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

Consultation: Proposed amendments to the Poisons Standard – ACCS #43 meeting, November 2026

11 September 2026

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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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 **November 2026** meeting of the Advisory Committee on Chemicals Scheduling (ACCS). Submissions must be received by close of business **12 October 2026**.

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 Chemicals Scheduling (ACCS).

This consultation closes on 12 October 2026.

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

1 Proposed amendments referred for scheduling advice to ACCS meeting #43

1.1 Phenyl methyl ketone (acetophenone)

Proposal

This is a Delegate initiated proposal based on recommendations from the Australian Industrial Chemicals Introduction Scheme (AICIS) in their Evaluation Statement on ethanone, 1-phenyl- (Acetophenone) (the Evaluation Statement). The Evaluation Statement recommended that the current scheduling of acetophenone be amended to restrict its concentration and/or functional use in cosmetic and domestic products to manage the potential developmental and foetal toxicity risks associated with acute and chronic exposure. To minimise the risk to users, the Evaluation Statement estimated that acetophenone would need to be at low concentrations (less than or equal to 0.1%) in paints and paint removers.

CAS Number

98-86-2

Alternative names

Ethanone, 1-phenyl-; Hypnone (historical brand name), 1-Phenylethanone, Acetylbenzene, Methyl phenyl ketone.

Proposed Scheduling

Phenyl methyl ketone (acetophenone) is currently included in the list for the *designated solvents* definition in Part 1, section 6 of the Poisons Standard. Phenyl methyl ketone is classified as a Caution (Schedule 5) substance except in preparations containing 25% or less of designated solvents. It also requires the following first aid instructions (Appendix E, clause 3):

> A: For advice, contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor (at once).
>
> G3: If swallowed, do NOT induce vomiting.
>
> E1: If in eyes wash out immediately with water.

The proposed amendments to the Poisons Standard are[1]:

Schedule 5 – Amend Entry

PHENYL METHYL KETONE: ~~except in preparations containing 25% or less of designated solvents~~

i) in paints and paint removers **except** in preparations containing 0.1% or less of phenyl methyl ketone; or
ii) in preparations for domestic and cosmetic use **except** in preparations containing 0.2% or less of phenyl methyl ketone.

Phenyl methyl ketone would also be deleted from the list in the *designated solvents* definition in Part 1, section 6 of the Poisons Standard.

[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.

Background

Acetophenone is an aromatic ketone used as a solvent in domestic products, such as paints and paint removers, in combination with other designated solvents. It is also used as a chemical intermediate and fragrance in a range of products including personal care, cleaning and furniture care, laundry and dishwashing, and air care products.

Summary of reasons for the proposal

Acetophenone has been shown to cause adverse effects on fertility and foetal development following acute exposure. AICIS calculated a Margin of Exposure (MOE) of 300 for use in paints and paint removers containing 0.1% acetophenone based on developmental toxicity following inhalation and dermal systemic exposure. MOE values of 300 or higher were considered acceptable, while MOE values below 300 indicate potential risks to human health. The MOE methodology is commonly used to characterise risks to human health associated with exposure to chemicals. The MOE approach compares estimated human exposure with a toxicological Point-of-Departure, to determine whether a sufficient margin exists to protect against a particular adverse health effect.

When used as a fragrance at low concentrations of 0.2% or less, acetophenone was considered unlikely to pose a health risk. In cosmetic and air care products (including for infants and toddlers), assuming worst-case combined daily systemic exposure, acetophenone was considered unlikely to pose a risk to human health.

As amending the exempt concentration of acetophenone would result in the limit no longer aligning with the 25% exemption for designated solvents, a new maximum concentration of 0.2% acetophenone when used in domestic and cosmetic products is also being proposed. This is based on the maximum use concentration in fine fragrances identified in the Evaluation Statement, which is the most frequent use reported for domestic and cosmetic products.

Key uses / expected use

Acetophenone is used as a fragrance ingredient in a range of cosmetic and domestic products, including personal care products, cleaning and furniture care products, laundry and dishwashing products, and air care products. It has also been identified in other domestic and commercial products, including paints and coatings (including thinners and removers), lubricants and greases, adhesives and sealants, fillers, putties, plasters and modelling clays. The functional use and concentrations in these other products are not known, although acetophenone is listed as a designated solvent in the Poisons Standard and may be used as a solvent in some products.

