Australian Government
Department of Health
Therapeutic Goods Administration

Notice of interim decisions on proposed amendments to the Poisons Standard (sodium nitrite) - June 2021

12 October 2021

This consultation closes on 11 November 2021.

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

This web publication constitutes a notice for the purposes of regulation 42ZCZP of the *Therapeutic Goods Regulations 1990* (the **Regulations**). In accordance with regulation 42ZCZP, this notice sets out:

- the interim decisions made by a delegate of the Secretary under regulation 42ZCZN in relation to proposed amendments to the current Poisons Standard which were referred to an expert advisory committee under subdivision 3D.2 of the Regulations in June 2021;
- the proposed date of effect of the proposed amendments (in circumstances where the interim decision proposes an amendment to the current Poisons Standard).

In accordance with regulation 42ZCZP, interested persons (including the applicant requesting the amendment) are invited to make submissions to the Secretary in relation to these interim decisions on or before **11 November 2021**.

> We have changed the way to make submissions.
>
> Submissions should now be provided through our consultation hub (https://consultations.health.gov.au/tga/june_2021_interim_sodium_nitrite/). Submissions will be considered by the Delegate in making the final decision.

Please note that in accordance with subregulation 42ZCZQ(4) of the Regulations, the Secretary must publish all relevant submissions received, unless the Secretary considers the information to be confidential information.

2. Interim decisions on proposed amendments referred to the Advisory Committee on Medicines and Chemicals Scheduling in joint session (Joint ACMS-ACCS #28, June 2021)

2.1 Interim decision in relation to sodium nitrite

CONTENT WARNING

The Department of Health (the 'Department') recognises that each of the numbers reported within this document 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 (https://www.lifeline.org.au/): 13 11 14
- Suicide Call Back Service (https://www.suicidecallbackservice.org.au/): 1300 659 467
- Beyond Blue (https://www.beyondblue.org.au/get-support/online-forums): 1800 512 348
- MensLine Australia (https://mensline.org.au/): 1300 789 978

Youth

- Kids Helpline (https://kidshelpline.com.au/) (5-25 years): 1800 551 800
- Headspace (https://headspace.org.au/): 1800 650 890
- ReachOut (https://au.reachout.com/)

Proposal

A Delegate of the Secretary of the Department of Health proposed to create a new Schedule 10 entry for sodium nitrite that would capture all products with concentrations of sodium nitrite above 15%. As part of this change, the Schedule 7 entry would be deleted and the cut-off in the Schedule 6 entry would be lowered from 40% to 15%. The proposal did not include any changes to the existing entries in Schedules 2 or 5, or exceptions for uses at low concentrations.

Interim decision

Note

New text is shown as green, larger font, with a horizontal line above it.

Deleted text is shown as ~~red, smaller font, with a strikethrough~~.

Pursuant to regulation 42ZCZN of the Regulations, a Delegate of the Secretary has, in relation to the proposed amendment, made an interim decision to amend the scheduling for sodium nitrite in the current 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 - 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.

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	
• when included in Schedule 7	**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)). **G1** (Urgent hospital treatment is likely to be needed.) **G3** (If swallowed, do NOT induce vomiting.)
• when included in Schedule 5 or 6	**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

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

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Materials considered

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

- A report (pdf,353kb) (//www.tga.gov.au/sites/default/files/ncis-sodium-nitrite-sodium-nitrate-related-deaths-australia-2009-2018.pdf) on sodium nitrite and sodium nitrate-related deaths in Australia, prepared by the National Coronial Information System Unit;
- An abstract on nitrite poisonings and deaths submitted to the Committee prior to publication;[1]
- The seven public submissions (https://consultations.health.gov.au/tga/june_2021_joint_sodium_nitrite/), all including a written component, received in response to the pre-meeting consultation (pdf,224kb) (//www.tga.gov.au/sites/default/files/consultation-proposed-amendments-poisons-standard-sodium-nitrite-joint-acmsaccs-28-june-2021.pdf) under regulation 42ZCZK of the Regulations;
- The advice received from the meeting of the Advisory Committee on Medicines and Chemicals Scheduling in joint session (Joint ACMS-ACCS #28);
- Subsection 52E(1) of the *Therapeutic Goods Act 1989*, in particular (a) risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; (e) the potential for abuse of a substance; and (f) any other matters that the Secretary considers necessary to protect public health;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (//www.tga.gov.au/publication/ahmac-scheduling-policy-framework-medicines-and-chemicals) (SPF 2018); and
- The Scheduling handbook: Guidance for amending the Poisons Standard (//www.tga.gov.au/publication/scheduling-handbook-guidance-amending-poisons-standard).

Summary of ACCS advice to the delegate

The Committee advised that the current scheduling for sodium nitrite remains appropriate.

Members agreed that the relevant matters under Section 52E(1) of the *Therapeutic Goods Act 1989* included: (a) risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; (e) the potential for abuse of a substance; and (f) any other matters that the Secretary considers necessary to protect public health.

