Australian Government

Department of Health

Therapeutic Goods Administration

Consultation: Proposed amendments to the Poisons Standard – Joint ACMS-ACCS meetings, June 2021

29 April 2021

TGA Health Safety Regulation

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.

Contents

1 Intentionally blank

2 Proposed amendments referred for scheduling advice to the Joint ACMS-ACCS #28

2.1 Ethanol

Proposal

The applicant proposes a new entry in Schedule 6 for ethanol, when present in hand sanitiser preparations at concentrations ≥ 50%.

CAS Number

64-17-5

Alternative names

Ethyl alcohol, absolute alcohol, anhydrous alcohol, dehydrated alcohol, ethyl hydrate, ethyl hydroxide

Applicant

Private applicant

Current scheduling

Ethyl alcohol (ethanol) is currently listed in Appendix B, Part 3 – Substances considered not to require control by scheduling.

Appendix B, Part 3

SUBSTANCE	DATE OF ENTRY	REASON FOR LISTING	AREA OF USE
ETHYL ALCOHOL	Nov 1974	**a** (Low Toxicity)	**7.1** (Any use)

Index

ETHYL ALCOHOL

Appendix B, Part 3

Proposed scheduling

Schedule 6 – New Entry

ETHANOL when present in hand sanitiser preparations at concentrations ≥ 50% v/v or when the sum of concentrations of ethanol and isopropanol is 50% or more, **except**:

(a) when packaged in a container with a restricted flow or metered flow device; or

(b) when containing a separate bittering agent denatured according to the Australian Taxation Office Excise (Denatured Spirits) Determination 2016 (no.3) (apart

from denaturation with methanol, isopropanol, n-propanol or n-hexane); or

(c) when the kinematic viscosity is within the range of 6,000 - 17,000 mm^2/s (20°C), and

(d) when packaged in a container less than or equal to 2L that is readily distinguishable from a container in which food, wine or other beverage is sold; and

(e) when the immediate container and primary pack are labelled with the following statements and warnings or their equivalent:

(i) HAND SANITISER
Contains XX% v/v ethanol; and

(ii) KEEP OUT OF THE REACH OF CHILDREN - use under adult supervision

FOR EXTERNAL USE ONLY - DO NOT SWALLOW

FLAMMABLE - Keep away from heat or flame. Store below 30°C

WARNING - this product contains ingredients which may be injurious to the eye

Discontinue use if skin irritation occurs

If swallowed, splashed in eyes contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766)

Written in letters not less than 1.5mm in height

Appendix F, Part 3 – New Entry

Poison	Warning Statements	Safety Directions
ETHANOL	**8** (WARNING – May be fatal to children)	**1** (Avoid contact with eyes)
	79 (Will irritate eyes)	**23** (Keep away from heat, sparks and naked flames)

Index

ETHANOL
Cross reference: ETHYL ALCOHOL

Schedule 6
~~Appendix B, Part 3~~
Appendix F, Part 3

Proposed addition to Part 1 (Interpretation) of the Poisons Standard

The proposed wording for Part1 is based in the definition of hand sanitiser in the *Consumer Goods (Cosmetics) Information Standard 2020*[1]

"**Hand sanitiser preparation**" means an antimicrobial skin care product:

a) that consists of, contains or generates one or more antimicrobial active substances; and

b) that is represented in any way to be, or is likely to be taken to be (whether because of the way in which it is presented or for any other reason):

i) for use on hands when soap and water are not available; and

ii) applied to the hands without rinsing off; and

iii) intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any microbes on the skin.

Key uses / expected use

Cosmetic, domestic and industrial. Used in the manufacture of hand sanitisers, which may be classed as therapeutic or cosmetic depending on the claims made by the manufacturer. Ethanol is a highly effective biocide and is used not only in domestic consumer products such as cosmetics but is also used in food preservation and as a fuel additive.