Acetophenone also has site-limited industrial applications, including use as an intermediate, solvent, catalyst and corrosion inhibitor.

Australian regulations

- According to the TGA Ingredient Database, acetophenone is available for use as an active ingredient in: Biologicals and Prescription Medicines.
- As of 2 September 2026, there were no medicines currently active on the Australian Register of Therapeutic Goods (ARTG) that contain acetophenone as an active ingredient.
- According to the Therapeutic Goods (Permissible Ingredients) Determination No. 2 of 2026, acetophenone is permitted to be included in listed medicines as follows:

Item	Ingredient name	Purpose	Specific requirements
344	ACETOPHENONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Item	Ingredient name	Purpose	Specific requirements
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
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 include acetophenone.
- There are no warning statements pertaining to acetophenone in the Therapeutic Goods (Medicines Advisory Statements) Specification 2021.
- As of 2 September 2026, there were 2 products containing acetophenone as a constituent ingredient registered on the Public Chemical Registration Information System Search (PubCRIS).
- In 2009-2019 there were no adverse experiences recorded for acetophenone in the APVMA Adverse Experience Reporting Program database (AERP).

International regulations

- The United States Food and Drug Administration Approved Drug Products Database (Drugs@FDA) and United States Environmental Protection Agency's (US EPA) Office of Pesticides Programs do not include acetophenone.
- The European Commission database for information on cosmetic substances and ingredients database lists acetophenone for use as fragrance and perfuming. The European Chemicals Agency (ECHA) requires hazard statements regarding acute toxicity (category 4) and eye irritation (category 2). The European Scientific Committee on Consumer Safety (SCCS) issued in May 2026, an opinion on acetophenone considering the substance to be safe in cosmetic products in concentrations up to 0.01%. In March 2025, the European Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA) issued an opinion recommending classification for acetophenone as 'Reprotoxic of Category 1B (H360FD)'. Following the RAC opinion, the European Commission may propose a classification for acetophenone as a 'Reprotoxic of Category 1B,' prohibiting its use in cosmetic products.
- The New Zealand Inventory of Chemicals (NZIoC) includes acetophenone (as methyl phenyl ketone) as not having individual approval but may be used under an appropriate group standard. Acetophenone is not classified on the New Zealand Medicines and Medical Devices Safety Authority (MedSafe) database.
- Acetophenone is not listed as an active ingredient on the Canada's Pest Management Regulation Agency or authorised for sale by inclusion on the Canadian (Health Canada) Drug Product Database.

1.2 Vitamin A

Proposal

This is a Delegate initiated proposal to amend the current Poisons Standard in relation to vitamin A. The proposal is based on recommendations made in the Australian Industrial Chemicals Introduction Scheme (AICIS) Evaluation Statement on Evaluation statement on retinol and retinol esters (the Evaluation Statement).

Currently, vitamin A for human therapeutic or cosmetic use is classified as a Prescription only medicine (Schedule 4) with certain exceptions including preparations for topical use containing 1% or less of vitamin A. The vitamin A entry covers retinol and retinol esters unless specifically scheduled or excluded from scheduling.

The Evaluation Statement included a recommendation for restricting the use of these substances to a lower concentration in cosmetic and personal care products. The Evaluation Statement also included recommendations that the chemicals covered by the current vitamin A entry should be clarified, and that the concentrations permitted in topical products should be expressed in retinol equivalents (RE) rather than a percentage.

CAS Number

68-26-8

Alternative names

Retinol, all-trans-retinol

Proposed Scheduling

The proposed amendments to the Poisons Standard are:[2]

Schedule 4 – Amend entry

VITAMIN A for human therapeutic or cosmetic use except:

a) in preparations for topical use containing ~~1% or less of Vitamin A~~ 0.05% retinol equivalents or less of Vitamin A in body lotion; or

b) in other preparations for topical use containing 0.3% retinol equivalents or less of Vitamin A; or

c) in preparations for internal use containing 3000 micrograms retinol equivalents or less of Vitamin A per daily dose; or

d) in preparations for parenteral nutrition replacement.

Index – Amend entry

Vitamin A

Cross reference: Retinol (CAS 68-26-8); Retinol, hexadecanoate (CAS 79-81-2); Retinol, acetate (CAS 127-47-9), Retinol, 15-[(9Z,12Z)-9,12-octadecadienoate] (CAS 631-89-0); and Retinol, 15-propanoate (CAS 7069-42-3).

