Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Consultation: Proposed amendments to the Poisons Standard – ACCS #40 and Joint ACMS-ACCS #39 meetings, March 2025

17 January 2025

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About this consultation

Subdivision 3D.2 of the Therapeutic Goods Regulations 1990 (the Regulations) sets out the procedure to be followed where the Secretary receives an application under section 52EAA of the Therapeutic Goods Act 1989 (the Act) to amend the current Poisons Standard or decides to amend the Poisons Standard on his or her own initiative and decides to refer the proposed amendment to an expert advisory committee. These include, under regulation 42ZCZK, that the Secretary publish (in a manner the Secretary considers appropriate) the proposed amendment to be referred to an expert advisory committee, the committee to which the proposed amendment will be referred, and the date of the committee meeting. The Secretary must also invite public submissions to be made to the expert advisory committee by a date mentioned in the notice as the closing date, allowing at least 20 business days after publication of the notice.

In accordance with regulation 42ZCZK of the Regulations, the Secretary invites public submissions on scheduling proposals referred to the March 2025 meetings of the Advisory Committee on Chemicals Scheduling (ACCS) and Advisory Committee on Medicines Scheduling (ACMS) and ACCS in joint session (Joint ACMS-ACCS). Submissions must be received by close of business 17 February 2025.

Submissions should be provided through our consultation hub. Any submission about any of the proposals to amend the Poisons Standard will be considered at the next meeting of the Advisory Committee on Medicines Scheduling (ACMS), meeting of the Advisory Committee on Chemicals Scheduling (ACCS), or a joint meeting of these two committees.

This consultation closes on 17 February 2025.

We aim to provide documents in an accessible format. If you're having problems using this document, please contact medicines.scheduling@health.gov.au.

Proposed amendments referred for scheduling advice to ACCS meeting #40

Sodium hydroxide and potassium hydroxide

Proposal

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

- high concentrations (greater than 5%) and high pH (greater than12.5) 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 Prohibited substances (Schedule 10).

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.

CAS Number

1310-73-2 (Sodium hydroxide)

1310-58-3 (Potassium hydroxide)

Alternative names

Sodium hydroxide: Caustic Soda, White Caustic, Lye

Potassium hydroxide: Caustic Potash, Potash, Lye

Applicant

Private applicant

Proposed Scheduling

Sodium hydroxide and potassium hydroxide are currently listed in Schedules 10, 6, and 5 of the Poisons Standard. These two substances in liquid or semi-solid food additive preparations for domestic use, when the pH is more than 11.5 are classified as Schedule 10. Preparations containing greater than 5% are listed as Poisons (Schedule 6) whilst preparations containing 5% or less of sodium hydroxide and potassium hydroxide that are greater than pH 11.5 are classified as Caution (Schedule 5). Preparations containing less than 5% of these substances with a pH less than 11.5 are exempt from scheduling. Additionally, preparations containing sodium hydroxide and potassium hydroxide are also required to carry first aid instructions (Appendix E) and warning statements and safety directions (Appendix F).

The applicant has proposed to amend the current Poisons Standard with regards to sodium hydroxide and potassium hydroxide as follows[1].

Schedule 10

SODIUM HYDROXIDE (excluding its salts and derivatives), in liquid or semi-solid food additive preparations, for domestic use, the pH of which is more than 11.5.

POTASSIUM HYDROXIDE (excluding its salts and derivatives), in liquid or semi-solid food additive preparations, for domestic use, the pH of which is more than 11.5.

Schedule 7 – New entries

SODIUM HYDROXIDE (excluding its salts and derivatives), in preparations greater than 5%:

(a) in solid formulations, the pH of which in a 500 g/L aqueous solution or mixture is more than 12.5; or

(b) in liquid or semi-solid formulations, the pH of which is more than 12.5.

POTASSIUM HYDROXIDE (excluding its salts and derivatives), in preparations greater than 5%:

(a) in solid formulations, the pH of which in a 500 g/L aqueous solution or mixture is more than 12.5 or

(b) in liquid or semi-solid formulations, the pH of which is more than 12.5.

Schedule 6 – Amend entries

SODIUM HYDROXIDE (excluding its salts and derivatives) except:

(a) when included in Schedule 5 or Schedule 7 or Schedule 10; or

(b) in preparations containing 5% or less of sodium hydroxide being:

(i) solid preparations, the pH of which in a ~~10~~500 g/L aqueous solution is 11.5 or less; or

(ii) liquid or semi-solid preparations, the pH of which is 11.5 or less.

POTASSIUM HYDROXIDE (excluding its salts and derivatives) except:

(a) when included in Schedule 5 or Schedule 7 or Schedule 10; or

(b) in preparations containing 5% or less of sodium hydroxide being:

(i) solid preparations, the pH of which in a ~~10~~500 g/L aqueous solution is 11.5 or less; or

(ii) liquid or semi-solid preparations, the pH of which is 11.5 or less.

Schedule 5 – Amend entries

SODIUM HYDROXIDE (excluding its salts and derivatives) in preparations containing 5% or less of sodium hydroxide being:

(a) solid preparations, the pH of which in a ~~10~~500 g/L aqueous solution or mixture is more than 11.5 but equal to or less than 12.5; or

(b) liquid or semi-solid preparations, the pH of which is more than 11.5 but equal to or less than 12.5 except in food additive preparations for domestic use.

[1] 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.

POTASSIUM HYDROXIDE (excluding its salts and derivatives) in preparations containing 5% or less of potassium hydroxide being:

(a) solid preparations, the pH of which in a ~~10~~500 g/L aqueous solution or mixture is more than 11.5 but equal to or less than 12.5; or

(b) liquid or semi-solid preparations, the pH of which is more than 11.5 but equal to or less than 12.5 except in food additive preparations for domestic use.

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SODIUM HYDROXIDE

cross reference: CAS No. 1310-73-2, LYE WATER

Schedule 10

Schedule 7

Schedule 6

Schedule 5

Appendix E, clause 3

Appendix F, clause 4

Appendix J, clause 1

POTASSIUM HYDROXIDE

cross reference: CAS No. 1310-58-3

Schedule 10

Schedule 7

Schedule 6

Schedule 5

Appendix E, clause 3

Appendix F, clause 4

Appendix J, clause 1

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

Poisons that must be labelled with first aid instructions		
Item	**Column 1** **Poison**	**Column 2** **Statement code**
263	POTASSIUM HYDROXIDE	A, G3, E2, S1
295	SODIUM HYDROXIDE	A, G3, E2, S1

Standard statements for first aid instructions			
Item	Column 1 Category	**Column 2** **Statement code**	**Column 3** **Statement**
1	Basic	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).
5	General	G3	If swallowed, do NOT induce vomiting.