Summary of applicants reasons for proposal

- The increased use of high concentration alcohol-based hand sanitisers (up to 90% concentration) in domestic settings has increased public health risks for accidental and deliberate ingestion.
- Poisons Information Centres (PIC) have identified increases in calls relating to the accidental ingestion of hand sanitiser products, particularly in children under the age of five. There was a >200% increase in poisonings in 2020 compared to the previous year with approximately 70% of these poisonings involving children under 5 years of age. An increase in intentional ingestion was also reported.
- PIC have reported intentional ingestion of hand sanitisers, particularly in the those suffering with neurodegenerative conditions such as dementia, and with adolescents and adult persons deliberately misusing hand sanitisers due to their increased availability. Currently there is no requirement to add a denaturant to hand sanitisers containing ethanol.
- It is proposed that ethanol-based hand sanitisers in containers up to 2L are captured in the scheduling proposal. The use of larger volumes is expected to be captured under workplace health and safety legislation as they are unlikely to be used domestically or found available for retail sale in the domestic market.
- Hand sanitisers have also been identified by the applicant for sale in bottles resembling children's 'pop top' drinks, water bottles and resembling alcoholic beverages.

[1] Consumer Goods (Cosmetics) Information Standard 2020
https://www.legislation.gov.au/Series/F2020L01469

- The applicant noted that some hand sanitisers were also of a clear liquid consistency, similar to the consistency of water, with no flow restriction controls on the containers.
- Safety information on labels of selected bottles were limited and did not include adequate warnings regarding the contents or their safe use.
- There are some gaps in existing regulatory systems for hand sanitisers with the TGA and ACCC, as primarily evidenced by the increased reporting of poisonings related to use of hand sanitisers in2020.
- Public health risks relating to access controls to accidently or intentionally consuming the contents have not been addressed.
- Ethanol is a moderate eye irritant in animal studies and is a skin irritant in humans following repeated exposure.

Australian regulations

- According to the TGA Ingredient Database[2], ethanol is:
  - available for use as an Active Ingredient in Biologicals, Export Only, Listed Medicines, Over the Counter and Prescription Medicines
  - not available as a Homoeopathic Ingredient in Listed Medicines
  - available for use as an Excipient Ingredient in Biologicals, Devices, Export Only, Listed Medicines, Over the Counter and Prescription Medicines
  - available for use as an Equivalent Ingredient in Listed Medicines.
- As of April 2021, there were 464 approved non-prescription medicines currently active in the Australian Register of Therapeutic Goods (ARTG)[3] that contain ethanol as an ingredient. This included 56 non-prescription medicines that contain ethanol as an active ingredient. These are predominantly include hand sanitisers, disinfectants and mouthwashes.
- According to the Therapeutic Goods (Permissible Ingredients) Determination[4] No.1 of 2021, ethanol is permitted to be used in listed medicines as follows:

[2] TGA Ingredient Database https://www.ebs.tga.gov.au/
[3] ARTG database https://www.tga.gov.au/artg
[4] Therapeutic Goods (Permissible Ingredients) Determination https://www.legislation.gov.au/Search/Therapeutic%20Goods%20LBPermissible%20IngredientsRB%20Determination

Item	Ingredient name	Purpose	Specific requirements
2048	ETHANOL	A, E	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time. When the concentration of ethanol from all ingredients in the medicine is more than 3%, the medicine requires the following warning statement on the medicine label: - (ETHAN) 'Contains ethanol or contains alcohol'.
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 *Therapeutic Goods (Excluded Goods Hand Sanitisers) Determination 2020* (the determination) includes exclusions when presented for supply in a particular way. Schedule 1 of the determination outlines the formulation requirements and specifies the ingredients.
- The determination also specifies the labelling requirements, including a statement that the product "*must not be presented for supply in any way that is likely to result in the goods being mistaken for or confused with food or beverages*".

  Schedule 2, part 1 of the determination outlines the requirements for labels as follows:

1 Front label

Ethanol hand sanitiser 80%

Hand rub [optional text: suitable for use in medical and health services]

DO NOT DRINK

[Insert volume of the product in mLs]

[Insert name of the manufacturer or supplier]

[Insert contact details of the manufacturer or supplier]

2 Back label

Contains:

Ethanol 80% v/v, water, glycerol and hydrogen peroxide.

[Insert name of denaturant used, if applicable]

Use:

Antiseptic hand rub when soap and water are not available.

Directions for use:

Apply sufficient amount of product on hands to cover all surfaces.

Rub hands together until dry.

Warnings:

For external use only. Flammable. Keep away from heat or flame.

Keep out of eyes, ears and mouth.

