency of these incidents but would create a significant impost from consumers as well as business and industry sectors that use these chemicals.

In considering s52E(1)(b) of the Act, I am in agreement with the Committee and a majority of the public submissions that sodium hydroxide and potassium hydroxide are very widely used in domestic, commercial, industrial, manufacturing, and educational settings. These substances are considered to be high volume chemicals in Australia. In the domestic environment they are mostly used as cleaning agents. Turning my mind to s52E(1)(d) of the Act, sodium hydroxide and potassium hydroxide are used in a variety of dosage forms including granular and liquid preparations. They are also available in formulations that require reconstituting and ready to use formulations; both with different use patterns and higher risk for more concentrated, higher pH formulations for reconstitution. As noted by one public submission, domestic products are commonly packaged with CRCs, though I note that this is required for all domestic product forms (such as aerosols).

Regarding s52E(1)(f) of the Act, I agree with the Committee that including high pH preparations sodium hydroxide and potassium hydroxide in Schedule 6 would mandate stronger warnings on these products. However, I am of the opinion that stronger warning labels through inclusion in Schedule 6 or Appendix J are unlikely to reduce the frequency of accidental ingestion based on the means of exposure reported in the case reports. The possible inclusion of bittering agents in high pH preparations to reduce severity of accidental paediatric ingestion was considered but ultimately rejected by the Committee. The Committee were of the opinion that bittering agents would be unlikely to reduce severity and morbidity as even brief oral exposure, without swallowing, of small volumes can result in severe injury.

While up scheduling may not be the most appropriate risk management response in this instance, the gravity of harm, especially to children is a key consideration. The Committee noted, and I agree, that future accidental ingestion incidents could be reduced through increasing consumer education. The majority of accidental paediatric exposure cases reported were due to poor or improper storage of the products, or adult behaviour, particularly during product dilution, that allowed children access and the opportunity to consume these products.

Ultimately, I agree with the Committee that amending the scheduling of these substances is unlikely to significantly reduce the frequency of accidental paediatric ingestion. Furthermore, the substantial regulatory burden of the proposed 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 of these substances.

Interim 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).

Currently, MEKO is a classified as a Poison (Schedule 6) except for silicone adhesives or sealants containing less than 2.5% MEKO or less than 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.

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 methyl ethyl ketone oxime as follows:[6]

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

Scheule 6

Appendix E, Clause 3

Appendix F, Clause 4

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.	1 – Avoid contact with eyes 4 – Avoid contact with skin

[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.

		12 – Vapour is harmful to health on prolonged exposure 28 – (Over) (Repeated) exposure may cause sensitisation	8 – Avoid breathing vapour 9 – Use only in well-ventilated area 10 – Ensure adequate ventilation when using

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 ethyl ketone oxime (the **Application**)
- The 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**)
- 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; 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 were in support of the amendment to the Schedule 6 entry to reduce risks to the public from intentional or inadvertent exposure of consumers to products containing MEKO. Restricting the concentration to up to 0.1% is consistent with overseas regulatory actions.

The Committee advised that sufficient time should be allowed to revise labelling of warning and safety statements and for industries to adjust formulations. Thus, an implementation date of 1 February 2028 was recommended.

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:

- There is a public health risk from exposure to methyl ethyl ketone oxime (MEKO).
- Long term damage to nasal epithelium with potential for skin irritation and the potential for effects on the blood system.

Benefits:

- Paints: functions to prevent skin formation on paints, reducing wastage.
- Sealants: extensively used in building and industrial uses in products that prevent water penetration into building and other structures and preventing water damage.

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

- Anti-skinning agent in product formulations of paints, varnishes, stains and coatings for domestic use and minor components in some silicone sealants.
- MEKO also has other reported commercial uses in corrosion inhibitors, insulating materials, solvents, viscosity adjustors and fuel additives.

c) the toxicity of a substance

- Moderate acute oral and dermal toxicity, and low acute inhalation toxicity
- Skin irritant, skin sensitiser, causes eye irritation and serious eye damage
- Potential to cause long term damage to the nasal epithelium after inhalation exposures at low doses
- Causes systemic health effects on the blood system from repeated exposures (oral and inhalation). Small increase in methaemoglobin and white blood cells, small falls in red blood cells.
- MEKO is not expected to have genotoxic potential or cause specific adverse effects on fertility/sexual function and foetal development.