The reasons for the advice included:

a. *the risks and benefits of the use of a substance*
   - Main benefits are associated with industrial applications and food preservation; no contemporary therapeutic use.
   - Risks associated with toxicity due to methemoglobinemia, mainly via intention ingestion. Risks are high if general access to the substance is granted to the public.

b. *the purposes for which a substance is to be used and the extent of use of a substance*
   - Historically the substance has been used as an antidote to cyanide poisoning, although due to toxicity concerns alternative treatments are now preferred in humans.
   - A registered product containing sodium nitrite is used as a feral animal control agent.
   - Sodium nitrite is widely used in the food industry, as a precursor to several industrial dyes and rubber additives, as a corrosion inhibitor and additive in greases, in solution within closed loop cooling systems, and in production of explosives.
   - There are some inconsistencies in the labelling and understanding of the toxicity and use of sodium nitrite.

c. *the toxicity of a substance*
   - Sodium nitrite ingestion can lead to methemoglobinemia which can lead to death.
   - Acute oral toxicity a definite danger and warrants inclusion in Schedule 7.

d. *the dosage, formulation, labelling, packaging and presentation of a substance*
   - Sodium nitrite naturally presents as a colourless salt, which can be dyed pink by manufacturers to avoid confusion with common table salt.
   - The substance is sold packaged as a curing salt (often without meeting the labelling requirements for Schedule 5 or 6 poisons) and as an industrial product.
   - There has been a particular lack of compliance with labelling requirements in products sold online.

e. *the potential for abuse of a substance*
   - There is established evidence that sodium nitrite is increasingly being consumed in the context of intentional self-poisoning.

f. *any other matter that the Secretary considers necessary to protect public health*
   - A wide range of industrial uses for the substance complicate a means restriction approach to reduce self-poisoning.

- An on-line seller has already instituted a policy not to allow sales of the substance on their website.

Reasons for the interim decision (including findings on material questions of fact)
I have decided not to create a Schedule 10 entry for sodium nitrite, as I am not of the view that the substance warrants prohibition. However, I have made an interim decision to amend the Schedule 6 entry for sodium nitrite to reduce the cut-off concentration from 40% to 15%. Under the proposed scheduling, products with a concentration above 15% would be captured by the existing Schedule 7 entry. The detailed reasons for my decision follow.

I have initiated this process to consider the scheduling of sodium nitrite, and sought advice from the Committee, in response to increasing reports of self-harm involving the misuse of the substance. Ingestion of sodium nitrite can induce methemoglobinemia, which can lead to death. This has led to the substance being promoted as a suicide agent by the voluntary euthanasia movement. The diagnosis and treatment of individuals who have ingested the substance for this purpose can be difficult. In addition, this property may also affect the accuracy of information collected regarding the number of cases and fatalities involving deliberate misuse of sodium nitrite. On occasion, case reports and deaths have been incorrectly attributed to the ingestion of sodium nitrate. It is likely that the number of fatalities attributable to deliberate ingestion of sodium nitrite is higher than officially reported.

Re-scheduling of this substance is complicated by the breadth of its use. Sodium nitrite has a multitude of legitimate applications in a variety of industries, including food, pharmaceuticals (human and veterinary medicines), explosives, dyes and pesticides. Any decision to restrict the availability of the substance must take into consideration the flow-on effect to these industries, and care must be taken not to unduly inhibit the operations of these stakeholders.

For example, I note the use of sodium nitrite in the livestock industry, where in most cases it is the only viable antidote (in combination with sodium thiosulfate) to cyanogenic glycoside poisoning in cattle. Without an effective, affordable alternative treatment for this condition in grazing stock, the prohibition of sodium nitrite would be potentially devastating to this industry.

I have noted that the states and territories possess no mechanism under their legislation to approve the use of a Schedule 10 substance. In addition to the effects that a Schedule 10 entry would have on existing legitimate industries, I am unconvinced that that up-scheduling in this manner would be effective in addressing the issue of misuse for self-harm. For these reasons, I have decided not to create a new Schedule 10 entry for sodium nitrite, which would prohibit its sale, supply and/or use above a certain concentration, but to reduce the concentration cut-off in Schedule 6.

I agree with the Committee's advice that based on the scheduling factors, the current scheduling of sodium nitrite is correct, and therefore creating new entries in the Poisons Standard for the substance may not be the optimal approach to addressing the issue of misuse of this substance for the purposes of self-harm. Nonetheless, I acknowledge the problems associated with this substance are a matter of great concern to public health, and therefore increased controls on

access to the substance are warranted. The proposed amendment to the Schedule 6 entry will place greater controls on preparations containing more than 15 per cent of sodium nitrite, while not placing undue restrictions on industrial use.

I have considered the eight public submissions that were received regarding the proposed changes, of which five were in support, one in support with caveats, and two opposed. I have noted that the submissions opposed to the proposal raised concerns over the impact of the changes on industrial uses of the substance, in particular in applications where public access to the substance was not possible, such as closed loop cooling systems and use as a corrosion inhibitor. The submissions in support highlighted the ease of access to the substance, and the importance of product labelling in raising awareness of the hazards associated with this substance among the general public.

I note that the single relevant registered animal control preparation, containing 10% w/w sodium nitrite, would not be affected by the proposed changes. In addition, preparations of sodium nitrite for therapeutic use would also be unaffected by the proposed changes and remain in Schedule 2 (pharmacy medicine), noting that the use of sodium nitrite as an antidote to cyanide poisoning in humans has been superseded in some jurisdictions by alternatives such as hydroxocobalamin or dicobalt edetate with glucose.

I agree with the Committee's findings that the relevant provisions of section 52E of the *Therapeutic Goods Act 1989* are: (a) risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; (e) the potential for abuse of a substance; and (f) any other matters that the Secretary considers necessary to protect public health.

Proposed implementation date
1 February 2022

Footnotes

[1] [PDF] 2E.005 Toxicovigilance for suicide prevention following Internet promotion of sodium nitrite | Semantic Scholar (https://www.semanticscholar.org/paper/2E.005%E2%80%85Toxicovigilance-for-suicide-prevention-of-Brown-Berling/3b4c4f007e895d05e424a763713bcf8620cf49fd)

Category: Scheduling
URL: https://www.tga.gov.au/node/940693 (https://www.tga.gov.au/node/940693)