Discontinue use if skin irritation or rash occurs.

Keep out of reach of children.

Poisons Information Centre 13 11 26.

Store below 30 °C.

Date of manufacture: [Insert dd mm yyyy]

- There are no warning statements pertaining to ethanol in the Therapeutic Goods (Permissible Ingredients) Determination[5]
- Since January 2010, there were 92 reports of adverse events for products containing ethanol as an active ingredient on the Database of Adverse Event Notifications (DAEN)[6], with 60 reports where ethanol was the single suspected medicine.
- As of April 2021, there were five products containing ethanol listed in the APVMA Public Chemical Registration Information System Search (PubCRIS) [7],

[5] Therapeutic Goods (Permissible Ingredients) Determination https://www.legislation.gov.au/Search/Therapeutic%20Goods%20LBPermissible%20IngredientsRB%20Determination

[6] Database of Adverse Event Notifications – medicines https://apps.tga.gov.au/Prod/daen/daen-entry.aspx

[7] Public Chemical Registration Information System Search https://portal.apvma.gov.au/pubcris

  - Five products are listed as fungicides or insecticides using ethanol as an active ingredient. Two products are Schedule 6 due to the presence of other scheduled ingredients; the remaining three products are unscheduled.

- In 2010-2020 no adverse experiences were recorded for ethanol in the APVMA Adverse Experience Reporting Program[8] database (AERP).

- The *Consumer Goods (Cosmetics) Information Standard 2020*[9]lists the following additional requirements for hand sanitisers. It also provides a definition of hand sanitisers.

Additional requirements for hand sanitisers

(1) This section applies to hand sanitiser that contains alcohol as the primary active ingredient.

Note: This instrument does not apply to hand sanitisers that are therapeutic goods within the meaning of the *Therapeutic Goods Act 1989*, or that are excluded goods for the purposes of that Act under the *Therapeutic Goods (Excluded Goods—Hand Sanitisers) Determination 2020* (see subsection 5(2) of this instrument).

(2) The amount of alcohol contained in the hand sanitiser must be shown as a percentage (%), by volume per volume (v/v), in a manner that is prominent and clearly legible:

(a) in the list of ingredients; or

(b) elsewhere on the container.

(3) The following warnings must be shown on the container (as the words set out below, or as other words, or pictograms, that could reasonably be regarded as having the same meaning):

Keep out of reach of children

For external use only

If ingested, seek immediate medical attention

Flammable—keep away from fire and heat

Discontinue use if skin irritation occurs

Note: If a supplier makes a claim or representation intended to promote a product, such as "kills 99.99% of germs", the supplier may be required to give information and/or produce documents to the regulator that could be capable of substantiating or supporting the claim or representation (see section 219 of the Australian Consumer Law).

International regulations

As of April 2021:

- Ethanol is included in the WHO Model List of Essential Medicines 2019 for use in antiseptics and disinfectants.

- There are no products containing ethanol in the United States Food and Drug Administration Approved Drug Products Database (Drugs@FDA) or European Commission database for information on cosmetic substances and ingredients database.

[8] Adverse Experience Reporting Program annual reports https://apvma.gov.au/node/10946

[9] Consumer Goods (Cosmetics) Information Standard 2020 https://www.legislation.gov.au/Series/F2020L01469

- The US Food and Drugs Administration guidance[10] recommends the addition of a denaturant to prevent accidental and intentional ingestion and have effectively excluded methanol from hand sanitiser products.[11]
- There are no products containing ethanol as an active ingredient in the Health Products Regulatory Authority of Ireland database.
- According to the Canadian (Health Canada) Drug Product Database, ethanol is available as an active ingredient in over-the-counter disinfectants and medicated wipes (including veterinary products), as well as injections for ethical use.
- Ethanol was first added to the New Zealand Inventory of Chemicals (NZIoC) on 1 December 2006.
- Ethanol is not included in the New Zealand Medicines and Medical Devices Safety Authority (MedSafe) classification database.

2.2 Isopropanol

Proposal

The applicant proposes a new entry in Schedule 6 for isopropanol, when present in hand sanitiser preparations at concentrations ≥ 50%.

CAS Number

67-63-0

Alternative names

2-propanol, isopropyl alcohol, propan-2-ol

Applicant

Private applicant

Current scheduling

Isopropanol is not specifically scheduled in the current Poisons Standard.