[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.

Background

Vitamin A is a fat-soluble vitamin that is present in food, dietary supplements and therapeutic goods. It is also used in a range of cosmetic products available in Australia, including face creams, body lotions, hand creams, nail products and lip products.

Summary of reasons for the proposal

Retinol and retinol esters are known human developmental toxicants, with effects primarily associated with conversion to retinoic acid. They are permitted to be present at concentrations up to 1% vitamin A in cosmetic products including body lotions, face creams and hand creams that are used daily.

The AICIS Evaluation Statement concluded that systemic exposure from cosmetic products, particularly from the concurrent use of multiple products, may exceed the tolerable upper intake level (UL) established for teratogenicity (3,000 µg RE/day) and the guidance level associated with bone health (GL; 1,500 µg RE/day).[3] Use of various cosmetics containing the chemicals at 1% RE was calculated in the Evaluation Statement to result in the following daily systemic exposures:

- 6,053 µg RE, 1672 µg RE and 1192 µg RE from use in body lotion, hand cream and face cream, respectively (use from body lotion alone can exceed the UL by more than 2-fold); and
- 11,257 µg RE from multiple cosmetic products simultaneously by an individual consumer.

In the EU, the maximum concentration of vitamin A and its derivatives permitted in cosmetic products is restricted to 0.05% RE in body lotions and 0.3% RE in leave-on and rinse-off products other than body lotion. The European Commission Scientific Committee on Consumer Safety estimated that exposure via all such cosmetic products (including lip products) may lead to daily systemic dose of 1,458 µg RE for an adult of 60 kg (equates to 51% of the UL and 97% of the GL).[4]

In Canada, the chemicals are permitted in cosmetic products at maximum concentrations of 0.2% total RE in leave-on products intended for full body application, and 1.0% total RE in other cosmetics.

Different retinol esters correspond to different RE values and therefore contribute different amounts of vitamin A activity. This proposal would align with the restrictions in the EU.

Key uses

Vitamin A (retinol and its esters) is widely used in prescription and non-prescription medicines. It is also used in a range of personal care and cosmetic products including face creams, body lotions and hand creams. Chemicals in this group also have non-industrial uses, including in food, food supplements and topically applied therapeutic goods.

Australian regulations

Vitamin A is a mandatory component for retinol, retinol acetate and retinol palmitate. It is possible that the number of medicines and adverse events have been counted more than once under different ingredients. Therefore, the total number of medicines containing vitamin A or adverse events associated with vitamin A are likely to be lower than the sum of the medicines or events reported for each ingredient.

[3] This guidance level is set for a sub-population of individuals at greater risk of osteoporosis and bone fracture, particularly post-menopausal women.

[4] European Commission Scientific Committee on Consumer Safety (2016; updated 1 December 2021) SCCS - Final opinion on vitamin A (Retinol, Retinyl Acetate, Retinyl Palmitate).

- According to the TGA Ingredient Database:
  - Vitamin A is available for use as an active ingredient in Biologicals, Export Only, Over the Counter and Prescription Medicines. It is also available as an Equivalent Ingredient in Export Only and Listed Medicines.
  - Retinol palmitate and retinol acetate are available for use as an active ingredient in Biologicals, Export Only, Listed Medicines, Over the Counter and Prescription Medicines. It is not available as an equivalent Ingredient in any application.
- As of 9 September 2026, the Australian Register of Therapeutic Goods (ARTG), listed:
  - 463 medicines containing vitamin A as an active ingredient (1 prescription, 398 non-prescription; the rest are export-only)
  - 484 medicines containing retinol as an active ingredient (17 prescription, 384 non-prescription; the rest are export-only)
  - 263 medicines containing retinol acetate as an active ingredient (13 prescription, 209 non-prescription; the rest are export-only)
  - 217 medicines containing retinol palmitate as an active ingredient (4 prescription, 173 non-prescription; the rest are export-only).
- Vitamin A is not specifically listed in the Therapeutic Goods (Permissible Ingredients) Determination No. 2 of 2026. However, it is a mandatory component of retinol, retinol acetate and retinol palmitate which are permitted to be included in listed medicines as follows.