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

- The levels in paints in Australia are unspecified but are typically less than 1.0%.
- Paint containers are also variable with a range of volumes and a range of application methods (brush roller, spray).
- The concentration of MEKO in sealants is highly variable. Maximum concentrations in sealants and adhesives are 5% and 2%, respectively.
- Sealants are typically packaged in cartridges or sausage type of receptacles which limit user exposure.

e) the potential for abuse of a substance

- Abuse of these substances is not expected.

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

– Sufficient time should be allowed to revise warning statements and/or adjust formulations.

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.

The proposal aims to strike a balance between reducing public risk of intentional or inadvertent exposure of consumers to products containing MEKO. The proposal acknowledges the need for these preparations to carry additional warning statements and safety directions to mitigate risks regarding potential for inhalation carcinogenicity and the need to avoid breathing vapours of MEKO and ventilation, considering the wide inclusion of MEKO in preparations such as paints and sealants.

I have considered that a total of 8 public submissions were received during the pre-meeting consultation period. Out of 5 submissions with written responses, 2 were fully supportive of the applicant's proposal, 3 were partially supportive and no submissions opposed the proposal.

Two of the submissions raised that silicone sealants and adhesives are typically packaged and used in cartridges or sausage format in order to dispense them in a controlled and effective manner. Additional packaging requirements of these products (child resistant enclosures, tactile identification via embossing, etc.) would have a significant impact on the practical use and functionality. One of the submissions proposed that a lower scheduling classification for silicone adhesives or sealants containing less than 2.5% MEKO, with more prominent workplace ventilation information, should be considered. However, I agree with the Committee that the toxicity endpoint data for MEKO as presented in the AICIS Evaluation Statement, aligns more with a Schedule 6 classification, rather than Schedule 5.

A public submission mentioned that the proposal would create technical and trade barriers for overseas without providing detailed supporting evidence. I acknowledge that the Committee expressed inability to comment authoritatively on trade implications.

I note that the Interim Decision, if implemented, is generally consistent with the proposed concentration limits in Canada. Indoor products have much lower proposed concentration limits, ranging from 0.0032% for non-spray paints to 0.20% for adhesives and sealants. Outdoor products allow higher limits, from 0.18% for non-spray paints up to 0.55% for spray paints and 0.42% for silicone sealants[7].

With regard to s 52E(1)(a) and (c) of the Act, I have considered that MEKO exhibits moderate acute oral and dermal toxicity, with low acute inhalation toxicity, and it is classified as a skin irritant and sensitiser, capable of causing eye irritation and potentially serious eye damage. Repeated exposure, even at low inhalation doses, has been associated with long-term damage to the nasal epithelium and systemic effects on the blood system. There is sufficient evidence that the chemical has carcinogenic effects in animals, though the mode of action for carcinogenicity is uncertain, and relevance to humans cannot be ruled out. Despite these concerns, MEKO is not expected to be genotoxic or to adversely affect fertility, sexual function, or foetal development. In total, the available toxicology data are aligned with the Schedule 6 policy framework factors 1,2, and 4.

In relation to s 52E(1)(b) and (d) of the Act, MEKO is largely used in paints for prevention of skin formation on paints and reduced wastage. The levels in paints in Australia are unclear but are typically greater than 0.1% and less than 1.0%. As for use in sealants and adhesives, MEKO is extensively applied in building and industrial uses to prevent water penetration and damage. Maximum concentrations in sealants and adhesives are 5% and 2%, respectively. MEKO also has commercial uses in corrosion inhibitors, insulating materials, solvents, viscosity adjustors and fuel additives.

I agree with the Committee that additional labelling would improve the safe use of products containing MEKO, to reduce the potential hazards from inhalation exposure. Paints contain MEKO to prevent skin

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

formation on the paint surface are capable of sustained emissions for up to 20 hours. Adequate ventilation reduces this to 7.5 hours with paints containing 0.3% MEKO, which is below the sensory irritation threshold and significantly below the lowest adverse effect concentration (LOAEC) for acute systemic toxicity. I note that since the regulatory changes in the EU, that manufacturers have changed their product formulations to include alternatives to MEKO.

In summary, I agree with the advice of the Committee that amendment to the Schedule 6 entry is appropriate to reduce public risk from intentional or inadvertent exposure of consumers to products containing MEKO with exemptions in products up to 0.1% concentration. The proposed changes will not require the introduction of child-resistant closures as MEKO will not be included under section 49 of the Poisons Standard.

I note that if industry decides to discontinue the use of MEKO in their products, another agent will need to be evaluated to match the performance of MEKO.

Given the significant role these products play in building and construction industries, I have decided on an implementation date of 1 February 2028 to allow industry sufficient time to reformulate products or implement the labelling and packaging revisions in response to the decision.