[10] Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency Immediately in Effect Guidance for Industry
https://www.fda.gov/media/136118/download

[11] Coronavirus (COVID-19) Update: FDA Continues to Ensure Availability of Alcohol-Based Hand Sanitizer During the COVID-19 Pandemic, Addresses Safety Concerns
https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-continues-ensure-availability-alcohol-based-hand-sanitizer-during

Proposed scheduling

Schedule 6 – New Entry

ISOPROPANOL when present in hand sanitiser preparations at concentrations ≥ 50% v/v or when the sum of concentrations of ethanol and isopropanol is 50% or more, except:

(a) when packaged in a container with a restricted flow or metered out; or

(b) when containing a separate bittering agent denatured according to the Australian Taxation Office Excise (Denatured Spirits) Determination 2016 (no.3) (apart from denaturation with methanol, n-propanol or n-hexane); or

(c) when the kinematic viscosity is within the range of 6,000-17,000 mm^2/s (20°C), and

(d) when packaged in a container less than or equal to 2L that is readily distinguishable from a container in which food, wine or other beverage is sold; and

(e) when the immediate container and primary pack are labelled with the following statements and warnings or their equivalent

(i) HAND SANITISER

Contains XX% v/v Isopropanol; and

(ii) KEEP OUT OF THE REACH OF CHILDREN - use under adult supervision

FOR EXTERNAL USE ONLY DO NOT - SWALLOW:

FLAMMABLE - Keep away from heat or flame. Store below 30°C

WARNING this product contains ingredients which may be injurious to the eye

If swallowed, splashed in eyes contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766)

Written in letters not less than 1.5mm in height.

Appendix F, Part 3 – New Entry

Poison	Warning Statements	Safety Directions
ISOPROPYL ALCOHOL	**8** (WARNING – May be fatal to children)	**1** (Avoid contact with eyes)
	79 (Will irritate eyes)	**23** (Keep away from heat, sparks and naked flames)

Index

ISOPROPANOL
Cross reference: ISOPROPYL ALCOHOL

Schedule 6

Proposed addition to Part 1 (Interpretation) of the Poisons Standard

The proposed wording for Part1 is based in the definition of hand sanitiser in the *Consumer Goods (Cosmetics) Information Standard 2020*[12]

"**Hand sanitiser preparation**" means an antimicrobial skin care product:

a) that consists of, contains or generates one or more antimicrobial active substances; and

b) that is represented in any way to be, or is likely to be taken to be (whether because of the way in which it is presented or for any other reason):

i) for use on hands when soap and water are not available; and

ii) applied to the hands without rinsing off; and

iii) intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any microbes on the skin.

Key uses/expected use

Cosmetic, domestic and industrial. Used in the manufacture of hand sanitisers, which may be classed as therapeutic or cosmetic depending on the claims made by the manufacturer.

Reasons for the proposal

- Alcohols, such as isopropanol, are known to deactivate lipophilic and enveloped viruses such as COVID-19. Alcohols are highly effective, cheap biocides used in many consumer products for this purpose.
- Isopropanol is a severe eye irritant in animal studies and it is a skin irritant in humans following repeated exposure.
- It is proposed that isopropanol-based hand sanitisers in containers up to 2L are captured in the scheduling proposal. The use of larger volumes is expected to be captured under workplace health and safety legislation as they are unlikely to be found available for retail sale in the domestic market.
- National Poison Information Centres have reported intentional ingestion of hand sanitisers, particularly in the those suffering with neurodegenerative conditions such as dementia, and with adolescents and adult persons deliberately misusing hand sanitisers due to their availability. Currently there is no mandated requirements to add a denaturant to hand sanitisers.
- Although these products are not designed for or specifically intended for ingestion, any of the products can be purchased and consumed by an individual who is intentionally seeking to become inebriated. These products are not regulated in the same way alcoholic beverages are and can potentially be purchased by minors.
- Alcohol abuse is a significant medical and social problem. At sufficiently high doses it can cause both short term and long-term toxic health effects in humans.

