Australian Government
Department of Health
Therapeutic Goods Administration

Notice of final decisions to amend (or not amend) the current Poisons Standard - ACMS #34, Joint ACMS-ACCS #28, ACCS #31

20 December 2021

TGA Health Safety Regulation

Contents

1 Notice of final decisions to amend (or not 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 decisions made by a delegate of the Secretary pursuant to regulation 42ZCZR;
- the reasons for those final decisions; and
- the date of effect of those decisions.

2 Final decisions on proposed amendments referred to the Advisory Committee on Medicines Scheduling (ACMS #34, June 2021)

2.1 Final decisions in relation to amygdalin and hydrocyanic acid

Proposal

The applicant proposed amygdalin be rescheduled from Schedule 10 to Schedule 4 when present in low doses as a natural component of traditional Chinese medicines, with a similar amendment for hydrocyanic acid from Schedule 7 to Schedule 4 in traditional Chinese medicines.

Final decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has made a final decision to confirm the interim decision and amend the current Poisons Standard in relation to amygdalin and hydrocyanic acid as follows:

Index – New Entry

APRICOT KERNELS
cross reference: AMYGDALIN, HYDROCYANIC ACID

Index – Amend Entry

AMYGDALIN
cross reference: APRICOT KERNELS

Schedule 10

HYDROCYANIC ACID
cross reference: CYANIDES, APRICOT KERNELS

Schedule 7
Schedule 4
Appendix F, Part 3
Appendix G
Appendix J, Part 2

Materials considered

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

- The application to amend the current Poisons Standard with respect to amygdalin and hydrocyanic acid;
- 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 Advisory Committee on Medicines Scheduling (ACMS meeting #34);
- 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 Australian Health Ministers' Advisory Council's 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 confirm my interim decision to not amend the current Poisons Standard with respect to amygdalin and hydrocyanic acid. My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the material detailed in the interim decision and the two public submissions received before the second closing date in response to the call for further submissions published on 30 September 2021 under regulation 42ZCZP of the Regulations.

I have considered the written public submission received from Complementary Medicines Australia (CMA), which is opposed to the interim decision. The CMA submission states that amygdalin is a naturally occurring contaminant in naturally sourced materials that are permitted for use in herbal medicines, and therefore the zero tolerance for amygdalin established by its entry in Schedule 10 of the Poisons Standard is not practicable. The CMA submission reasserts that there are established safety margins for the presence of amygdalin, and that the scheduling of amygdalin (which was established prior to the determination of these safety margins) should be updated to reflect these assessments. The CMA submission also refers to European Food Safety Authority (EFSA) and WHO recommendations on the content of amygdalin in foods and extrapolates these to recommend amendments to the scheduling of amygdalin.

I have considered the points raised in the CMA submission but, consistent with the interim decision, I remain unconvinced that the risks associated with the presence of amygdalin in traditional Chinese medicines are outweighed by any health benefits, as outlined in the scheduling factors for a Schedule 10 substance. The potential for toxic effects even at low doses of amygdalin, coupled with the hazards presented to children and the evidence that this substance is misused in the treatment of cancer and other serious health conditions, supports the decision that the scheduling for amygdalin and hydrocyanic acid should remain unchanged.

I note that the second written public submission received in response to the interim decision, from the Pharmacy Guild of Australia, was supportive of the decision for the reasons outlined in the interim decision.

For clarity, I have decided to retain the new cross reference to apricot kernels, as outlined in the interim decision.

Implementation date

1 February 2022

2.2 Final decision in relation to bufexamac

Proposal

A Delegate of the Secretary of the Commonwealth Department of Health (the Delegate) proposed to amend the Schedule 4 entry for bufexamac to remove the existing exceptions for suppositories and dermal use.