Item	Ingredient name	Purpose	Specific requirements
4305	RETINOL	A, E	Vitamin A is a mandatory component of retinol. When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%. When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.'
4306	RETINOL ACETATE	A, E	Vitamin A is a mandatory component of retinol acetate. When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%.

Item	Ingredient name	Purpose	Specific requirements
			When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.'
4307	RETINOL PALMITATE	A, E	Vitamin A is a mandatory component of retinol palmitate. When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%. When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.'
A = active ingredient for a medicine has the same meaning as in the Regulations 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 specifically classify retinol acetate and retinol palmitate. However, vitamin A (retinol) is classified as a Category D substance i.e. substances which have caused, are suspected to have caused or may be expected to cause

an increased incidence of human foetal malformations or irreversible damage. These substances may also have adverse pharmacological effects.

- While retinol or its esters are not specifically mentioned in the Therapeutic Goods (Medicines Advisory Statements) Specification 2021, the following warning statements are required to be included on the labels for vitamin A preparations.

Substance	Conditions	Required statements
Vitamin A	In medicines for oral use that are labelled to be used by females of childbearing age containing MORE THAN: • 33 micrograms retinol equivalents of vitamin A per dosage unit of a divided preparation; or • 33 micrograms retinol equivalents of vitamin A per gram of an undivided preparation	• The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men. • WARNING – When taken in excess of 3,000 micrograms retinol equivalents, vitamin A can cause birth defects. • If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.

- As of 26 August 2026, the Database of Adverse Event Notifications (DAEN) listed: [5]
  - 52 adverse events for products containing vitamin A as an active ingredient of which 43 reported vitamin A as the single suspected medicine. There were no reports of death associated with vitamin A.
  - 793 adverse events for products containing retinol as an active ingredient of which 658 reported retinol as the single suspected medicine. There were 12 reports of deaths associated with retinol use.
  - 441 adverse events for products containing retinol acetate as an active ingredient of which 380 reported retinol acetate as the single suspected medicine. There were no reports of death associated with retinol acetate use.
  - 333 adverse events for products containing retinol palmitate as an active ingredient of which 269 reported retinol palmitate as the single suspected medicine. There were 12 reports of deaths associated with retinol palmitate use.
- As of 8 September 2026, the Australian Pesticides and Veterinary Medicines Authority's Public Chemical Registration Information System (PubCRIS) listed:
  - 18 products containing vitamin A as an active ingredient/constituent or scheduled substance.
  - 2 products containing 'retinol as the palmitate' as an active ingredient/constituent or scheduled substance.
  - 5 products containing 'retinyl acetate' as an active ingredient/constituent or scheduled substance.

[5] Anyone can report an adverse event, including members of the public, health professionals and pharmaceutical companies. Adverse event reports reflect the observations of the people submitting them and can be incomplete or inaccurate. Inclusion of a medicine in the DAEN does not mean that the adverse event has been confirmed or that it was caused by a medicine or vaccine. The DEAN data also cannot be used on its own to assess the frequency of an adverse event, a product's safety or compare its safety to other products.

- In 2009-2019 no adverse experiences were recorded for vitamin A, retinol, retinol acetate or retinol palmitate in the APVMA Adverse Experience Reporting Program database (AERP).

International regulations

- The Health Canada Drug Product Database includes 4 drug products that contain vitamin A as an active ingredient. Whilst the database includes cancelled drug products containing retinol, retinol acetate and retinol palmitate, there are no currently approved drug products that contain these active ingredients.
- The New Zealand Medsafe Medicines Classification Database does not list retinol or its esters specifically, however it includes vitamin A as follows:

Substance	Conditions (if any)	Classifications
Vitamin A	for internal use in medicines containing more than 3 milligrams of retinol equivalents per recommended daily dose except in parenteral nutrition replacement preparations; for external use in medicines containing more than 1%	Prescription
Vitamin A	for internal use in medicines containing 3 milligrams or less of retinol equivalents per recommended daily dose; in parenteral nutrition replacement preparations; for external use in medicines containing 1% or less	General Sale

- The United States Food and Drug Administration Approved Drug Products Database (Drugs@FDA) lists 19 products that contain vitamin A as an active ingredient; all of which have been discontinued. There are no products on the database that include retinol, retinol acetate or retinol palmitate as an active ingredient. The Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations includes 5 entries for prescription products that contain vitamin A and 4 that contain vitamin A palmitate. There are no products on the database that include retinol, retinol acetate or retinol palmitate as an active ingredient.
- In the United Kingdom, the Medicines and Healthcare Products Regulatory Agency (MHRA) lists 2 products with vitamin A as an active ingredient, along with 5 products that list vitamin A palmitate as an active ingredient. The MHRA also lists 1 product containing retinol, 8 products containing retinol palmitate and no products containing retinol acetate as active ingredients.