[12] Consumer Goods (Cosmetics) Information Standard 2020
https://www.legislation.gov.au/Series/F2020L01469

Australian regulations

- As of April 2021, there were 223 approved non-prescription medicines currently active in the Australian Register of Therapeutic Goods (ARTG) that contain isopropanol as an ingredient. This included 20 non-prescription medicines that contain isopropanol as an active ingredient. These include a range of products such as hand rubs, antiseptic swabs and wipes and disinfectants.
- According to the TGA Ingredient Database, isopropanol is:
  - available for use as an Active Ingredient in Biologicals, Over the Counter, and Prescription Medicines.
  - available for use as an Excipient Ingredient in Biologicals, Devices, Export Only, Listed Medicines, Over the Counter, and Prescription Medicines.
  - not available as an Equivalent Ingredient in any application.
- The *Therapeutic Goods (Excluded Goods Hand Sanitisers) Determination 2020* (the determination) includes exclusions when presented for supply in a particular way. Schedule 1 of the determination outlines the formulation requirements and specifies the ingredients.
- The determination also outlines the labelling requirements and advertising, including a statement that the product should *"not presented for supply in a way that is likely to result in the goods being mistaken for or confused with food or beverages"*.

  Schedule 2, part 1 of the determination outlines the requirements for labels as follows:

1 Front label

Isopropyl alcohol hand sanitiser 75%

Hand rub [optional text: suitable for use in medical and health services]

DO NOT DRINK

[Insert volume of the product in mLs]

[Insert name of the manufacturer or supplier]

[Insert contact details of the manufacturer or supplier]

2 Back label

Contains:

Isopropyl alcohol 75% v/v, water, glycerol and hydrogen peroxide.

Use:

Antiseptic hand rub when soap and water are not available.

Directions for use:

Apply sufficient amount of product on hands to cover all surfaces.

Rub hands together until dry.

Warnings:

For external use only. Flammable. Keep away from heat or flame.

Keep out of eyes, ears and mouth.

Discontinue use if skin irritation or rash occurs.

Keep out of reach of children.

Poisons Information Centre 13 11 26.

Store below 30 °C.

Date of manufacture: [Insert dd mm yyyy]

- Isopropanol is not permitted to be included in listed medicines as it is not included in the Therapeutic Goods (Permissible Ingredients) Determination[13] No.1 of 2021.
- The TGA prescribing medicines in pregnancy database[14] does not specifically identify isopropanol.
- There are no warning statements pertaining to isopropanol in the Therapeutic Goods (Medicines Advisory Statements) Specification 2019[15]

[13] Therapeutic Goods (Permissible Ingredients) Determination https://www.legislation.gov.au/Search/Therapeutic%20Goods%20LBPermissible%20IngredientsRB%20Determination

[14] TGA prescribing medicines in pregnancy database https://www.tga.gov.au/prescribing-medicines-pregnancy-database

[15] Therapeutic Goods (Medicines Advisory Statements) Specification 2019 https://www.legislation.gov.au/Details/F2019L00213

- Since January 2010, there have been 19 reports of adverse events for isopropanol in the Database of Adverse Event Notifications (DAEN)[16] In all events isopropanol was the single suspected medicine. No deaths have been recorded that were associated with isopropanol.
- There were three products containing isopropanol in the Public Chemical Registration Information System Search (PubCRIS) [17]
  - All three products are unscheduled gels for relief from muscular pain.
- The *Consumer Goods (Cosmetics) Information Standard 2020*[18]lists the following additional requirements for hand sanitisers. It also provides a definition of hand sanitisers.

Additional requirements for hand sanitisers

(1) This section applies to hand sanitiser that contains alcohol as the primary active ingredient.

Note: This instrument does not apply to hand sanitisers that are therapeutic goods within the meaning of the *Therapeutic Goods Act 1989*, or that are excluded goods for the purposes of that Act under the *Therapeutic Goods (Excluded Goods—Hand Sanitisers) Determination 2020* (see subsection 5(2) of this instrument).

(2) The amount of alcohol contained in the hand sanitiser must be shown as a percentage (%), by volume per volume (v/v), in a manner that is prominent and clearly legible:

(a) in the list of ingredients; or

(b) elsewhere on the container.