Standard statements for first aid instructions			
Item	Column 1 Category	**Column 2 Statement code**	**Column 3 Statement**
10	Eyes	E2	If in eyes, hold eyelids apart and flush the eye continuously with running water. Continue flushing until advised to stop by a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor, or for at least 15 minutes.
13	Skin	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 general safety directions for poisons

Poisons that must be labelled with warning statements and safety directions			
Item	**Column 1 Poison**	**Column 2 Warning statement item number**	**Column 3 Safety direction item number**
292	POTASSIUM HYDROXIDE—in preparations containing 0.5% or less of potassium hydroxide	5	1, 4, 6
293	POTASSIUM HYDROXIDE—in solid preparations containing more than 0.5% of potassium hydroxide	2, 10, 78	3, 5, 28
294	POTASSIUM HYDROXIDE—in liquid preparations containing more than 0.5% of potassium hydroxide	2, 10, 78	3, 5
319	SODIUM HYDROXIDE—in preparations containing 0.5% or less of sodium hydroxide	5	1, 4, 6
320	SODIUM HYDROXIDE—in solid preparations containing more than 0.5% of sodium hydroxide	2, 10, 78	3, 5, 28
321	SODIUM HYDROXIDE—in liquid preparations containing more than 0.5% of sodium hydroxide	2, 10, 78	3, 5

Warning statements	
Item	**Column 1 Warning statement**
2	Corrosive.
5	Irritant.
10	May produce severe burns.
78	Attacks skin and eyes.

Safety directions	
Item	**Column 1 Safety direction**
1	Avoid contact with eyes.
3	Wear eye protection when mixing or using.
4	Avoid contact with skin.
5	Wear protective gloves when mixing or using.
6	Wash hands after use.
28	Do not mix with hot water.

Appendix J, clause 1 – Conditions for availability and use of certain poisons included in Schedule 7

Conditions for supply of certain poisons included in Schedule 7		
Item	**Column 1** **Poison**	**Column 2** **Condition**
70	POTASSIUM HYDROXIDE	
72	SODIUM HYDROXIDE	

Background

Sodium hydroxide and potassium hydroxide are relatively cheap, strong alkalis that are used in chemical engineering, industry and manufacturing processes including production of soap and sanitisers. As consumer products, sodium hydroxide and potassium hydroxide are commonly used in cleaning and degreasing agents. Commercial cleaners, such as dishwashing powders and degreasers often have higher levels of alkalis such as sodium hydroxide and potassium hydroxide. Both substances are also widely used to adjust pH in industrial and food processes, and cleaning of aquariums and pools.

Most formulated cleaners for domestic use contain with low concentrations (less than 1%) of sodium and/or potassium hydroxide. However, domestic drain cleaners, as well as other commercial cleaners, can contain these substances in high concentrations and high pH. Sodium and potassium hydroxide in concentrations greater than 5% with a pH greater than 12.5 pose a high risk of harm when they come in contact with any human tissue including the skin, eyes and mucous membranes as they can cause caustic burns.

Summary of applicant's reasons for the proposal

- Exposures to sodium hydroxide or potassium hydroxide can cause severe irreversible injury with lifelong morbidity and can result in death.
- Unlike many other poisons, there is no antidote to a caustic exposure, only mitigation. For young children who ingest caustic agents, oesophageal scarring requires management with repeated surgical procedures including endoscopic dilatations and, at times, oesophageal resection, interposition or bypass with colonic transplanted material (which are not without risk).
- There have been persistent incidences of severe caustic injuries due to a range of products, predominantly domestic, that contain significant amounts of these caustic chemicals. Data from the NSW, Victorian and Queensland Poisons Information Centres (PIC) shows 756 cases of exposure to products containing greater than 5% sodium hydroxide or potassium hydroxide in the period from January 2022 to December 2023, of which 487 were unintentional exposures in the home. There were also 224 unintentional exposure incidents in the workplace. Over the past 20 years there have been 4 reported fatalities in Queensland associated with ingestion of highly caustic domestic consumer products, which occurred in children 1-10 years of age.
- Previous scheduling changes which restricted access to alkali dishwashing detergents and food additive products (lye water) has resulted in a decrease in the severity of injury, demonstrating the effectiveness of such restrictions.
- Sodium hydroxide and potassium hydroxide are also causing serious harm in deliberate self-poisoning exposures. Reducing access to highly toxic substances has also been demonstrated as an effective method of reducing harm from deliberate self-poisoning.
- The proposal would align the scheduling of these substances in Australia with access restrictions currently in place in the United Kingdom.

Key uses / expected use

Medicines, domestic, agriculture, industrial use, and food manufacturing.

Australian regulations

- According to the TGA Ingredient Database, sodium hydroxide is:
  - available for use as an Active Ingredient in: Biologicals, Prescription Medicines
  - available for use as an Excipient Ingredient in: Biologicals, Devices, Export Only, Listed Medicines, Over the Counter, Prescription Medicines
  - not available as an Equivalent Ingredient in any application.
- Potassium hydroxide is:
  - available for use as an Active Ingredient in: Biologicals, Export Only, Over the Counter, Prescription Medicines
  - available for use as an Excipient Ingredient in: Biologicals, Devices, Export Only, Listed Medicines, Over the Counter, Prescription Medicines
  - not available as an Equivalent Ingredient in any application.
- As of 10 January 2025, there was 1 medicine currently active on the Australian Register of Therapeutic Goods (ARTG) that contains sodium hydroxide as an active ingredient, which is a prescription medicine. There are no medicines currently active on the ARTG that contain potassium hydroxide.
- According to the Therapeutic Goods (Permissible Ingredients) Determination No.3 of 2024, potassium hydroxide and sodium hydroxide are permitted to be included in listed medicines as follows:

Item	Ingredient name	Purpose	Specific requirements
4090	POTASSIUM HYDROXIDE	E	The concentration in the medicine must be no more than 5%. When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.
4587	SODIUM HYDROXIDE	E	The concentration of sodium hydroxide in the medicine must not be more than 5%. When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.
E = excipient for a medicine meaning an ingredient that is not an active ingredient or a homoeopathic preparation ingredient.			