Proposed implementation date

1 February 2028

Interim 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 of acrylates and methacrylates based on bisphenol A (BPA).[8] BPA glycidyl dimethacrylate and BPA glycidyl diacrylate are not specifically scheduled in the current Poisons Standard.

Interim decision

The Advisory Committee on Chemicals Scheduling recommended the creation of Schedule 6 entries for BPA glycidyl dimethacrylate and BPA glycidyl diacrylate and that these be amended with entries Appendix E and F entries. It was recommended that dental and orthodontic products containing these substances may need to be considered separately.

Pursuant to regulation 42ZCZN of the Regulations, the Delegate has, in relation to the proposed amendment, made an interim decision as follows:[9]

Schedule 6 – New entries

BPA GLYCIDYL DIMETHACRYLATE in preparations for cosmetic use.

BPA GLYCIDYL DIACRYLATE in preparations for cosmetic use.

[8] Acrylates and methacrylates based on bisphenol A (BPA) - Evaluation statement - 26 June 2024

[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 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

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BPA GLYCIDYL DIACRYLATE

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The Committee recommended an implementation date of **1 February 2026** for the purpose of allowing industry additional time to comply with the amendments, given the substantial wide range of products that may be affected by the decision.

Materials considered

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

- The proposal to amend the current Poisons Standard with respect to Acrylates and methacrylates based on bisphenol A (BPA) (the **Proposal**)
- The 6 public submissions, with 2 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 #40 meeting of the Advisory Committee on Chemicals 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; 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 to create the Schedule 6 entries for BPA glycidyl dimethacrylate and BPA glycidyl diacrylate as well as new entries in Appendix E and F in the Poisons Standard as follows. However, dental and orthodontic products containing these substances may need to be considered separately.

Schedule 6 – New entries

BPA GLYCIDYL DIMETHACRYLATE **except** in dental products

BPA GLYCIDYL DIACRYLATE **except** in dental products

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).

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BPA GLYCIDYL DIMETHACRYLATE

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BPA GLYCIDYL DIACRYLATE

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The Committee also recommended an implementation date of **1 February 2026** for the purpose of allowing industry additional time to comply with the amendments, given the substantially wide range of products will be affected by the decision.

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:

– Dermal exposure, particularly prolonged dermal exposure, can result in skin sensitisation and/or allergic skin reactions.

– Both BPA Glycidyl Methacrylates and BPA Glycidyl are listed as potential endocrine disrupting compounds in the NORMAN Suspect List Exchange Data base.[10]

Benefits:

– These are quick curing products forming strong bonds.

– The substances are used extensively in a wide range of products including adhesives, coatings, and printing inks with site limiting use in manufacturing other chemicals and polymer products.

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

– These substances are used commercially in paints and coatings, ink, toner and colourants, adhesive and sealants, water treatment products, lubricant and grease products, construction products, solvents and reprographic agents.

– Domestic uses are in adhesives, sealants and cosmetic nail products. There is risk of skin exposure in domestic DIY use scenarios that need to be managed.

– The substances are used in food contact materials including plastics, coatings, paperboard, adhesives and printing inks.

– The substances are used in dental and orthodontic adhesives and other dental products overseas and likely to be used in Australia.

c) the toxicity of a substance

– Potential skin sensitisation and/or allergic reactions have been observed based on animal and human data at low concentrations (less than 10 ppm).

– Not considered to have genotoxic potential and are not expected to cause serious systemic health effects.

– Both substances are not expected to release BPA because the ether bond is resistant to hydrolysis. The release of BPA through the degradation release of ether linkages is not expected under most conditions and the availability toxicity and toxicokinetic data does not provide evidence of BPA release.

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

– The referral is specific to products for cosmetic use on nails.

– Highly variable, depending on product and use as a wide range of products will be captured by this proposal.

e) the potential for abuse of a substance

– Abuse of these substances would be unlikely.

[10] Norman Suspect List Exchange

- Use of nail polish requires risk management as there is potential for skin irritation if the polish is not cured.
- Incorrect use in domestic situations may occur.

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

- Agree with the recommendation for Safe Work Australia (SWA) to update the Hazardous Chemical Information System (HCIS) to include classifications relevant to Workplace Health and Safety.
- ACMS to consider use in dental products.
- Occupational allergic contact dermatitis has been reported in humans.

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.

I have made an interim decision to create Schedule 6 entries for BPA glycidyl dimethacrylate and BPA glycidyl diacrylate. I have decided to create Appendix E and F entries for first aid instructions and warning statements and safety directions relating to skin sensitisation. Currently, BPA glycidyl dimethacrylate and BPA glycidyl diacrylate are both unscheduled.