(3) The following warnings must be shown on the container (as the words set out below, or as other words, or pictograms, that could reasonably be regarded as having the same meaning):

Keep out of reach of children

For external use only

If ingested, seek immediate medical attention

Flammable—keep away from fire and heat

Discontinue use if skin irritation occurs

Note: If a supplier makes a claim or representation intended to promote a product, such as "kills 99.99% of germs", the supplier may be required to give information and/or produce documents to the regulator that could be capable of substantiating or supporting the claim or representation (see section 219 of the Australian Consumer Law).

[16] Database of Adverse Event Notifications – medicines
https://apps.tga.gov.au/Prod/daen/daen-entry.aspx
[17] Public Chemical Registration Information System Search https://portal.apvma.gov.au/pubcris
[18] Consumer Goods (Cosmetics) Information Standard 2020
https://www.legislation.gov.au/Series/F2020L01469

International regulations

As of April 2021:

- Isopropanol is included in the WHO Model List of Essential Medicines 2019[19]
- The United States Food and Drug Administration (FDA) approve use of isopropanol as an over-the-counter medicine (Drugs@FDA[20]).
- Isopropanol is included in the European Commission database for information on cosmetic substances and ingredients database[21]
- Products containing isopropanol as an active ingredient in the Canadian (Health Canada) Drug Product Database[22] include over-the-counter disinfectants and medicated wipes, including for veterinary use.
- There are four products containing isopropanol as an active ingredient in the Health Products Regulatory Authority of Ireland[23] database. These are cutaneous solutions, which may be available as prescription or non-prescription goods.
- Isopropanol was first added to the New Zealand Inventory of Chemicals (NZIoC)[24] on 1 December 2006.
- Isopropanol is not included in the New Zealand Medicines and Medical Devices Safety Authority (MedSafe)[25] classification database.

2.3 Methanol

Proposal

The applicant proposes a new schedule entry for methanol in Schedule 10 for hand sanitiser preparations containing more than 2% methanol to mitigate public health risk from accidental or intentional consumption of alcohol-based hand sanitisers.

CAS Number:

67-56-1

[19] WHO model list of essential medicines – 21st list, 2019
www.who.int/publications/i/item/WHOMVPEMPIAU2019.06
[20] FDA Approved Drug Products Database https://www.accessdata.fda.gov/scripts/cder/daf/
[21] European Commission database for information on cosmetic substances and ingredients database
https://ec.europa.eu/growth/tools-databases/cosing/
[22] Canadian (Health Canada) Drug Product Database https://health-products.canada.ca/dpd-bdpp/index-eng.jsp
[23] Health Products Regulatory Authority (HPRA)
https://www.hpra.ie/homepage/medicines/medicines-information/find-a-medicine/results?query=&field=
[24] New Zealand Inventory of Chemicals (NZIoC)
https://www.epa.govt.nz/database-search/new-zealand-inventory-of-chemicals-nzioc/DatabaseSearchForm/?SiteDatabaseSearchFilters=36&Keyword=acequinocyl&DatabaseType=NZIOC
[25] New Zealand Medicines and Medical Devices Safety Authority (MedSafe)
https://www.medsafe.govt.nz/profs/class/classintro.asp

Alternative names

Methyl alcohol, carbine, wood spirit, wood alcohol.

Applicant

Private applicant.

Current scheduling

Methanol is currently in Schedules 5 and 6, and Appendix E and F of the Poisons Standard as follows:

Schedule 6

METHANOL (excluding its derivatives) **except**:

a) when included in Schedule 5; or

b) in preparations containing 2 per cent or less of methanol.

Schedule 5

METHANOL (excluding its derivatives) in preparations containing 10 per cent or less of methanol **except** in preparations containing 2 per cent or less of methanol.

Index

METHANOL

Schedule 6
Schedule 5
Appendix E, Part 2
Appendix F, Part 3

Appendix E, Part 2

POISON	First Aid Instructions
METHANOL	
• above 10 per cent	**A, G3**
• 10 per cent or less	**A**
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.	

Appendix F, Part 3

Poison	Warning Statements	Safety Directions
METHANOL **except** in methylated spirit		**1** (Avoid contact with eyes), **4** (Avoid contact with skin), **8** (Avoid breathing dust (or) vapour (or) spray mist)

Proposed scheduling

Schedule 10 - New Entry

METHANOL in hand sanitiser preparations containing more than 2% methanol.