- The TGA prescribing medicines in pregnancy database does not classify sodium hydroxide or potassium hydroxide.
- There are no warning statements pertaining to sodium hydroxide or potassium hydroxide in the Therapeutic Goods (Medicines Advisory Statements) Specification 2021.

- As of 10 January 2025, there were 9 reports of adverse events for products containing sodium hydroxide as an active ingredient on the Database of Adverse Event Notifications (DAEN), with 6 reports where sodium hydroxide was the single suspected medicine. There were no reports of deaths associated with sodium hydroxide use. There were no reported adverse events for products containing potassium hydroxide as an active ingredient on the DAEN.
- As of 10 January 2025, there were 41 products containing sodium hydroxide, and 8 products containing potassium hydroxide, as an active ingredient/constituent or scheduled substance listed on the Public Chemical Registration Information System Search (PubCRIS).
- During 2009-2019 there were no adverse experiences recorded for sodium hydroxide or potassium hydroxide in the APVMA Adverse Experience Reporting Program database (AERP).
- Sodium hydroxide and potassium hydroxide are listed on the Australian Inventory of Industrial Chemicals (AICIS).

International regulations

- Sodium hydroxide and potassium hydroxide are listed in the United States Environmental Protection Agency's (US EPA) Office of Pesticides Programs as an approved active constituent, with sodium hydroxide currently undergoing a registration review. Neither substance are approved drugs in the US according to the United States Food and Drug Administration Approved Drug Products Database (Drugs@FDA), though both are listed on the FDA's Global Substance Registration System.
- The European Chemicals Agency (ECHA) includes a corrosive hazard classification for sodium hydroxide and potassium hydroxide, but a health hazard classification for the latter only.
- Both sodium and potassium hydroxide are listed on the European Commission database for information on cosmetic substances and ingredients database as a buffering and denaturant.
- The United Kingdom's Medicines & Healthcare products Regulatory Agency (MHRA) lists 23 medicines containing sodium hydroxide as an active ingredient and 10 medicines containing potassium hydroxide.
- In New Zealand, sodium hydroxide and potassium hydroxide are approved with controls for chemical use according to the New Zealand Inventory of Chemicals (NZIoC). Sodium hydroxide is classified for general sale according to the New Zealand Medicines and Medical Devices Safety Authority (MedSafe), whilst potassium hydroxide is not classified in the database.
- Canada's Pest Management Regulation Agency allows sodium hydroxide and potassium hydroxide for use as a hard-surface disinfectant. Both substances are available in only over-the-counter products according to the Canadian (Health Canada) Drug Product Database, though there are currently no medical products containing potassium hydroxide registered on the database.

Methyl ethyl ketone oxime

Proposal

The applicant proposed to amend the current scheduling of methyl ethyl ketone oxime (MEKO) such that preparations containing more than 0.1% MEKO are classified as Poison (Schedule 6) substance. These preparations will also be required to carry additional warning statements and safety directions regarding potential for inhalation carcinogenicity and need to avoid breathing vapours of MEKO.

CAS Number

96-29-7

Alternative names

2-Butanone, oxime

Methyl ethyl ketoxime

Applicant

Private applicant

Proposed Scheduling

Currently, MEKO is a classified as a Schedule 6 substance 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. The applicant's proposed amendments to the Poisons Standard are[2]:

Schedule 6 – Amend Entry

METHYL ETHYL KETONE OXIME except preparations containing less than 0.1 % methyl ethyl ketone oxime.

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

~~(b) in other preparations containing 1% or less of methyl ethyl ketone oxime.~~

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METHYL ETHYL KETONE OXIME

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.

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

Appendix 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 - except for adhesives and sealants containing less than 2.5% methyl ethyl ketone oxime	5 – irritant 6 – May cause cancer. 12 – Vapour is harmful to health on prolonged exposure 28 – (Over) (Repeated) exposure may cause sensitisation	1 – Avoid contact with eyes 4 – Avoid contact with skin 8 – Avoid breathing vapour 9 – Use only in well-ventilated area 10 – Ensure adequate ventilation when using
214	METHYL ETHYL KETONE OXIME - adhesives and sealants containing less than 2.5% methyl ethyl ketone oxime	5 – irritant 6 – May cause cancer 12 – Vapour is harmful to health on prolonged exposure ~~28 – (Over) (Repeated) exposure may cause sensitisation~~	1 – Avoid contact with eyes 4 – Avoid contact with skin 8 – Avoid breathing vapour 9 – Use only in well-ventilated area 10 – Ensure adequate ventilation when using

Background

MEKO is a widely used as curing and anti-skinning agent in paints, varnishes, stains, finishes, coatings, adhesives, and sealants. In Australia, MEKO containing primers, stains, varnishes and sealants are widely available from hardware stores and online.

Currently, MEKO is a classified as a Schedule 6 substance except for less than 2.5% in silicone adhesives or sealants or less than 1% in all other preparations. MEKO products are required to carry warning statements and first aid instructions regarding eye and skin irritation. There is no requirement regarding for warning statements regarding its inhalation toxicity or carcinogenic potential.

Summary of applicant's reasons for the proposal

- MEKO is present in silicone sealants, paints and adhesives widely available in Australia from hardware stores. The chemical is slowly released from sealants, adhesives or paints over several days.
- MEKO is categorised as a Category 1b Cancer Inhalation hazard and may cause serious health effects when present in silicon sealants, adhesives and paints at concentrations greater than 0.1%.
- In the European Union, use of MEKO is restricted to only professional users in the EU since March 2022. Preparations containing more than 0.1% MEKO is not allowed for public use, for example, silicone resin sealants with MEKO.
- An evaluation of MEKO by AICIS (evaluation statement, December 2023) found sufficient evidence that MEKO has carcinogenic effects in animals and the relevance to humans could not be ruled out. The report noted that the Australian public may be exposed to the chemical by inhaling aerosols or vapours from DIY products and adverse health effect can occur under from infrequent domestic use. The evaluation recommended that the potential risks could be managed through amending the labelling requirements to provide safety directions on adequate ventilation, and through consideration of the concentration cutoffs that exempt the substance from scheduling.

Key uses/ expected use

- Silicon sealants, paints and adhesives (domestic and industrial use).