I have considered the 6 public submissions received during the pre-meeting consultation period. All of these submissions were in full support of the proposal with 2 submissions providing a written response. The written responses indicated their support of these amendments to reduce the risk of unintentional and intentional exposure of the chemicals but did not elaborate any further.

With regards to s 52E(1)(a), (b) and (d) of the Act, I note that BPA glycidyl dimethacrylate and BPA glycidyl diacrylate have extensive industrial and domestic usage in quick curing products, forming strong bonds.

I note that the Committee also discussed the application of these chemicals and their benefits such as commercial usages in paints and coatings, ink, toner and colourants, adhesive and sealants, water treatment products, lubricant and grease products, construction products, solvents and reprographic agents. The Committee acknowledged that many BPA containing chemicals are used in food contact materials including plastic food storage containers. It was discussed that evaluating the impact of BPA from food contact material is complex and typically undertaken by Food Standards Australia New Zealand (FSANZ). I acknowledge that a FSANZ study demonstrated that dietary exposure to BPA in Australian consumers is low and reducing.

Furthermore, I note that the key concern identified was the potential harm from direct application of nail products containing BPA glycidyl dimethacrylate and BPA glycidyl diacrylate. Overseas data suggests that 5–10% concentrations may cause skin sensitisation, while the US Cosmetic Ingredient Review (CIR)[11] panel deemed them safe if skin contact can be avoided. However, prolonged dermal exposure can still lead to sensitisation or allergic reactions reported in human. I agree with the Committee's finding that prolonged skin contact is more likely to occur in the DIY home situation due to the growing availability DIY nail enhancement kits online and through retail outlets. Given their use in adhesives, sealants, and cosmetic nail products, especially in DIY settings, appropriate risk mitigation is necessary.

I am also aware that both substances are listed in the potential endocrine disrupting compounds of the NORMAN Suspect List Exchange database.[12]

In relation to s 52E(1)(c) and (d) of the Act, I am aware that adverse reactions were reported for artificial nail applications using BPA containing adhesives. Adverse effects included fingertip

[11] Cosmetic Ingredient Review

[12] Norman Suspect List Exchange

dermatitis, nail fold dermatitis, nail dystrophy, paraesthesia (pins and needles), ulnar border hand dermatitis, and eyelid and neck dermatitis. I acknowledge the advice of the Committee that the release of BPA through the degradation of ether linkages is not expected under most conditions, and the available toxicity and toxicokinetic data do not provide evidence of BPA release. I note that the Committee raised the potential for adopting concentration thresholds for BPA glycidyl dimethacrylate and BPA glycidyl diacrylate based on their various usages in products (such as cosmetics or dental products). However, I have decided that concentration thresholds are not appropriate, as adverse effects have been reported at very low exposure concentrations.

Turning my mind to s 52E(1)(d) and (e) of the Act, I have considered that BPA containing products are used in dental and orthodontic adhesives as well as other dental products used overseas and likely to be used in Australia. I also note that the Committee remarked that the primary exposure pathway is dermal for both the public and workers (beauticians and/or nail technicians). However, in the professional setting there may be the additional risk of inhalation exposure from dust particles containing these chemicals when filing, buffing, or removing nails.

Concerning other matters relevant to public health (s 52E(1)(f) of the Act), I agree with the Committee that adopting the recommendations for additional warning statements and safety directions related to skin sensitisation were appropriate, but dental products should be excluded. Additional labelling with warnings and safe use statements could manage professional use for cosmetic products. Despite an applicant suggestion to include dental products containing BPA in the scheduling, I acknowledge the Committee's recommendation for their exclusion due to different exposure pathways and professional oversight.

I agree dental products should be excluded from the proposed entries due to the different exposure pathway and lack of evidence provided on this matter. I have decided to amend the proposed entry so the Schedule 6 entry only covers use in cosmetic products. Currently, this is the primary source of risk to the public. By changing the proposed entry, the use of the substances in products such as paints, inks and coatings will not require changes to labelling and packaging by industry. The substances function as a cross-linking agent in the formation of polymers, providing fast cure speeds and low odour. Unlike cosmetic products, there is no intentional application to the skin with prolonged contact and, therefore, the risks to the user are lower.

