



Australian Government

Department of Health

Therapeutic Goods Administration

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

27 April 2021

TGA Health Safety
Regulation

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

3.3 Sodium nitrite

The Department of Health (the 'Department') recognises that each of the numbers reported represents an individual. The Department acknowledges the devastating effects associated with acts of self-harm on individuals, their families, friends and communities. A list of support services and information sources is provided below.

The information below contains details of self-poisonings some people may find distressing. If you or someone you know is in need of additional support, please contact any of the below crisis support helplines:

Support services and information sources

Adult

- [Lifeline](#): 13 11 14
- [Suicide Call Back Service](#): 1300 659 467
- [Beyond Blue](#): 1800 512 348
- [MensLine Australia](#): 1300 789 978

Youth

- [Kids Helpline](#) (5-25 years): 1800 551 800
- [Headspace](#): 1800 650 890
- [ReachOut](#)

Proposal

The Delegate of the Secretary of the Commonwealth Department of Health (the Delegate) proposes to create a new Schedule 10 entry for sodium nitrite for products containing concentrations above 15% of sodium nitrite; delete the Schedule 7 entry; and amend the Schedule 6 entry to allow for concentrations of up to 15%, other than when it is excluded from these entries. Sodium nitrite is also in Schedule 2 and some concentrations and uses are unscheduled.

Alternative names

NaNO₂; Nitrous acid; Sodium salt; Sodiumnitrite; Erinitrit

CAS Number:

7632-00-0

Applicant

Delegate of the Secretary of the Commonwealth Department of Health

Current scheduling

Sodium nitrite is currently listed in Schedule 2, Schedule 5, Schedule 6, Schedule 7, Appendix E, Part 2 and Appendix F, Part 3 of the Poisons Standard as follows:

Schedule 7

SODIUM NITRITE **except:**

- a) when included in Schedule 2, 5 or 6;
- b) in preparations containing 0.5 per cent or less of sodium nitrite;
- c) when present as an excipient in preparations for therapeutic use; or
- d) in aerosols containing 2 per cent or less of sodium nitrite.

Schedule 6

SODIUM NITRITE in preparations containing 40 per cent or less of sodium nitrite **except:**

- a) when included in Schedule 2 or 5;
- b) in preparations containing 0.5 per cent or less of sodium nitrite;
- c) when present as an excipient in preparations for therapeutic use; or
- d) in aerosols containing 2 per cent or less of sodium nitrite.

Schedule 5

SODIUM NITRITE in preparations containing 1 per cent or less of sodium nitrite **except:**

- a) in preparations containing 0.5 per cent or less of sodium nitrite;
- b) when present as an excipient in preparations for therapeutic use; or
- c) in aerosols.

Schedule 2

SODIUM NITRITE for therapeutic use (excluding when present as an excipient).

Appendix E, Part 2

POISON	STANDARD STATEMENTS
SODIUM NITRITE	
<ul style="list-style-type: none"> when included in Schedule 7 	<p>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)).</p> <p>G1 (Urgent hospital treatment is likely to be needed.)</p> <p>G3 (If swallowed, do NOT induce vomiting.)</p>
<ul style="list-style-type: none"> when included in Schedule 5 or 6 	<p>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)).</p> <p>G3 (If swallowed, do NOT induce vomiting.)</p>

Appendix F, Part 3

POISON	WARNING STATEMENTS
SODIUM NITRITE in pickling or curing salts.	94 (WARNING – Contains nitrite. Substitution for table or cooking salt may be dangerous, particularly for young children.)

Index**SODIUM NITRITE**

Schedule 7
 Schedule 6
 Schedule 5
 Schedule 2
 Appendix E, Part 2
 Appendix F, Part 3

Proposed scheduling

It has been proposed to amend the Poisons Standard as follows:

Schedule 10 – New Entry**SODIUM NITRITE except:**

- when included in Schedule 2, 5 or 6;
- in preparations containing 0.5 per cent or less of sodium nitrite;
- when present as an excipient in preparations for therapeutic use; or
- in aerosols containing 2 per cent or less of sodium nitrite.