Australian regulations

- MEKO is not listed in as an active ingredient in the TGA Ingredient Database.
- As of 14 November 2024, there were no products containing MEKO as an active ingredient or scheduled substance listed on the Public Chemical Registration Information System Search (PubCRIS).
- MEKO is listed on the Australian Inventory of Industrial Chemicals Inventory for chemicals being manufactured or imported into Australia for industrial use.

International regulations

- MEKO is listed as Carcinogenic class 2 in the European Commission database for information on cosmetic substances and ingredients database. In European Union, products containing ≥0.1% of MEKO cannot be sold to the public[3,4].
- Canada's current Code of Practice recommends reducing the concentration of MEKO in interior and dual use consumer alkyd paints and coating products to the lowest level feasible and to increase ventilation in the work area during and after painting. The limitation of the concentration is 0.0032-0.55% in paints and 0.2-0.42% in sealants[5]. Workplace exposure limits to MEKO have been set at 0.3 ppm in Germany and 10 ppm in the USA[6].
- In New Zealand and ASEAN countries, cosmetic products are prohibited from containing MEKO[7,8].
- According to the ASEAN-Japan Chemical Safety Database, in ASEAN countries and Japan, products containing more than 0.1% MEKO are required to carry statements regarding skin irritation and workers must wear PPE.
- In New Zealand, the Environmental Protection Authority has classified MEKO in Category 4 hazard for acute inhalation toxicity and in Category 1 for carcinogenicity9. The New Zealand Inventory of Chemicals (NZIoC) provides that MEKO cannot be used as a pesticide or a veterinary medicine, but can be used in the formulation of pesticides, veterinary medicines, antifouling paints or timber treatment preservatives.

[3] European Parliament and Council (2021) Commission Regulation (EU) 2021/2204 accessed 9 December 2024

[4] European Parliament and Council (2023) Commission Regulation (EU) 2023/1132 accessed 9 December 2024

[5] Butanone oxime - information sheet - Canada.ca accessed 9 December 2024

[6] European Chemicals Agency (ECHA) SEV Conclusion MEKO, PACT - Public Activities Coordination Tool - ECHA

[7] HSA (Health Sciences Authority) (2019) Annexes of the ASEAN Cosmetic Directive – List of substances which must not form part of the composition of cosmetics.pdf

[8] EPA - Cosmetic Products Group Standard 2020 (HSR002552)

[9] New Zealand Inventory of Chemicals (NZIoC) – 2-Butanone_oxime_HSR001191.pdf

Cyanoacrylate esters

Proposal

The Department of Health and Aged Care has proposed creating a Dangerous poisons (Schedule 7) entry for eyelash adhesives containing cyanoacrylate esters to restrict their usage to professional settings. The proposal also includes amending the current Caution (Schedule 5) entry such that to be exempt from Schedule 5 classification contact adhesives containing cyanoacrylate esters will require an additional warning regarding skin sensitisation. The proposal is based on the recommendations from the Australian Industrial Chemicals Introduction Scheme (AICIS) evaluation of cyanoacrylates published in June 2024.

CAS number

6606-65-1 (2-Propenoic acid, 2-cyano-, butyl ester)

7085-85-0 (2-Propenoic acid, 2-cyano-, ethyl ester)

7324-02-9 (2-Propenoic acid, 2-cyano-, 2-propenyl ester)

10586-17-1 (2-Propenoic acid, 2-cyano-, 1-methylethyl ester)

137-05-3 (2-Propenoic acid, 2-cyano-, methyl ester)

1069-55-2 (2-Propenoic acid, 2-cyano-, 2-methylpropyl ester)

27279-62-5 (2-Propenoic acid, 2-cyano-, 2-methoxy-1-methylethyl ester)

27816-23-5 (2-Propenoic acid, 2-cyano-, 2-methoxyethyl ester)

21982-43-4 (2-Propenoic acid, 2-cyano-, 2-ethoxyethyl ester)

Alternative names

Butyl cyanoacrylate (CAS 6606-65-1)

Ethyl cyanoacrylate (CAS 7085-85-0)

Allyl 2-cyanoacrylate (CAS 7324-02-9)

Isopropyl cyanoacrylate (CAS 10586-17-1)

Methyl cyanoacrylate, Methyl 2-cyanoacrylate, mecrylate (CAS 137-05-3)

Bucrilate (CAS 1069-55-2)

2-Propenoic acid (CAS 27279-62-5)

Methoxyethyl cyanoacrylate (CAS 27816-23-5)

Ethoxyethyl cyanoacrylate (CAS 21982-43-4)

Proposed scheduling

Cyanoacrylate esters are currently included in Schedule 5 with some exceptions. The proposed amendments to the current Poisons Standard are:[10]

Schedule 5 – Amend Entry

CYANOACRYLATE ESTERS in contact adhesives except:

(a) when included in Schedule 7; or

(b) 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 to certain individuals. A preliminary test according to the accompanying directions should be made before use;

or

(c) 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 to certain individuals. A preliminary test according to the accompanying directions should be made before use.

Schedule 7 – Create Entry

CYANOACRYLATE ESTERS when used in eyelash adhesives.

Index – Amend Entry

CYANOACRYLATE ESTERS

Schedule 5

Schedule 7

[10] 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.

Background

Cyanoacrylates are skin sensitisers and can cause eye irritation. Cyanoacrylates are used in fast setting adhesives for cosmetic, domestic, commercial and site-limited applications. They are commonly used in eyelash adhesives and nail enhancement products for professional and consumer use, with reported concentrations of typically 85−100%.

There is also widespread consumer and professional use of adhesives containing cyanoacrylates (60-100%), often referred to as superglue. These substances are also used as adhesives and have site-limited uses in polymerisation and manufacturing processes. Finally, cyanoacrylates have non-industrial uses in Australia as a tissue adhesive and sealant.

Summary of reasons for the proposal

- Cyanoacrylate esters have the potential to cause skin sensitisation, particularly among workers with known exposure to (meth)acrylates or in people that had used nail products due to prolonged contact with skin. The mechanism for skin sensitisation is not known, though polymers of these substances may degrade to form formaldehyde, a strong skin sensitiser.
- There are several reported incidences of allergic contact dermatitis in individuals with direct exposure to cosmetic products containing ethyl cyanoacrylate.
- The risk of sensitisation is considered greatest for exposures due to eyelash glues where intentional prolonged contact of skin around the eye with the adhesive is expected and there is a high frequency of reapplication.
- Canada has restricted use of cyanoacrylate-based eyelash glues to professional settings (equivalent to Schedule 7).