Proposed addition to Part 1 (Interpretation) of the Poisons Standard

The proposed wording for Part1 is based in the definition of hand sanitiser in the *Consumer Goods (Cosmetics) Information Standard 2020*[26]

"**Hand sanitiser preparation**" means an antimicrobial skin care product:

c) that consists of, contains or generates one or more antimicrobial active substances; and

d) that is represented in any way to be, or is likely to be taken to be (whether because of the way in which it is presented or for any other reason):

iv) for use on hands when soap and water are not available; and

v) applied to the hands without rinsing off; and

vi) intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any microbes on the skin.

Key uses / expected use

Used in the petrochemical industry and as a denaturant additive. Used in the manufacture of hand sanitisers, which may be classed as therapeutic or cosmetic depending on the claims made by the manufacturer.

Methanol is a clear, colourless and volatile liquid with a characteristic odour. It is highly flammable. It is widely used as an industrial solvent; a chemical intermediate; a fuel source for picnic stoves, racing cars and soldering torches; an anti-freeze agent; and an octane booster for gasoline. Methanol mixes readily with water and many organic liquids. Methanol rapidly absorbs water from the air. It mixes readily with most organic liquids.

[26] Consumer Goods (Cosmetics) Information Standard 2020
https://www.legislation.gov.au/Series/F2020L01469

Reasons for proposal

- Methanol, as an alcohol, has the potential to be added intentionally to hand sanitisers as a substitute for ethanol or isopropanol, by use of methanol-denatured ethanol, or inadvertently as a by-product of distillation.
- Methanol in small quantities can cause irreversible toxic effects in humans. The current Scheduling entries in Schedule 5 (between 2 and 10% concentration) and Schedule 6 greater than 10% concentration) are based on animal toxicological studies which indicate that methanol poses a low risk from all exposure routes. However, humans are more susceptible to toxic effects of methanol than animals.
- The current Scheduling arrangements allows domestic products such as hand sanitisers to contain methanol which poses a public health risk. The application seeks to prevent the addition of methanol to hand sanitiser preparations as a substitute for ethanol or isopropanol or as a denaturant (at high concentration) due to it toxic effects. There have been deaths reported internationally (US, Europe and Mexico) due to ingestion of hand sanitisers containing methanol.

Australian regulations

As of April 2021:

- There were thirty-eight approved products currently active in the Australian Register of Therapeutic Goods (ARTG)[27] containing methanol as an ingredient and no products containing methanol as an active ingredient.
- According to the TGA Ingredient Database[28] methanol is:
  - available for use as an Active Ingredient in Biologicals, Export Only, Over the Counter and Prescription Medicines.
  - available for use as an Excipient Ingredient in Biologicals, Devices, Export Only, Listed Medicines, Over the Counter and Prescription Medicines.
  - available for use as an Equivalent Ingredient in Listed Medicines.
- Methanol is not specifically referred to in the *Therapeutic Goods (Excluded Goods Hand Sanitisers) Determination 2020*[29]
- According to the Therapeutic Goods (Permissible Ingredients) Determination[30] No.1 of 2020, methanol is permitted to be included in listed medicines as follows:

[27] ARTG database https://www.tga.gov.au/artg
[28] TGA Ingredient Database https://www.ebs.tga.gov.au/
[29] Therapeutic Goods (Excluded Goods-Hand Sanitisers) Determinations https://www.legislation.gov.au/Details/F2020C00357
[30] Therapeutic Goods (Permissible Ingredients) Determination https://www.legislation.gov.au/Search/Therapeutic%20Goods%20LBPermissible%20IngredientsRB%20Determination

Item	Ingredient name	Purpose	Specific requirements
3283	METHANOL	E	The residual solvent limit is 30 mg per recommended daily dose. The concentration in the medicine must be no more than 0.3%.
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[31] does not specifically identify methanol.
- There are no warning statements pertaining to methanol in the Therapeutic Goods (Medicines Advisory Statements) Specification 2019[32]
- There were no adverse events for methanol in the Database of Adverse Event Notifications (DAEN)[33]
- There were thirty products containing methanol in the Public Chemical Registration Information System Search (PubCRIS) [34]
- The *Consumer Goods (Cosmetics) Information Standard 2020*[35]lists the following additional requirements for hand sanitisers. It also provides a definition of hand sanitisers.