In summary, I agree with the advice of the Committee that the proposed creation of Schedule 6 entries could reduce the risk of unintentional and intentional consumer exposure to products containing BPA glycidyl dimethacrylate and BPA glycidyl diacrylate. Given the substantial and wide range of products in industrial and domestic usages as well as food contact materials, I have amended entry proposed entry and I have decided on an implementation date of 1 October 2026 to allow sufficient time for industry to comply with the changes.

Proposed implementation date

1 October 2026

Interim decision in relation to cyanoacrylate esters

Proposal

The Delegate has proposed amendments to the current Poisons Standard to amend the current scheduling of cyanoacrylate esters and create a Dangerous poisons (Schedule 7) entry for eyelash adhesives containing cyanoacrylate esters to restrict their usage to professional settings. The proposal is based on the recommendation from the Australian Industrial Chemicals Introduction Scheme (AICIS) evaluation of cyanoacrylate esters published in June 2024.[13]

[13] Cyanoacrylates - Evaluation Statement - 26 June 2024

The proposal also included amending the current Caution (Schedule 5) entry, such that exemption from Schedule 5 classification for contact adhesives containing cyanoacrylate esters will require an additional warning regarding skin sensitisation.

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 cyanoacrylate esters as follows:[14]

Schedule 5 – Amend Entry

CYANOACRYLATE ESTERS in contact adhesives **except**:

(a) 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

(b) 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.

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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 interim decision, the Delegate considered the following material:

- The proposal to amend the current Poisons Standard with respect to cyanoacrylate esters (the **Proposal**)

[14] 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 11 public submissions, with 7 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**)
- 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; 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 considered the proposal to create a Dangerous Poisons (Schedule 7) entry for eyelash adhesives containing cyanoacrylate esters to restrict their usage to professional settings. The proposal also included a proposed amendment to the current Caution (Schedule 5) entry so that contact adhesives containing cyanoacrylate esters would require an additional warning regarding skin sensitisation to be exempted from Schedule 5 classification.

The Committee noted that the main concern for cyanoacrylate esters is skin sensitisation and there was insufficient information to recommend restricting the products under Schedule 7. Inclusion in Schedule 7 would require licensing and permits for usage, effectively prohibiting domestic use.

In consideration of the information above, the Committee recommended that the Schedule 5 classification of cyanoacrylate esters remains appropriate. However, the Committee recommended that the existing entry for cyanoacrylate esters be amended to include a warning statement to address the risk of skin sensitisation such that to be exempted from the Schedule 5 entry, a preparation containing cyanoacrylate must carry the warning statement.

The Committee recommended that an Appendix F warning statement (e.g. (Over) (Repeated) exposure may cause sensitisation) be included for preparations captured by the Schedule 5 entry. The Committee requested that the Secretariat confirm whether the proposed wording is appropriate and consistent with the committee's advice.

The Committee further recommended that the use of cyanoacrylate esters in wound repair should be referred to the ACMS for further consideration.

The reasons for the advice included:

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

Risks:

– Risks are associated with the wide applicability of these chemicals – from large scale industrial uses to small scale craft and hobby applications. Cosmetic applications where the substances are deliberately applied to the skin may be a special case.

– Sensitisation concern when directly applied to skin, especially near the eyes. The mechanism of sensitisation is not known but it could be related to formaldehyde (a strong sensitiser) that formed by breaking down of the polymer that created by cyanoacrylate esters.

– Risks in non-cosmetic applications are managed by Work Health and Safety (WHS) practices in industry by labelling for smaller scale uses.

Benefits:

– Provided that normal precautions are taken to avoid skin and eye contact and to use products in a well-ventilated area, the risk of adverse effects where the public is infrequently using these products (non-cosmetic adhesives e.g. superglue) is considered low.

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

– Multiple widespread cosmetics, domestic, professional and industrial use as an adhesive.

– Cosmetic eyelash and nail glues

– Superglue for specific hobby and professional use such as model building, woodworking etc.

c) the toxicity of a substance

– Low acute dermal and inhalational toxicity

– Not expected to cause serious systemic health effects following repeated oral, dermal or inhalation exposure

– Not considered to have genotoxic or carcinogenic potential or to cause adverse effects on fertility or development.

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

– Based on international use information, cyanoacrylates are used in eyelash adhesives and nail enhancement products for professional and consumer use with reported concentrations typically 85–100%. The substance is used at concentrations of 60–100% in superglue.

– The packaging and presentation of these products is similar to other products such as eye drops which may cause confusion for consumers.

e) the potential for abuse of a substance

– Nil

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

– The popularity of the product among consumers means that there is an increasing trend in the consumer use of nail products, in particular, fast setting cyanoacrylate-based polishes and application of false eyelashes.