Key uses / expected use

Cosmetics

Australian regulations

- According to the TGA Ingredient Database, cyanoacrylate esters are not approved therapeutic ingredients.
- As of January 2025, there were no products containing cyanoacrylate esters as an active ingredient/constituent or scheduled substance listed on the Public Chemical Registration Information System Search (PubCRIS).
- All of the above listed cyanoacrylate esters are listed on the Australian Inventory of Industrial Chemicals Inventory for chemicals being manufactured or imported into Australia for industrial use.

International regulations

- The European Commission database for information on cosmetic substances and ingredients database) lists ethyl cyanoacrylate (7085-85-0), isopropyl cyanoacrylate (10586-17-1) and ethoxyethyl cyanoacrylate (21982-43-4) as film forming agents. It also lists methoxyethyl cyanoacrylate (27816-23-5) as a binding agent.
- The Canadian Cosmetic Ingredient Hotlist restricts ethyl cyanoacrylate (7085-85-0); methyl cyanoacrylate (137-05-3); isopropyl cyanoacrylate (10586-17-1) as cyanoacrylate-based adhesives for application by trained professionals only along with the following warning statements:
  - Ensure the eye is protected and immobilized during application
  - WARNING. BONDS SKIN INSTANTLY. AVOID CONTACT WITH EYES, MOUTH AND SKIN. KEEP AWAY FROM CHILDREN.

  - Eyelid bonding: consult a physician.
  - Skin bonding: soak and ease apart gently.

- Ethyl cyanoacrylate (7085-85-0), methyl 2-cyanoacrylate (137-05-3) and Butyl cyanoacrylate (6606-65-1) are included on the New Zealand Inventory of Chemicals (NZIoC), but do not have individual approval. They can, however, be used as single component products under an appropriate group standard approval based on GHS hazard classification and toxicity information.

Acrylates and methacrylates based on bisphenol A (BPA)

Proposal

The Department of Health and Aged Care has proposed creating new Poisons (Schedule 6) entries in the current Poisons Standard for two chemicals BPA glycidyl dimethacrylate and BPA glycidyl diacrylate. Additional warning statement and safety directions relating to skin sensitisation also have been 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) published in April 2024.

CAS Number

1565-94-2 (BPA glycidyl dimethacrylate)

4687-94-9 (BPA glycidyl diacrylate)

Alternative names

BPA glycidyl dimethacrylate

2-Propenoic acid, 2-methyl-, (1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] ester

1,2-Propanediol, 3,3′-[isopropylidenebis(p-phenyleneoxy)]di-, 1,1′-dimethacrylate (8CI)

Methacrylic acid, isopropylidenebis[p-phenyleneoxy(2-hydroxytrimethylene)] ester (7CI)

2,2-Bis(4-(2-hydroxy-3-methacryloxypropoxy)phenyl)propane

Bis-GMA

Bisphenol A bis(2-hydroxy-3-methacryloxypropyl) ether

BPA glycidyl diacrylate

2-Propenoic acid, (1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] ester

Acrylic acid, 1,1′-diester with 3,3′-[isopropylidenebis(p-phenyleneoxy)]di-1,2-propanediol (7CI, 8CI)

1,1′-[Isopropylidenebis(p-phenyleneoxy)]di-2-propanol diacrylate

Bisphenol A bis(3-acrylato-2-hydroxypropyl) ether

Bisphenol A diglycidyl ether diacrylate

Proposed Scheduling

BPA glycidyl dimethacrylate and BPA glycidyl diacrylate are not specifically scheduled in the current Poisons Standard. The proposed amendments to the Poisons Standard are[11]:

Schedule 6 – New Entries

BPA GLYCIDYL DIMETHACRYLATE

BPA GLYCIDYL DIACRYLATE

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BPA GLYCIDYL DIMETHACRYLATE

Schedule 6

Appendix F, Clause 4

BPA GLYCIDYL DIACRYLATE

Schedule 6

Appendix F, Clause 4

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
51	BPA GLYCIDYL DIACRYLATE	4 – Avoid contact with skin

Background

Acrylates and methacrylates based on bisphenol A (BPA) are primarily used commercially in a wide range of products such as adhesives, coatings, and printing inks, with site-limited use in manufacturing other chemicals and polymer products. Many of these chemicals are also used in food contact materials, including plastics, coatings, paperboard, adhesives, and printing inks. Additionally, five of these chemicals are used in cosmetic nail products.

- BPA glycidyl dimethacrylate (CAS No.1565-94-2)
- BPA glycidyl diacrylate (CAS No. 4687-94-9)
- ethoxylated BPA dimethacrylate (CAS No. 41637-38-1)
- ethoxylated BPA diacrylate (CAS No. 64401-02-1)
- BPA bis(methacryloyloxyethoxyethyl ether) (CAS No. 56744-60-6)

The public may be exposed to some of these chemicals by direct application of these chemicals to the nails from using nail enhancement products (such as artificial nails) at concentrations 5-10%.

Summary of reasons for the proposal

- Based on overseas exposure data, the Australian public are potential exposed to up to 10% acrylates and methacrylates based on BPA through nail enhancement products.

[11] 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.

- Use of DIY at home cosmetic nail products that are used outside of professional settings is increasing.
- Based on animal and human data, the elicitation of skin sensitisation has been observed at low concentrations (<10 ppm) of BPA glycidyl dimethacrylate and BPA glycidyl diacrylate.
- The United States of America Cosmetic Ingredient Review Committee concluded that BPA glycidyl dimethacrylate is safe for use in nail enhancement products provided skin contact is avoided. The Committee noted that products should be accompanied with directions to avoid skin contact due to the sensitising potential of methacrylates.

Australian regulations

- According to the TGA Ingredient Database, BPA glycidyl dimethacrylate and BPA glycidyl diacrylate are not listed as of 7 January 2025.
- As of 7 January 2025, there were no products containing BPA glycidyl dimethacrylate or BPA glycidyl diacrylate as an active ingredient/constituent or scheduled substance listed on the Public Chemical Registration Information System Search (PubCRIS).
- During 2009-2019, there was no recorded for BPA glycidyl dimethacrylate and BPA glycidyl diacrylate in the APVMA Adverse Experience Reporting Program database (AERP).
- BPA glycidyl dimethacrylate and BPA glycidyl diacrylate are included in the Australian Inventory of Industrial Chemicals.

