

SHANAHAN, Bart

From: [REDACTED]
Sent: Thursday, 12 October 2017 8:19 AM
To: Medicines Scheduling
Cc: [REDACTED]
Subject: RE: Alkyl nitrites and lubricants exemption in Appendix A [SEC=UNCLASSIFIED]

No problem. Can you let [REDACTED] know please.
Thanks
[REDACTED]

Sent with BlackBerry Work
(www.blackberry.com)

From: Medicines Scheduling <MedicinesScheduling@health.gov.au>
Date: Thursday, 12 Oct 2017, 7:45 am
To: [REDACTED]
Cc: [REDACTED]
Subject: FW: Alkyl nitrites and lubricants exemption in Appendix A [SEC=UNCLASSIFIED]

Hi [REDACTED]
Please see email below from [REDACTED]. We don't have enough time to conduct the required consultation ahead of the November meeting, so if it were to be referred, it would need to go to the March meeting.

Kind regards,

The Chemicals and Medicines Scheduling Secretariat Team
Scheduling and Committee Governance Section (SCGS)
Phone: 1800 020 653
Email: chemicals.scheduling@health.gov.au and medicines.scheduling@health.gov.au

Therapeutic Goods Administration

The Department of Health

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Woden, ACT 2606

Australia

www.tga.gov.au

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

Please note that this response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met

From: [REDACTED]
Sent: Monday, 9 October 2017 3:22 PM
To: Chemicals Scheduling; Medicines Scheduling
Cc: [REDACTED]

Subject: Alkyl nitrites and lubricants exemption in Appendix A [SEC=No Protective Marking]

Dear Secretariat staff

Misinterpretation of the exemption for lubricants

[REDACTED] we have received information from a couple of “adult shop” type businesses that suppliers of “poppers” (which contain various short chain volatile alkyl nitrites, although not usually amyl nitrite anymore) are claiming their products are exempt from the SUSMP on the basis that they are marketed as “lubricants”. One of the “adult shop” businesses claimed to have a “letter from the TGA” indicating that a particular alkyl nitrite would be classified as a lubricant and therefore be exempt from the SUSMP – of course they could/would not provide a copy of the letter or the name of the signatory or even the area of the TGA from which the letter was sent. I strongly suspect the letter does not exist or was provided by the wholesale supplier of the “poppers”.

Of course, the volatility of the alkyl nitrites contained in these products would mean the products could not have a lubricating action. These products are generally labelled as “leather cleaners” or “room odourisers” but there is no credible evidence they are actually used for either of these purposes. Rather the contents of the little bottles which cost about \$30 to \$50 are inhaled

I am wondering if the Appendix A entry for lubricants could be clarified to ensure its original intention is retained? In other words, that this exemption is referring to motor/engineering lubricants rather than any other type of lubricant i.e. the exemption is for preparations that provide a lubricating action between machinery parts. I could not find much in the meeting minutes and lubricants seem to have been on the list of exemptions from the late 1960’s i.e. since this list first existed as an “exemption list”.

Scheduling of alkyl nitrites

Also there is quite a bit of information on the web indicating that “popper” manufacturers are using other alkyl nitrites to try and circumvent any regulatory controls – isopentyl nitrite, cyclohexyl nitrite, propyl nitrite and isopropyl nitrite are all mentioned. There is some anecdotal evidence that isopropyl nitrite is already being used in Australian products. There are case reports in the medical literature linking isopropyl nitrite inhalant use with maculopathy. There is some information that this has occurred in Australia – see <http://www.optometry.org.au/blog-news/2015/3/24/poppers-on-the-program-at-super-sunday/>

NDARC’s Ecstasy and Related Drugs Reporting System (EDRS) shows use of amyl nitrite (which I assume includes other alkyl nitrites) running at 27% of those who participated in the survey in 2016 (up from 21% in 2015). The demographics of the survey group suggest popper use has expanded to the community more generally – it was once associated more with the LGBTI community.

[https://ndarc.med.unsw.edu.au/sites/default/files/ndarc/resources/National_EDRS_%202016_FINALwith%20customs.p](https://ndarc.med.unsw.edu.au/sites/default/files/ndarc/resources/National_EDRS_%202016_FINALwith%20customs.pdf)
[df](https://ndarc.med.unsw.edu.au/sites/default/files/ndarc/resources/National_EDRS_%202016_FINALwith%20customs.p)

Specific listing of these alternative alkyl nitrites or the crafting of an entry to ensure clarity of the intent of capturing any volatile alkyl nitrite in S4 would be ideal.

For your consideration – let me know if you want me to provide further information/detail.

Regards, [REDACTED]

[REDACTED]

[REDACTED]

Note: signatory a State/Territory health authority employee