– ACMS to consider medical applications of cyanoacrylate glues as a wound repair polymer. There have been case studies published where skin sensitisation has occurred.

– In surgical and general situations where time is not important patch testing can be carried out to evaluate susceptibility to sensitization.

– In emergency department situations, patch testing is unlikely to be carried out, where the substance 2-propenoic acid, 2-cyano-, 1-methylheptyl ester (CAS 133978 15-1) (2-octylcyanoacrylate – Dermabond) is used for medical applications.

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.

I have made an interim decision that the Schedule 5 (Caution) classification of cyanoacrylate esters remains appropriate. I agree with the Committee's recommendation that the existing entry for cyanoacrylate esters should be amended to include a warning statement to address the risk of skin sensitisation.

I have considered the 11 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 with or without providing a written component. Six responses received in full support of the applicant's proposal, 2 partially supportive and 3 were opposed. Seven written submissions were received, comprising 2 supportive submissions, 2 partially supportive submissions and 3 submissions in opposition of the proposal.

The supportive submissions highlighted that the proposed amendment would prevent and mitigate intentional exposure, while the main point against was the need to address regulatory concerns.

The partially supportive submission stated that the proposal indicated that the highest risk of skin sensitisation was due to eyelash adhesives applied directly to the skin rather than nail products. Nail products containing cyanoacrylate esters are currently in retail stores as well as distribution warehouse and as these products come in small packs, it would require significant re-working of the labelling to include the additional statements. Increase in regulatory burden was also a consideration as, Schedule 7 requirements include licensing for the use and supply of these products in some states and territories.

The 3 opposing submissions argued that the proposed label warning is not fit for non-cosmetic adhesives. The general warning on non-cosmetic adhesives already explicitly states to avoid skin contact and wear gloves during use. Generic messaging will lead to confusion and misuse in non-cosmetic applications, which are not intended for skin contact. The risk of skin sensitisation for non-cosmetic products is considered low, as skin contact is discouraged and guidance on safe use is provided to customers and consumers. A submission commented that any label change should be accompanied by sufficient transition time to minimise the impact to businesses to allow business to run-out existing labelling and packaging stock and mitigate against wasteful disposal of products and packaging.

In relation to sections 52E(1)(a) and (b) of the Act, I note that cyanoacrylate esters are used in a wide range of products, including contact adhesives (e.g. superglue), eyelash adhesives, and nail enhancement products. International reports also indicate their use in adhesives for specialised hobby and professional applications, such as model building, woodworking, and archery fletching.

I have considered the potential for skin and eye sensitisation when cyanoacrylate esters are applied directly. I agree with the proposed amendment introduces labelling requirements that include warning statements and safety directions related to skin sensitisation for cyanoacrylate esters containing products.

I concur with the Committee's view that, the current entry for cyanoacrylate esters should be amended to include a warning statement highlighting the risk of skin sensitisation. The inclusion of Appendix F warning statement 28, which addresses skin sensitisation during human use, is appropriate for all products containing cyanoacrylate esters—whether cosmetic or non-cosmetic. The amendment clarifies that to qualify for exemption from the Schedule 5 entry, any preparation containing cyanoacrylate must display this warning statement.

In relation to sections 52E(1)(c) and (d) of the Act, I have considered that cyanoacrylate esters exhibit low acute toxicity via dermal and inhalation routes. They are not expected to cause serious systemic health effects following repeated oral, dermal, or inhalation exposure, and are not considered to have genotoxic or carcinogenic potential, nor to adversely affect fertility or development.

However, I remain concerned about the risk of accidental ocular exposure, particularly given that cyanoacrylate esters are often present in preparations at high concentrations (typically 85–100%). In Australia, cosmetic products such as eyelash and nail glues may contain cyanoacrylate esters in concentrations ranging from 60% to 100%. Accidental exposure may occur when these products are mistaken for eye drops. Some superglue products closely resemble eyelash adhesives in packaging, increasing the likelihood of confusion in domestic settings. Although such incidents are relatively rare, exposure to these adhesives can result in significant harm. There is also a risk that individuals may

attempt to remove the adhesive using acetone, which is appropriate for dermal exposure but poses serious health risks if applied near the eyes. Consumers need to remain vigilant and aware of the packing similarities between nail or false eyelash glue and eye drop products.

In relation to section 52E(1)(f), I note a growing trend in consumer use of domestic nail products, particularly fast-setting cyanoacrylate-based adhesives and the application of false eyelashes.