International regulations

- European Chemicals Agency (ECHA) noted that BPA glycidyl dimethacrylate (1565-94-2) causes serious eye damage and skin irritation and may cause an allergic skin reaction and respiratory irritation. ECHA also noted that BPA glycidyl diacrylate (4687-94-9) may cause an allergic skin reaction.
- In European Commission database for information on cosmetic substances and ingredients database (CosIng), BPA glycidyl dimethacrylate (1565-94-2) is listed for film forming in cosmetic agents.
- As of January 2025, no record of BPA glycidyl dimethacrylate (1565-94-2) and BPA glycidyl diacrylate (4687-94-9) were listed in EU Pesticides Database - Active substances and Canada's Pest Management Regulation Agency.
- BPA glycidyl dimethacrylate (1565-94-2) was on New Zealand Inventory of Chemicals (NZIoC), the substance is present in New Zealand but do not have individual approval. They can, however, be used as single component products under an appropriate group standard approval based on GHS hazard classification and toxicity information.
- According to the AJCSD (ASEAN-Japan Chemical Safety Database), utensils and containers or packaging (UCP) containing the BPA glycidyl diacrylate (4687-94-9) can be used as a raw material for the following food categories, including:
  - Acidic foods
  - Fats/oils and fatty/oily foods
  - Milk/milk products
  - Alcoholic beverages
  - Other foods

- The Cosmetic Ingredient Review (CIR) Expert Panel from USA concluded that BPA glycidyl dimethacrylate (1565-94-2) is safe for use in nail enhancement products where skin contact is avoided due to the sensitising potential of methacrylates[12,13].

Medium and Long Chain Alkyl Sulfates

Proposal

The Department of Health and Aged Care has proposed amendments to the current Poisons Standard to include medium and long chain (C6-C15) alkyl sulfates as Poisons (Schedule 6) with additional warning statements and first aid instructions. The proposal is based on the recommendations from the Australian Industrial Chemicals Introduction Scheme (AICIS) evaluation of medium and long chain alkyl sulfates published in June 2024.

Chemical names and CAS numbers

Item	Name	CAS number
1	Sulfuric acid, monododecyl ester, compound with 2,2',2''-nitrilotris[ethanol] (1:1)	139-96-8
2	Sulfuric acid, monooctyl ester, sodium salt	142-31-4
3	Sulfuric acid, monodecyl ester, sodium salt	142-87-0
4	Sulfuric acid, monododecyl ester, compound with 2,2'-iminobis[ethanol] (1:1)	143-00-0
5	Sulfuric acid, monododecyl ester	151-41-7
6	1-Tetradecanol, hydrogen sulfate, sodium salt	1191-50-0
7	Sulfuric acid, monohexyl ester, sodium salt	2207-98-9
8	1-Tridecanol, hydrogen sulfate, sodium salt	3026-63-9
9	1-Tetradecanol, hydrogen sulfate, compound with 2,2',2''-nitrilotris[ethanol] (1:1)	4492-78-8
10	Sulfuric acid, monododecyl ester, compound with 2-aminoethanol (1:1)	4722-98-9
11	Sulfuric acid, monodecyl ester, ammonium salt	13177-52-1
12	Sulfuric acid, monododecyl ester, compound with 1-amino-2-propanol (1:1)	21142-28-9
13	1-Tetradecanol, hydrogen sulfate, magnesium salt	25446-91-7
14	Sulfuric acid, monoisononyl ester, sodium salt	26856-96-2
15	Sulfuric acid, monooctyl ester, compound with 2,2',2''-nitrilotris[ethanol] (1:1)	30862-34-1
16	Sulfuric acid, monodecyl ester, compound with 2,2',2''-nitrilotris[ethanol] (1:1)	39943-70-9

[12] CIR (Cosmetic Ingredient Review) (2023) Methacrylate Ester Monomers

[13] CIR (Cosmetic Ingredient Review) (2005) Final Report of the Safety Assessment of of Methacrylate Ester Monobers Used in Nail enhancement products

Item	Name	CAS number
17	Sulfuric acid, monododecyl ester, compound with 2-(diethylamino) ethanol (1:1)	65104-49-6
18	Sulfuric acid, monododecyl ester, compound with 1,1',1''-nitrilotris[2-propanol]	66161-60-2
19	Sulfuric acid, mono-C6-10-alkyl esters, ammonium salts	68187-17-7
20	Isodecanol, hydrogen sulfate, sodium salt	68299-17-2
21	Sulfuric acid, mono-C12-15-alkyl esters, compounds with triethanolamine	68815-25-8
22	Sulfuric acid, mono-C12-15-alkyl esters, sodium salts	68890-70-0
23	Sulfuric acid, mono-C9-13-alkyl esters, sodium salts	72906-11-7
24	Sulfuric acid, mono-C9-11-alkyl esters, sodium salts	84501-49-5
25	Sulfuric acid, mono-C12-14-alkyl esters, sodium salts	85586-07-8
26	Sulfuric acid, mono-C8-14-alkyl esters, compounds with triethanolamine	85665-45-8
27	Sulfuric acid, mono-C12-14-alkyl esters, compounds with isopropanolamine	85681-66-9
28	Sulfuric acid, mono-C8-14-alkyl esters, ammonium salts	90583-10-1
29	Sulfuric acid, mono-C12-14-alkyl esters, compounds with ethanolamine	90583-16-7
30	Sulfuric acid, mono-C12-14-alkyl esters, compounds with triethanolamine	90583-18-9
31	Sulfuric acid, mono-C12-14-alkyl esters, magnesium salts	90583-23-6
32	Sulfuric acid, mono-C6-12-alkyl esters, sodium salts	90583-25-8

Proposed scheduling

Currently, only two long chain alkyl sufates, sodium tetradecyl (C14) sulfate in preparations for injection and lauryl (C12) sulfate salts are listed in the Poisons Standard as Prescription only (Schedule 4) and Poison (Schedule 6) substances, respectively. The proposed new entry for medium to long chain (C6-C15) alkyl sulfates is as follows[14]:

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

[14]

(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.

Appendix E, Clause 3

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.