1.3 Methyl ethyl ketone oxime (MEKO) – releasing silanes

Proposal

This is a Delegate initiated proposal based on recommendations from the Australian Industrial Chemicals Introduction Scheme (AICIS) in their Evaluation Statement on 2-Butanone oxime (MEKO)-releasing silanes (the Evaluation Statement).

MEKO-releasing silanes are alkoxysilanes containing 2, 3 or 4 methyl ethyl ketone oxime (MEKO) groups attached to a silicon atom. These substances may also contain vinyl, methyl, phenyl, methoxy and/or ethoxy substituents. They are used in adhesives and sealants at concentrations of up to 10% and rapidly hydrolyse in the presence of moisture, including moisture in air or on the surface of the skin, to release MEKO. As released MEKO is expected to be the primary contributor to the systemic toxicity profile of these substances, their health risks are principally associated with exposure to MEKO during use, particularly inhalation exposure during curing. MEKO-releasing silanes are not currently captured by a specific Poisons Standard entry. The proposal is to amend the Poisons (Schedule 6) entry for methyl ethyl ketone oxime to explicitly include MEKO-releasing silanes through a cross-reference.

A final decision in relation to the Poisons Standard entry MEKO was published in May 2026[6]

The AICIS Evaluation Statement covered the substances below.

CAS Number

2-Butanone, 2,2′,2″-[O,O′,O″-(ethenylsilylidyne)trioxime] CAS No. 2224-33-1

2-Butanone, 2,2′,2″-[O,O′,O″-(methylsilylidyne)trioxime] CAS No. 22984-54-9

2-Butanone, 2,2′,2″-[O,O′,O″-(phenylsilylidyne)trioxime] CAS No. 34036-80-1

2-Butanone, 2,2′,2″,2‴-(O,O′,O″,O‴-silanetetrayltetraoxime) CAS No. 34206-40-1

2-Butanone, O,O′-(dimethylsilylene)dioxime CAS No. 37843-26-8

2-Butanone, O,O′-(methylphenylsilylene)dioxime CAS No. 69373-66-6

2-Butanone, 2,2′-[O,O′-(methoxymethylsilylene)dioxime] CAS No. 83817-72-5

2-Butanone, 2,2′-[O,O′-(diethoxysilylene)dioxime] CAS No. 93917-75-0

2-Butanone, 2,2′,2″-[O,O′,O″-(ethoxysilylidyne)trioxime] CAS No. 101371-00-0

Alternative names

CAS No. 2224-33-1	Vinyltris(MEKO)silane; Butan-2-one O,O',O''-(vinylsilylidyne)trioxime; Vinyltris(methylethylketoximino)silane; Vinyl oximino silane (VOS)
CAS No. 22984-54-9	Methyltris(MEKO)silane; Methyltris(methylethylketoxime)silane; Methyl oximino silane (MOS)
CAS No. 34036-80-1	Phenyltris(MEKO)silane
CAS No. 34206-40-1	Tetrakis(MEKO)silane
CAS No. 37843-26-8	Dimethylbis(MEKO)silane
CAS No. 69373-66-6	Methylphenyldibutanoximesilane
CAS No. 83817-72-5	Bis(ethylmethylketoxime)methoxymethylsilane
CAS No. 93917-75-0	Diethoxybis(ethylmethylketoximo)silane
CAS No. 101371-00-0	Ethoxytris(ethylmethylketoximo)silane

[6] Notice of final decisions to amend (or not amend) the current Poisons Standard - ACCS #40, Joint ACMS-ACCS #39

Proposed Scheduling

Currently, MEKO-releasing silanes are not specifically scheduled. MEKO has amendments for its current entry dues to be implemented on 1 February 2028. The proposal is to amend the Poisons (Schedule 6) entry for methyl ethyl ketone oxime and to identify the most commonly known MEKO-releasing silanes via cross-references in the Index. For clarity, the proposed changes below, are based on the MEKO entry as it will appear in the February 2028 Poisons Standard, and not the current entry. No other changes to concentration or use made in the May 2026 Final Decision are being proposed.