I agree with the Committee that in the medical use of cyanoacrylate glues as wound closure agents needs more consideration. Although these products, such as 2-octylcyanoacrylate (CAS 133978-15-1) commonly known as Dermabond, are widely used in clinical practice, published case studies have reported instances of skin sensitisation. In elective surgical or general medical settings, where time permits, patch testing may be conducted to assess individual susceptibility to sensitisation. However, in emergency care, such testing is typically not feasible. This raises concerns about the potential for adverse reactions in sensitive individuals when these adhesives are used without prior evaluation. I agree that the use of cyanoacrylate esters in wound repair products should be referred to the Committee for further consideration.

Furthermore, I agree with the Committee that the available data, when considered against the established scheduling factors, does not provide sufficient justification for the creation of a new entry under Schedule 7. Schedule 7 substances are characterised by a high potential for harm, even at low exposure levels, and require stringent controls during manufacture, handling, and use. These substances should be restricted to specialised or authorised users with the appropriate expertise to manage them safely. Depending on the jurisdiction, additional regulatory measures may apply, including restrictions on availability, possession, storage, and use, and may require individual authorisation for each user of a Schedule 7 product.

Finally, I agreed with the Committee that the scheduling amendment would impact a large number of cosmetic and domestic products. Therefore, I recommend a long transition period to assist industry in complying with the new warning statement and safety direction amendments.

Proposed implementation date

1 June 2027

Interim decision on proposed amendments referred to the Advisory Committees on Medicines and Chemicals Scheduling in joint session (ACMS-ACCS #39, March 2025)

Interim decision in relation to chromium-DL methionine (Chromium organic chelates)

Proposal

The applicant proposed to amend the current Poisons Standard by including chromium-DL methionine as a Poison (Schedule 6) 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 currently not listed in the current Poisons Standard and is not covered by other entries for chromium compounds.

Interim decision

Pursuant to regulation 42ZCZN of the Regulations, the Delegate has, in relation to the proposed amendment, made an interim decision to not amend the current Poisons Standard in relation to Chromium-DL-methionine (CHROMIUM ORGANIC CHELATES).

Materials considered

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

- The application to amend the current Poisons Standard with respect to chromium-DL-methionine (the **Application**).
- The 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 the Advisory Committees 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; 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 scheduling of chromium-DL-methionine remains appropriate. The Committee did not support the creation of a new Schedule 6 entry for chromium organic chelates.

Members agreed that the relevant matters under Section 52E(1) of the Therapeutic Goods Act 1989 included (a) the risks and benefits of the use of a substance; (b) the purpose for which a substance is

to be used and the and 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:

– Exposure risks to workers (respiratory, dermal, and ocular exposure/contact) and risks of exposure to consumers of animal products, such as milk from animals consuming these products.

Benefits:

– Chromium III is available in different forms as a supplement. However, there is not well documented and accepted benefits of human supplementation of Chromium III.

– Methionine is an essential amino acid with a well understood safety profile and has little to no toxicity risk at doses used for supplementation.

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

– The substance intended to be used as an additive in feed for ruminants, pigs, poultry and fin fishes, in a professional context. There is a potential for daily use in feeding these animals.

– Predominantly used in dairy cows to increase milk yield.

c) the toxicity of a substance

– Chromium III, which has no recorded toxicity or carcinogenicity, is typically available as a supplement in forms such as chromium picolinate, chromium citrate, chromium nicotinate, chromium edetate, and chromium yeast. There are no reported risks of toxicity in international reviews.

– Data for this particular substance is limited. The information provided on the toxicity of chromium-DL-methionine was incomplete. Most toxicological endpoints were estimated by using read-across data from related substances.

– Notable potential for skin contact and dust inhalation by workers during expected use. Irritant if inhaled and sensitisation risks have been observed but limited to occupational exposure.

– Personal protective equipment is likely necessary, for which the applicant has established label safety directions.

– Limited evidence for dermal or ocular effects, although individual sensitivity is possible.

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

– The proposed product would contain 1 g/kg (0.1%) chromium (III) as chelated DL-methionine (chromium-DL-methionine) in a powder formulation in 25 kg and 1,000 kg bulk bags. Future products may have different specifications.

e) the potential for abuse of a substance

– Nil

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

– Organic chromium and methionine are included in the TGA Permissible Ingredients Determination (for oral administration).

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 agree that no changes should be made to the current scheduling of chromium-DL-methionine, nor should a new generic entry be created under Schedule 6.