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MEDIUM AND LONG CHAIN (C6-15) ALKYL SULFATES

Cross reference: Sulfuric acid, monododecyl ester, compound with 2,2',2''-nitrilotris[ethanol] (1:1) (CAS No. 139-96-8), Sulfuric acid, monooctyl ester, sodium salt (CAS No. 142-31-4), Sulfuric acid, monodecyl ester, sodium salt (CAS No. 142-87-0), Sulfuric acid, monododecyl ester, compound with 2,2'-iminobis[ethanol] (1:1) (CAS No. 143-00-0), Sulfuric acid, monododecyl ester (CAS No. 151-41-7), 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, monododecyl ester, compound with 2-aminoethanol (1:1) (CAS No. 4722-98-9), Sulfuric acid, monodecyl ester, ammonium salt (CAS No. 13177-52-1), Sulfuric acid, monododecyl ester, compound with 1-amino-2-propanol (1:1) (CAS No. 21142-28-9), 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, monododecyl ester, compound with 2-(diethylamino) ethanol (1:1) (CAS No. 65104-49-6), Sulfuric acid, monododecyl ester, compound with 1,1',1''-nitrilotris[2-propanol] (CAS No. 66161-60-2), 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).

Schedule 6

Appendix E, clause 3

Background

Medium and long chain alkyl sulfates and alkyl sulfuric acids are a group of structurally similar chemicals. They are widely used as anionic surfactants in a variety of consumer products including personal care products and household cleaning and laundry products.

These chemicals also have many commercial uses including in fire-fighting foams and chemical and polymer manufacture. Available Australian and international data indicate that these chemicals are used in high volumes (more than 1,000 tonnes per year).

The quantity of surfactant can vary in different formulations. Maximum reported concentrations for some of these chemicals 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%.

Summary of reasons for the proposal

- The public may be exposed to medium and long chain alkyl sulfates and alkyl sulfuric acids by direct application of products containing the chemicals to the skin and hair and incidental skin and eye contact during use of domestic products.
- Alkyl sulfates are irritating to skin with varying degrees of severity. The majority of them are expected to cause serious eye damage at high concentrations. Irreversible eye damage has been reported in several eye irritation studies.
- The eye irritating potential appears to decrease with increasing alkyl chain length with available data indicating that alkyl sulfates with carbon chains of C16 to C18 cause less and reversible irritation.
- Based on the strong acidic nature, alkyl sulfuric acids are expected to be corrosive to skin and cause serious eye damage.
- Accidental exposure of children to these chemicals by ingestion and eye and skin contact leading to adverse effects has occurred from liquid laundry detergent capsules.

Key uses / expected use

- Medium and long chain alkyl sulfates have widespread use in both personal care products and household products. Nearly half of the chemicals have reported cosmetic uses as foaming, cleansing, emulsifying and surfactant agents including in hand washes and soaps, hair shampoos, body washes, colourants, shaving products and skin care products. The predominant domestic use of these chemicals is in household cleaning products including dishwashing liquids and laundry detergents.
- These chemicals have reported commercial uses including in adhesives and binding agents, paints, lacquers and varnishes leather tanning, flame retardant and fire extinguishing fluids, antifreeze agents, photochemicals and reprographic agents and may also have non-industrial pharmaceutical and pesticide uses.

Australian regulations

- The following medium and long chain alkyl sulfates and alkyl sulfuric acids are listed in the TGA Ingredient Database as follows.
  - Sulfuric acid, monododecyl ester, compound with 2,2',2''-nitrilotris[ethanol] (1:1) (CAS 139-96-8; also known as trolamine lauril sulfate)
    - Available for use as an Active Ingredient in Biologicals, Export Only, Over the Counter, Prescription Medicines.
    - Not available as an Active Ingredient in any application
    - Available for use as an Excipient Ingredient in: Biologicals, Devices, Export Only, Listed Medicines (only for use in topical medicines for dermal application), Over the Counter, Prescription Medicines
    - Not available as an Equivalent Ingredient in any application.
  - Sulfuric acid, mono-C8-14-alkyl esters, ammonium salts (90583-10-1)
    - Available for use as an Excipient Ingredient in Devices
    - Not available as an Active or Equivalent Ingredient in any application.
- As of January 2025, there are 2 registered medicines currently active on the Australian Register of Therapeutic Goods (ARTG) that contain trolamine lauryl sulfate as an active ingredient.
- None of the medium and long chain alkyl sulfates listed above are permitted to be included in listed medicines as it is not included in the Therapeutic Goods (Permissible Ingredients) Determination (No.3) 2024; are included in the TGA prescribing medicines in pregnancy database; or have any warning statements in the Therapeutic Goods (Medicines Advisory Statements) Specification 2021.
- As of January 2025, there were no reports of adverse events for products containing the Medium and Long Chain Alkyl Sulfates listed above as an active ingredient on the Database of Adverse Events Notifications (DAEN).
- Medium to long chain (C6-C15) alkyl sulfates and alkyl sulfuric acids that are listed on the Australian Inventory of Industrial Chemicals.
- As of January 2025, there were no products containing the medium and long chain alkyl sulfates listed above as an active ingredient/constituent or scheduled substance listed on the Public Chemical Registration Information System Search (PubCRIS) and there were no events of adverse experiences recorded in the APVMA Adverse Experience Reporting Program database (AERP).

International regulations

- The United States Environmental Protection Agency's (US EPA) Office of Pesticides Program has listed Sulfuric acid, monododecyl ester, compound with 2,2',2''-nitrilotris[ethanol] (1:1) (CAS 139-96-8) as an conventional pesticide (conventional pesticides are all active ingredients other than biological pesticides and antimicrobial pesticides).
- European Commission database for information on cosmetic substances and ingredients database includes 12 of the medium and long chain alkyl sulfates listed above as surfactants and cleansing, denaturing or foaming agents (CAS numbers: 139-96-8, 66161-60-2, 68890-70-0, 68815-25-8, 90583-18-9, 142-87-0, 85586-07-8, 4722-98-9, 21142-28-9, 3026-63-9, 1191-50-0, 143-00-0 and 97375-27-4).
- In New Zealand Inventory of Chemicals database:
  - 10 of the substances (CAS No. 139-96-8, 142-31-4, 142-87-0, 1191-50-0, 4722-98-9, 85586-07-8, 85665-45-8, 90583-10-1, 90583-16-7 and 90583-18-9) were listed as without having an individual approval but may be used under an appropriate group standard with similar GHS classification and toxicity data.
  - 9 of the substances (CAS no. 143-00-0, 151-41-7, 3026-63-9, 21142-28-9, 26856-96-2, 68187-17-7, 68299-17-2, 72906-11-7 and 84501-49-5) were listed as without having an individual approval but may be used as a component in a product covered by a group standard.
  - 13 of the substances (CAS No. 4492-78-8, 2207-98-9, 13177-52-1, 25446-91-7, 30862-34-1, 39943-70-9, 65104-49-6, 66161-60-2, 68815-25-8, 68890-70-0, 85681-66-9, 90583-23-6 and 90583-25-8) were not listed.

