



Australian Government

Department of Health

Therapeutic Goods Administration

Notice of final decisions to amend the current Poisons Standard - sodium nitrite

19 January 2022

TGA Health Safety
Regulation

A large, abstract graphic element in the lower half of the page. It consists of several thick, diagonal bands that overlap each other. The colors of the bands transition from dark navy blue on the left to a lighter teal on the right. A thin, light green line runs diagonally across the bottom of the graphic.

Copyright

© Commonwealth of Australia 2022

This work is copyright. You may reproduce the whole or part of this work in unaltered form for your own personal use or, if you are part of an organisation, for internal use within your organisation, but only if you or your organisation do not use the reproduction for any commercial purpose and retain this copyright notice and all disclaimer notices as part of that reproduction. Apart from rights to use as permitted by the *Copyright Act 1968* or allowed by this copyright notice, all other rights are reserved and you are not allowed to reproduce the whole or any part of this work in any way (electronic or otherwise) without first being given specific written permission from the Commonwealth to do so. Requests and inquiries concerning reproduction and rights are to be sent to the TGA Copyright Officer, Therapeutic Goods Administration, PO Box 100, Woden ACT 2606 or emailed to [<tga.copyright@tga.gov.au>](mailto:tga.copyright@tga.gov.au)

Contents

1	Notice of final decisions to amend the current Poisons Standard	4
2	Final decision on a proposed amendment referred to the Advisory Committee on Medicines and Chemicals Scheduling in joint session (Joint ACMS-ACCS #28, June 2021)	5
2.1	Final decision in relation to sodium nitrite-----	5

1 Notice of final decisions to amend the current Poisons Standard

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

- the decision made by a delegate of the Secretary pursuant to regulation 42ZCZR;
- the reasons for the final decision; and
- the date of effect of the decision.

2 Final decision on a proposed amendment referred to the Advisory Committee on Medicines and Chemicals Scheduling in joint session (Joint ACMS-ACCS #28, June 2021)

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 needs 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](#)

2.1 Final decision in relation to sodium nitrite

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.

Final Decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has made a final decision to depart from the interim decision and amend the current Poisons Standard in relation to sodium nitrite 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:

- a) in preparations containing ~~40~~ 15 per cent or less of sodium nitrite **except:**
 - i) when included in Schedule 2 or 5;
 - ii) in preparations containing 0.5 per cent or less of sodium nitrite;
 - iii) when present as an excipient in preparations for therapeutic use; or
 - iv) in aerosols containing 2 per cent or less of sodium nitrite.
- b) **for use in closed-loop water treatment systems (products).**

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

Materials considered

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

- A [report](#) 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

¹ [\[PDF\] 2E.005 Toxicovigilance for suicide prevention following Internet promotion of sodium nitrite | Semantic Scholar](#)

- The seven [public submissions](#), all including a written component, received in response to the [pre-meeting consultation](#) 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);
- The [two public submissions](#) received in response to the [interim decision consultation](#) under regulation 42ZCZP of the Regulations;
- 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 [Scheduling Policy Framework](#) (SPF 2018); and
- The [Scheduling handbook: Guidance for amending the Poisons Standard](#).

Reasons for the final decision (including findings on material questions of fact)

I have made a final decision to amend my [interim decision](#) regarding the scheduling of sodium nitrite. My final decision includes an exemption in the Schedule 6 entry for use in closed-loop water treatment systems. I have decided to make this change after consideration of the public submissions, and I agree that this additional amendment is required to avoid unduly hindering legitimate industrial uses of this substance while still addressing the issue of misuse of the substance for self-harm.

I have considered the written public submissions received from the NSW Poisons Information Centre (PIC) and Accord Australasia after I made my interim decision, both of which were partially in support of the proposed changes to the scheduling of sodium nitrite, although of opposing views on the preferred course of action.

I note in particular that Accord expressed concerns regarding the effects of the interim decision on industry and suggested that container size be considered as part of the final decision. The Accord submission specifies water treatment in closed-loop systems as the primary industrial application of sodium nitrite that would be affected by the amendment proposed in the interim decision. Therefore, I have decided to amend the interim decision by explicitly specifying the use of sodium nitrite in closed-loop water systems in the Schedule 6 entry, enabling this legitimate industrial use of the substance, while not compromising the original intent of the interim decision. Regarding the inclusion of a container size in the Schedule 6 entry, I note that reports of self-harm associated with use of sodium nitrite have generally resulted from the purchase of small packages of the substance, and that industrial quantities of sodium nitrite have not been implicated in recent reports of self-harm. Therefore, in making this final decision I consider that restrictions on container size are inappropriate at this time.

I acknowledge the concerns raised in the submission from the NSW PIC, which included recommendations for further measures to control the misuse of sodium nitrite. The standardisation of substance handling across all jurisdictions is at the discretion of the States and Territories given they implement and enforce controls established in the Poisons Standard. Generally these controls flow from the schedule in which the poison has been included. However, particularly in the case of Schedule 6 substances such as sodium nitrite, there can be significant differences in the controls on supply and distribution according to the relevant legislation in each jurisdiction. Ultimately the scheduling framework acknowledges that States and Territories have the discretion to determine what are the appropriate controls implemented in their jurisdiction.

I have considered the NSW PIC's suggestion of restrictions on purchaser identity, such as the prevention of direct personal importation and person-to-person sales of sodium nitrite. While I consider these measures to be potentially effective in mitigating the public health risks associated with sodium nitrite, I do not consider that such restrictions are consistent with the Schedule 6 scheduling factors. Moreover, significant hurdles exist to the implementation and enforcement of such measures by States and Territories, particularly in cases involving online sales to private purchasers. This may involve changes to State and Territory medicines and poisons, and potentially other, legislation and regulatory frameworks. In view of these challenges, I am not satisfied that an amendment to the Poisons Standard is the appropriate means to introduce such controls. I acknowledge the important work already done by State and Territory authorities in addressing the misuse of sodium nitrite; the scheduling of this substance in the Poisons Standard should be viewed as a supplementary measure to regulations already instituted by these bodies. The measures suggested in the NSW PIC submission could be considered by other regulatory bodies in future action targeting the misuse of sodium nitrite, should this scheduling amendment prove not to be sufficiently effective in restricting the misuse of the substance.

I have elected to postpone the implementation date proposed in the interim decision to ensure sufficient time is given to industry affected by the changes to the scheduling of sodium nitrite.

Implementation date

1 June 2022