Additional requirements for hand sanitisers

(1) This section applies to hand sanitiser that contains alcohol as the primary active ingredient.

Note: This instrument does not apply to hand sanitisers that are therapeutic goods within the meaning of the *Therapeutic Goods Act 1989*, or that are excluded goods for the purposes of that Act under the *Therapeutic Goods (Excluded Goods—Hand Sanitisers) Determination 2020* (see subsection 5(2) of this instrument).

(2) The amount of alcohol contained in the hand sanitiser must be shown as a percentage (%), by volume per volume (v/v), in a manner that is prominent and clearly legible:

(a) in the list of ingredients; or

(b) elsewhere on the container.

(3) The following warnings must be shown on the container (as the words set out below, or as other words, or pictograms, that could reasonably be regarded as having the same meaning):

Keep out of reach of children

For external use only

If ingested, seek immediate medical attention

[31] TGA prescribing medicines in pregnancy database https://www.tga.gov.au/prescribing-medicines-pregnancy-database

[32] Therapeutic Goods (Medicines Advisory Statements) Specification 2019 https://www.legislation.gov.au/Details/F2019L00213

[33] Database of Adverse Event Notifications – medicines https://apps.tga.gov.au/Prod/daen/daen-entry.aspx

[34] Public Chemical Registration Information System Search https://portal.apvma.gov.au/pubcris

[35] Consumer Goods (Cosmetics) Information Standard 2020 https://www.legislation.gov.au/Series/F2020L01469

Flammable—keep away from fire and heat
Discontinue use if skin irritation occurs

Note: If a supplier makes a claim or representation intended to promote a product, such as "kills 99.99% of germs", the supplier may be required to give information and/or produce documents to the regulator that could be capable of substantiating or supporting the claim or representation (see section 219 of the Australian Consumer Law).

International regulations

As of April 2021:

- Methanol is not included in the WHO Model List of Essential Medicines 2019[36]
- Methanol is not in the United States Food and Drug Administration Approved Drug Products database (Drugs@FDA) [37]
- Methanol is included in the European Commission database for information on cosmetic substances and ingredients database[38]
- There are no active products containing methanol in the Canadian (Health Canada) Drug Product Database[39] and Health Products Regulatory Authority of Ireland[40] database.
- Methanol was first added to the New Zealand Inventory of Chemicals (NZIoC)[41] on 1 December 2006.
- Methanol is not included in the New Zealand Medicines and Medical Devices Safety Authority (MedSafe)[42] classification database.

3 How to respond

Submissions must be provided by the closing date of **27 May 2021** through our consultation hub. Any submission about any of the proposals to amend the Poisons Standard will be considered at the next joint meeting of the Advisory Committee on Medicines Scheduling (ACMS) and Advisory Committee on Chemicals Scheduling (ACCS).

[36] WHO model list of essential medicines – 21st list, 2019
www.who.int/publications/i/item/WHOMVPEMPIAU2019.06
[37] FDA Approved Drug Products Database https://www.accessdata.fda.gov/scripts/cder/daf/
[38] European Commission database for information on cosmetic substances and ingredients database
https://ec.europa.eu/growth/tools-databases/cosing/
[39] Canadian (Health Canada) Drug Product Database https://health-products.canada.ca/dpd-bdpp/index-eng.jsp
[40] Health Products Regulatory Authority (HPRA)
https://www.hpra.ie/homepage/medicines/medicines-information/find-a-medicine/results?query=&field=
[41] New Zealand Inventory of Chemicals (NZIoC)
https://www.epa.govt.nz/database-search/new-zealand-inventory-of-chemicals-nzioc/DatabaseSearchForm/?SiteDatabaseSearchFilters=36&Keyword=acequinocyl&DatabaseType=NZIOC
[42] New Zealand Medicines and Medical Devices Safety Authority (MedSafe)
https://www.medsafe.govt.nz/profs/class/classintro.asp

4 What will happen

All public submissions will be published on the TGA website at Public submissions on scheduling matters, unless marked confidential or indicated otherwise.

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: Scheduling delegate's interim decisions & invitations for further comment in **September 2021**.

5 Enquiries

Any questions relating to submissions should be directed by email to medicines.scheduling@health.gov.au.