I have made an interim decision not to amend the Poisons Standard with regards to chromium-DL-methionine. In making this decision I have considered that introducing a new Schedule 6 entry could have broader implications, potentially restricting other products currently available on the market. This includes possible unintended consequences for human therapeutic goods. Notably, there are currently 8 medicines listed in the Australian Register of Therapeutic Goods (ARTG) that contain a chromium amino acid chelate as an active ingredient.

The proposal sought to cover all forms of organic chromium compounds, except when separately specified in the Schedules, and exempting preparations for human internal use containing 50 µg or less of chromium per recommended daily dose, or in in animal feed premixes containing 0.1% or less of chromium for the preparation of feeds containing a maximum of 1 g/ton (1,000 ppb) or less of chromium. I note that the proposed scheduling entry would create a scheduling exemption for veterinary feed additive products (containing chromium-DL-methionine as a component).

I have considered the 6 public submissions received during the pre-meeting consultation period. Four responses received were in full support of the applicant’s proposal, 1 was in partial support and 1 was opposed to the proposal. 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. One of the supportive submissions, the partially supportive and the opposed submission provided written justifications.

The submissions received in support of the proposal supported the proposal to reduce the risk of unintentional and intentional exposure of this chemical.

The partially supportive submission highlighted that the proposed Schedule 6 entry excludes the scheduling of chromium organic chelates in medicines for human therapeutic use in preparations containing 50 µg or less per recommended daily dose. As the maximum recommended daily dose (MRDD) of organic forms of chromium permitted by the Permissible Ingredients Determination is 50 µg, the submission commented that the proposal would not appear to affect listed medicines that are compliant with the requirements of the Permissible Ingredients Determination.

The submission in opposition of the proposal observed that since the pre-meeting notice stated chromium is already permitted in therapeutic goods, the proposal could have unintended consequences. They stated that the proposal should not be approved unless the new Schedule 6 entry specifically excludes goods for human therapeutic use as well as the proposed exclusion of goods for human internal use.

In relation to sections 52E(1)(a) and (b) of the Act, I agree that creating the proposed entry would cover all forms of organic chromium compounds. The term "organic chelates" is broad and it is not explicit in the proposal whether the chelating context covers chromium salts, such as chromium picolinate (considered an organic form of chromium and permitted for use in listed medicines) or chromium trichloride hexahydrate (currently Schedule 6).

In considering s 52E(c) of the Act data submitted within the Human Health risk assessment report states that the exposure risks associated with chromium-DL-methionine—via inhalation, dermal contact, and ocular exposure for workers, as well as potential risks to consumers of animal-derived products (e.g., milk from animals fed with these compounds)—are considered acceptable. However, it is important to note that the safety data provided pertains specifically to a product containing

chromium-DL-methionine, while the application seeks a broad exemption for the entire class of organic chromium chelates, which limits the relevance and applicability of the evidence presented.

With further regard to sections 52E(1)(c) and (d), I note that chromium (III) methionine is commonly available as a supplement in various forms, including chromium picolinate, chromium citrate, chromium nicotinate and chromium yeast. In the absence of direct studies, data extrapolated from other chromium chelates suggest that chromium—both as an individual substance and within the product—is slightly irritating to the eyes but non-irritating to the skin in rabbits. It is also likely to exhibit low acute oral and dermal toxicity in rats, although it may present risks to the respiratory system. It may provoke allergic reactions in sensitive individuals. Chromium (III) methionine has not demonstrated genotoxic or neurotoxic effects and read-across data indicate it is unlikely to be carcinogenic or linked to developmental or reproductive toxicity. I agree with the Committee that the available data do not support creation of a Schedule 6 entry for chromium-DL-methionine. The main concern is that chromium-DL-methionine may cause irritation if inhaled and may pose sensitisation risks, particularly during occupational exposure. However, consumer access to chromium-DL-methionine will be limited and risks for occupational exposures are mitigated by work health and safety requirements.

I considered that there was inadequate justification to support the proposed cut-off for chromium-DL-methionine concentrations of 50 µg or less for human therapeutic use. Especially as some of the products registered in the ARTG contain more than the recommended daily dose.

Overall, the limited data available did not align with the criteria for chromium-DL-methionine to be considered a Schedule 6 Poison, under the Scheduling Policy Framework.

Regarding 52E(1)(f), I concur with the Committee that scheduling may be reconsidered in the future if product applications are submitted that deviate from the currently recommended daily intake of chromium.

Based on the reasons outlined above and in consideration of broader implications such as unintendedly restricting products currently available on the market, I have made the decision that scheduling of chromium-DL-methionine remains appropriate and do not recommend the creation of a new generic Schedule 6 entry for chromium organic chelates.

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