Schedule 7 – Delete Entry**SODIUM NITRITE ~~except:~~**

- ~~a) when included in Schedule 2, 5 or 6;~~
- ~~b) in preparations containing 0.5 per cent or less of sodium nitrite;~~
- ~~c) when present as an excipient in preparations for therapeutic use; or~~
- d) ~~in aerosols containing 2 per cent or less of sodium nitrite.~~

Schedule 6 – Amend Entry

SODIUM NITRITE in preparations containing ~~40~~15 per cent or less of sodium nitrite **except:**

- a) when included in Schedule 2 or 5;
- b) in preparations containing 0.5 per cent or less of sodium nitrite;
- c) when present as an excipient in preparations for therapeutic use; or
- d) in aerosols containing 2 per cent or less of sodium nitrite.

Appendix E, Part 2 – Amend Entry

POISON	STANDARD STATEMENTS
SODIUM NITRITE	
• when included in Schedule 7	<p>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)).</p> <p>G1 (Urgent hospital treatment is likely to be needed.)</p> <p>G3 (If swallowed, do NOT induce vomiting.)</p>
• when included in Schedule 5 or 6	<p>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)).</p> <p>G3 (If swallowed, do NOT induce vomiting.)</p>

Key uses / expected use

Industrial use, medicines, food industry, pesticide formulations, agriculture

Summary of applicant's reasons for proposal

- The impetus for this proposal is reported misuse and concern associated with the increased use of sodium nitrite in deliberate, self-poisoning causing death.
- The proposal seeks to impose additional restrictions on the availability of sodium nitrite to minimise access for individuals who may misuse the substance while ensuring continuing access for industry stakeholders.

- Sodium nitrite is considered an essential nitrite salt for industry purposes, used as a precursor to organic compounds, such as pharmaceuticals, dyes, and pesticides, and most commonly as a food additive used for curing meats. It is used as a medicine, together with sodium thiosulfate, for treatment of cyanide poisoning.
- Sodium nitrite induces methaemoglobinaemia causing death. While sodium nitrite and sodium nitrate are different chemicals, both may result in toxicity by causing methaemoglobinaemia. It noted that it is possible the similarity in the terms 'sodium nitrite' and 'sodium nitrate' may result in reporting of the incorrect substance.
- According to [National Coronial Information System \(NCIS\) report on sodium nitrite and sodium nitrate-related deaths in Australia 2009–2018](#), there has been a substantial increase in sodium nitrite related deaths as of 2017. The report identified 17 deaths (4 cases in 2017 and 13 cases in 2018) where sodium nitrite or sodium nitrate were involved in the death, with no cases recorded from 2009 – 2016.
- The Therapeutic Goods Administration (TGA) has received direct reports from various State and Territory Departments on an increase in sodium nitrite-related deaths.

The Delegate seeks particular public comment on the following matters:

- Sodium nitrite is widely used in various industries. The Delegate is seeking public comment on the rescheduling proposal, particularly in regards to any possible unintended consequences to its use in the Australian market, if the proposed amendments are made final.
- There appears to be a lack of warning statements and child-proof packaging, particularly in sodium nitrite products accessed via pathways other than those approved by the relevant regulators. The Delegate is seeking public comment on the adequacy of the current labelling and supply of products containing sodium nitrite.
- There appears to be a need for greater uniform handling of products containing high concentrations of sodium nitrite. This includes the storage, supply and record keeping requirements stipulated in each state and territory. The Delegate is seeking public comment on the adequacy of the current handling of products containing sodium nitrite, and if there are additional measures that could be implemented to limit self-poisoning to the substance by the public.

Australian regulations

- According to the [TGA Ingredient Database](#),¹ sodium nitrite 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, Over the Counter, Prescription Medicines;
 - not available as an Equivalent Ingredient in any application.
- As of April 2021, there were 13 medicines currently active on the [Australian Register of Therapeutic Goods \(ARTG\)](#)² that contain sodium nitrite as an active ingredient. These include 3 prescription medicines, 3 non-prescription medicines, 1 medicine for export only, and 6 devices.