Schedule 6 – Amend entry

METHYL ETHYL KETONE OXIME and METHYL ETHYL KETONE OXIME releasing silanes except

a) in viscous silicone adhesives or viscous silicone sealants for outdoor use containing 0.5% 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.

Index – Amend entry

METHYL ETHYL KETONE OXIME

Cross reference: 2-Butanone, 2,2′,2″-[O,O′,O″-(ethenylsilylidyne)trioxime] (CAS No. 2224-33-1), 2-Butanone, 2,2′,2″-[O,O′,O″-(methylsilylidyne)trioxime] (CAS No. 22984-54-9), 2-Butanone, 2,2′,2″-[O,O′,O″-(phenylsilylidyne)trioxime] (CAS No. 34036-80-1), 2-Butanone, 2,2′,2″,2‴-(O,O′,O″,O‴-silanetetrayltetraoxime) (CAS No. 34206-40-1), 2-Butanone, O,O′-(dimethylsilylene)dioxime (CAS No. 37843-26-8), 2-Butanone, O,O′-(methylphenylsilylene)dioxime (CAS No. 69373-66-6), 2-Butanone, 2,2′-[O,O′-(methoxymethylsilylene)dioxime] (CAS No. 83817-72-5), 2-Butanone, 2,2′-[O,O′-(diethoxysilylene)dioxime] (CAS No. 93917-75-0), 2-Butanone, 2,2′,2″-[O,O′,O″-(ethoxysilylidyne)trioxime] (CAS No. 101371-00-0)

Schedule 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 8 – Avoid breathing vapour

Item	Poison	Warning statement item number and statement	Safety direction item number and statement
		12 – Vapour is harmful to health on prolonged exposure 28 – (Over) (Repeated) exposure may cause sensitisation	10 – Ensure adequate ventilation when using

Background

MEKO-releasing silanes are used in adhesives and sealants and may be present either individually or in combination with other MEKO-releasing silanes or MEKO. Information on their introduction, use and end use in Australia is limited. However, Australian information referenced in the AICIS Evaluation Statement indicates that phenyltris (MEKO) silane is used in adhesives and sealants at concentrations up to 10%, and local safety data sheets (SDS) identify the use of several other MEKO-releasing silanes in adhesive and sealant products at similar concentrations.

Internationally, these chemicals are primarily used in domestic and professional adhesive and sealant products. Typical concentrations in sealants are below 10%, although concentrations of up to 30% have been reported. Additional uses have been identified in some automotive care products, including gasket makers.

Summary of reasons for the proposal

The AICIS Evaluation Statement provided that:

- MEKO is hazardous by inhalation and the Schedule 6 entry for MEKO has been recently amended to restrict the concentrations in consumer products.
- MEKO-releasing silanes may be used as a substitute for MEKO in products following implementation of the scheduling changes in 2028.
- These chemicals hydrolyse rapidly in the presence of moisture and release volatile MEKO. The critical health risks are principally associated with exposure to released MEKO during use, particularly inhalation exposure during the curing of silicone sealants. Dermal and ocular exposure to the MEKO-releasing silanes may also be relevant, particularly for workers handling or formulating products containing these chemicals.
- Cross-referencing these chemicals to the existing MEKO scheduling entry may achieve same results as a separate listing.
- MEKO is also listed in Appendix E (first aid instructions) and Appendix F (warning statements and general safety directions) of the Poisons Standard. Additional warning statements and safety directions regarding potential for inhalation carcinogenicity, ventilation, and the need to avoid breathing the vapour of preparations containing MEKO will apply to the MEKO-releasing silanes.

Key uses / expected use

Silicon sealants, adhesives, and automotive care products including gasket makers (domestic and industrial use).

Australian regulations

- MEKO and MEKO-releasing silanes are not listed as active ingredients in the TGA Ingredient Database.
- As of 31 August 2026, there were no products containing MEKO or MEKO-releasing silanes as an active ingredient or scheduled substance listed on the Public Chemical Registration Information System Search (PubCRIS).