Proposed amendment referred for scheduling advice to Joint ACMS-ACCS meeting #39

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 with specific exceptions. All forms of organic chromium compounds will be covered by the generic entry CHROMIUM ORGANIC CHELATES, which will circumvent the requirement to apply for scheduling for other chromium chelates for use in animal feed premixes in the future.

Alternative names

Chromium-DL-2-amino-4-(methylthio) butanoic acid

Applicant

Australian Pesticides and Veterinary Medicines Authority (APVMA)

Proposed scheduling

The applicant's proposed amendments to the Poisons Standard are:[15]

Schedule 6 – New Entry

CHROMIUM ORGANIC CHELATES **except**;

(a) when separately specified in these Schedules; or

(b) in preparations for human internal use containing 50 µg or less of chromium per recommended daily dose; or

(c) 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.

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Schedule 6

Cross reference: Chromium-DL-methionine

Background

Chromium-DL-methionine belongs to the chemical group of amino acid chelates of Chromium. Chromium-DL-methionine is expected to dissociate in the digestive tract or in blood into its two components, chromium (as chromium (III) cation) and methionine.

Trivalent chromium (Cr (III)) is considered an essential trace element both in animal and human nutrition. It has been shown to influence carbohydrate, lipid, and protein metabolism via an effect on insulin action.

Methionine is an essential amino acid, widely used in human and animal nutritional supplements.

Chromium-DL-methionine is intended to be used in a powder formulation, for professional use as a nutritional supplement (feed additive) for ruminants, pigs, poultry and fin fish.

Summary of applicant's reasons for the proposal

- The APVMA has received an application for the approval of chromium-DL-methionine as a new veterinary active constituent and registration of a new product. Chromium-DL-methionine is not listed in the current Poisons Standard and is not covered by other entries for chromium compounds.
- Chromium-DL-methionine dissociates into chromium cation which is considered to be the entity of toxicological significance. Based on the available information and read across data, the substance has low oral and dermal toxicity, is non-genotoxic or neurotoxic and unlikely to be carcinogenic or associated with developmental or reproductive effects.
- Chromium-DL-methionine may cause respiratory effects from inhalation and allergic skin reactions in sensitive individuals. However, this can be managed through label directions.
- It is considered that the potential toxicity of chromium-DL-methionine is consistent with a Schedule 6 classification for veterinary use.

Key uses / expected use

Oral (powder formulation as a feed additive, for use as a nutritional supplement for ruminants, pigs, poultry and fin fish).

[15] 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.

Australian regulations

- While chromium-DL-methionine is not listed in the TGA Ingredient Database, chromium amino acid chelate is available for use as:
  - Active Ingredient in: Biologicals, Export Only, Over the Counter and Prescription Medicines
  - Excipient Ingredient in: Biologicals, Devices and Prescription Medicines

  and is not available as an Equivalent Ingredient in any application.
- As of 15 January 2025, there are 8 medicines listed in the Australian Register of Therapeutic Goods (ARTG) that contain chromium amino acid chelate as an active ingredient.
- Chromium amino acid chelate is not listed in the Therapeutic Goods (Permissible Ingredients) Determination No.3 of 2024. However, chromium is included as an essential component of chromium chloride hexahydrate, chromium nicotinate and chromium picolinate with the maximum recommended daily dose of chromium from organic sources being limited a maximum of 50 micrograms.
- Chromium amino acid chelate is not included in the TGA prescribing medicines in pregnancy database.
- There are no warning statements pertaining to chromium amino acid chelate in the Therapeutic Goods (Medicines Advisory Statements) Specification 2021.
- Between 1971 to 2024, 4 adverse events have been reported in the TGA's Database of Adverse Event Notifications (DAEN) where chromium amino acid chelate was an active ingredient.
- On 15 January 2024, there is 1 product listed in Public Chemical Registration Information System Search (PubCRIS) where chromium amino acid chelate is an active compound.
- Between 2015 and 2020, there were no reports adverse events for chromium amino acid chelate in the APVMA Adverse Experience Reporting Program database (AERP).
- Some chromium chelates for example chromium soya protein hydrolyzates complexes (CAS 104466-02-6) and chromium, *Saccharomyces cerevisiae* protein hydrolyzates complexes (CAS 104466-01-5) listed in the Australian Inventory of Industrial Chemicals, can be covered by the proposed new entry for chromium organic chelate.

International regulations

- Chromium organic chelate or chromium amino acid chelate or chromium-DL-methionine is not included in the following databases:
  - United States Environmental Protection Agency's (US EPA) Office of Pesticides Program
  - United States Food and Drug Administration Approved Drugs Database (Drugs@FDA)
  - European Commission database for information on cosmetic substances and ingredients database
  - New Zealand Inventory of Chemicals (NZIoC)
  - New Zealand MedSafe Medicines Classification Database
  - Pest Management Regulation Agency (Canada)
  - Health Products Regulatory Authority (Ireland)
- Two over-the-counter medicines, both currently cancelled, with chromium amino acid chelate as an active ingredient is listed in the Health Canada Drug Product Database.

How to respond

Submissions must be provided by the closing date of 17 February 2025 through our consultation hub. Any submission about any of the proposals to amend the Poisons Standard will be considered at the next meeting of the Advisory Committee on Chemicals Scheduling (ACCS), or a joint meeting of the ACCS and Advisory Committee on Medicines Scheduling (ACMS).

What will happen

All public submissions will be published on the TGA website, unless marked confidential.

Following consideration of public submissions received before the closing date and advice from the expert advisory committee/s, decisions on the proposed amendments will be published as interim decisions on the TGA website.

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