¹ TGA Ingredient Database <https://www.ebs.tga.gov.au/>

² ARTG database <https://www.tga.gov.au/artg>

- Sodium nitrite is not permitted to be included in listed medicines as it is not included in the [Therapeutic Goods \(Permissible Ingredients\) Determination](#)³ No.1 of 2021.
- Sodium nitrite is not included in the [TGA prescribing medicines in pregnancy database](#)⁴.
- There are no warning statements pertaining to sodium nitrite in the [Therapeutic Goods \(Medicines Advisory Statements\) Specification 2019](#)⁵
- As of April 2021, there were 3 reports of adverse events for products containing sodium nitrite as an active ingredient on the [Database of Adverse Event Notifications \(DAEN\)](#),⁶ with one report where sodium nitrite was the single suspected medicine. There were no reports of deaths associated with sodium nitrite use.
- As of April 2021, there was 1 registered product containing sodium nitrite listed on the [Public Chemical Registration Information System Search \(PubCRIS\)](#).⁷
 - A Schedule 6 vertebrate poison for control of feral pigs containing 10% sodium nitrite
- In 2010-2020 no adverse experiences were recorded for sodium nitrite in the [APVMA Adverse Experience Reporting Program database \(AERP\)](#)⁸.

International regulations

- Sodium nitrite is a prescription only medicine in Canada. According to the [Health Canada Drug Product Database](#)⁹, there is one registered product containing sodium nitrite, a dormant intravenous injection (30 mg/mL sodium nitrite) for use as an antidote.
- The [European Commission database of cosmetic substances and ingredients](#)¹⁰ lists sodium nitrite as an anticorrosive and rust inhibitor.
- The [Health Products Regulation Authority of Ireland](#)¹¹ regulates sodium nitrite as a prescription only medicine in solutions for injection. No medicines containing sodium nitrite as an active ingredient are currently marketed in Ireland.
- Sodium nitrite is included in the [New Zealand Inventory of Chemicals \(NZIoC\)](#)¹² as “nitrous acid, sodium salt”.

³ Therapeutic Goods (Permissible Ingredients) Determination [https://www.legislation.gov.au/Search/Therapeutic%20Goods%20LB\\$Permissible%20Ingredients\\$RB%20Determination](https://www.legislation.gov.au/Search/Therapeutic%20Goods%20LB$Permissible%20Ingredients$RB%20Determination)

⁴ TGA prescribing medicines in pregnancy database <https://www.tga.gov.au/prescribing-medicines-pregnancy-database>

⁵ Therapeutic Goods (Medicines Advisory Statements) Specification 2019 <https://www.legislation.gov.au/Details/F2019L00213>

⁶ Database of Adverse Event Notifications (DAEN) <https://apps.tga.gov.au/Prod/daen/daen-entry.aspx>

⁷ Public Chemical Registration Information System Search (PubCRIS) <https://portal.apvma.gov.au/pubcris>

⁸ APVMA Adverse Experience Reporting Program [database \(AERP\)](#) <https://apvma.gov.au/node/10946>

⁹ Canadian (Health Canada) Drug Product Database: health-products.canada.ca/dpd-bdpp/index-eng.jsp

¹⁰ European Commission database for information on cosmetic substances and ingredients: ec.europa.eu/growth/tools-databases/cosing/

¹¹ Health Products Regulatory Authority: www.hpra.ie/

¹² New Zealand Inventory of Chemicals: www.epa.govt.nz/database-search/new-zealand-inventory-of-chemicals-nzioc/

- The [United States Food and Drug Administration Approved Drug Products Database](#)¹³ approve use of sodium nitrite as a prescription medicine.
- According to the [New Zealand Medicines and Medical Devices Safety Authority \(Medsafe\)](#)¹⁴ sodium nitrite is available as follows:

Ingredient	Conditions	Classification
Sodium nitrite	except for use as an excipient	Pharmacy Only
Sodium nitrite	for use as an excipient	General Sale

4 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 \(ACCS\)](#).

5 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 in the submission coversheet (see [Privacy information](#)).

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**.

6 Enquiries

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

¹³ Food and Drugs Administration Approved Drugs Database: <https://www.accessdata.fda.gov/scripts/cder/daf/>

¹⁴ Medsafe Medicine Classification Database: <https://www.medsafe.govt.nz/profs/class/classintro.asp>

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
<https://www.tga.gov.au>

Reference/Publication #