- MEKO and the MEKO-releasing silanes are listed on the Australian Inventory of Industrial Chemicals (the Inventory) for chemicals being manufactured or imported into Australia for industrial use and have been assessed as a group as they all release MEKO.
  - 2-Butanone, 2,2′,2″-[O,O′,O″-(ethenylsilylidyne)trioxime] CAS No. 2224-33-1
  - 2-Butanone, 2,2′,2″-[O,O′,O″-(methylsilylidyne)trioxime] CAS No. 22984-54-9
  - 2-Butanone, 2,2′,2″-[O,O′,O″-(phenylsilylidyne)trioxime] CAS No. 34036-80-1
  - 2-Butanone, 2,2′,2″,2‴-(O,O′,O″,O‴-silanetetrayltetraoxime) CAS No. 34206-40-1
  - 2-Butanone, O,O′-(dimethylsilylene)dioxime CAS No. 37843-26-8
  - 2-Butanone, O,O′-(methylphenylsilylene)dioxime CAS No. 69373-66-6
  - 2-Butanone, 2,2′-[O,O′-(methoxymethylsilylene)dioxime] CAS No. 83817-72-5
  - 2-Butanone, 2,2′-[O,O′-(diethoxysilylene)dioxime] CAS No. 93917-75-0
  - 2-Butanone, 2,2′,2″-[O,O′,O″-(ethoxysilylidyne)trioxime] CAS No. 101371-00-0
- Besides, 2-butanone, 2,2′,2″-[O,O′,O″-(phenylsilylidyne)trioxime] (CAS No. 34036-80-1), was assessed as a new industrial chemical under section 23 of the Industrial Chemicals (Notification and Assessment) Act 1989 (ICNA Act). This chemical is being reassessed as new hazards have been identified including for the hydrolysis product MEKO.

International regulations

- In the European Union, products containing ≥0.1% of MEKO cannot be sold to the public. MEKO is listed as Carcinogenic class 2 in the European Commission database for information on cosmetic substances and ingredients database.
- In the Risk Management Option Analysis Conclusion Document, the German competent authority considered that MEKO-releasing silanes may warrant classification for carcinogenicity because they release carcinogenic MEKO during hydrolysis.
- Based on the opinion of the European Chemicals Agency (ECHA) Committee for Risk Assessment on a dossier proposing harmonised classification and labelling at the European level published in June 2026, a harmonised GHS classification for oxime-releasing silanes, including CAS No. 2224-33-1, CAS No. 22984-54-9, CAS No. 34036-80-1 and CAS No. 34206-40-1, is currently under consideration in Europe. MEKO has an EU harmonised classification including:
  - Carcinogenicity Category 1B, H350: may cause cancer;
  - Acute Toxicity Category 3, H301: toxic if swallowed;
  - Acute Toxicity Category 4, H312: harmful in contact with skin;
  - Skin Sensitisation Category 1, H317;
  - Serious Eye Damage Category 1, H318;
  - Skin Irritation Category 2, H315;
  - STOT SE Category 3, H336: may cause drowsiness or dizziness;
  - STOT SE Category 1, H370: upper respiratory tract effects; and
  - STOT RE Category 2, H373: effects on the blood system through prolonged or repeated exposure.
- 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

increasing 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.[7]

- In New Zealand and ASEAN countries, cosmetic products are prohibited from containing MEKO.[8,9]
  - 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 carcinogenicity.
- In the New Zealand Inventory of Chemicals (NZIoC),
  - MEKO cannot be used as a pesticide or veterinary medicine but can be used in the formulation of pesticides, veterinary medicines, antifouling paints, or timber treatment preservatives.
  - CAS No. 2224-33-1, and CAS No. 22984-54-9 were listed as without having an individual approval but may be used under an appropriate group standard with similar GHS classification and toxicity data.
  - CAS No. 34036-80-1, CAS No. 34206-40-1, CAS No. 37843-26-8, CAS No. 83817-72-5, CAS No. 93917-75-0 and CAS No. 101371-00-0 were listed as not having individual approval but may be used as components in products covered by a group standard as well as not approved for use as chemicals in their own right.
  - CAS No. 69373-66-6 was not listed in the database.

How to respond

Submissions must be provided by the closing date of **12 October 2026** 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).

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.

[7] Butanone oxime - information sheet - Canada.ca, accessed 4 September 2026

[8] 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

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

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