Final decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has, in relation to the proposed amendment, made a final decision to amend the scheduling of bufexamac in the current Poisons Standard as follows:

Schedule 4 – Amend Entry

BUFEXAMAC ~~**except:**~~

~~a) in preparations for dermal use containing 5 per cent or less of bufexamac; or~~

~~b) in suppositories.~~

Index

BUFEXAMAC

Schedule 4

Materials considered

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

- The two public submissions, both including a written component, received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;
- The advice received from the Advisory Committee on Medicines Scheduling (ACMS meeting #34);
- Subsection 52E(1) of the *Therapeutic Goods Act 1989,* in particular (a) the risks and benefits of the use of a substance; (b) the purpose for which a substance is to be used and the extent of use of a substance; (c) the toxicity 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 (SPF 2018);
- The Scheduling handbook: Guidance for amending the Poisons Standard;
- A recent TGA safety alert regarding first aid creams containing bufexamac.

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

I have made a final decision to confirm my interim decision to amend the current Poisons Standard with respect to bufexamac. My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the material detailed in the interim decision and I note that no written responses were received after the second call for public submissions, published on 20 July 2021 under regulation 42ZCZP of the Regulations.

Implementation date

1 February 2022

2.3 Final decision in relation to ibuprofen

Proposal

The applicant proposed that the Schedule 2 entry for ibuprofen be amended to include a modified release (MR) dosage form, each dosage unit containing 600 mg (specifically) of ibuprofen in a primary pack containing not more than 16 dosage units, when labelled:

- with a recommended daily dose of 1200 mg or less of ibuprofen; and
- not for the treatment of children under 12 years of age.

Final decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has, in relation to the proposed amendment, made a final decision to not amend the scheduling of ibuprofen in the current Poisons Standard.

Materials considered

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

- The application to amend the current Poisons Standard with respect to ibuprofen;
- The six 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 Advisory Committee on Medicines Scheduling (ACMS meeting #34);
- The five public submissions, including two written 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) the risks and benefits of the use of a substance; (b) the purpose 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 (SPF 2018);
- 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 confirm my interim decision to not amend the current Poisons Standard with respect to ibuprofen. My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the material detailed in the interim decision and the responses received after the second call for public submissions, published on 20 July 2021 under regulation 42ZCZP of the Regulations. I note that the written public submissions were weighted equally in support and against the interim decision. Despite the argument raised in opposition that labelling and packaging will adequately control the

potential risks of misuse or overdose, I find that the risks of adverse events and concerns of inappropriate use associated with the modified-release presentation require the intervention of a pharmacist, consistent with the Scheduling Factors of a Schedule 3 classification.

2.4 Final decision in relation to oral contraceptive substances

Proposal

Two applicants proposed the creation of new Schedule 3 entries for substances used in oral contraceptive pills currently included in Schedule 4 of the Poisons Standard. A brief summary of each application is given below:

- Application A: Proposal for the creation of a new Schedule 3 entry for ethinylestradiol and norethisterone, and expansion of the current Schedule 3 entry for levonorgestrel. Under the proposal, the three substances would also be subject to requirements set out in Appendix M. Advertising would also be permitted via inclusion in Appendix H.
- Application B: Proposal for the creation of a new Schedule 3 entry for ethinylestradiol, norethisterone, cyproterone, desogestrel, dienogest, drospirenone, estradiol, gestodene, mestranol and nomegestrol, and expansion of the current Schedule 3 entry for levonorgestrel. Under the proposal, the eleven substances would also be subject to requirements set out in Appendix M.

Final decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has made a final decision to confirm the interim decision and not amend the current Poisons Standard in relation to oral contraceptive substances.

Materials considered

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

- The two applications to amend the current Poisons Standard with respect to oral contraceptive substances;
- The 27 public submissions, 23 of which included 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 Scheduling (ACMS #34);
- The 24 public submissions, 20 of which included a written component, received in response to the interim decision consultation under regulation 42ZCZP of the Regulations;
- Subsection 52E(1) of the *Therapeutic Goods Act 1989* (the **Act**), 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; and (f) any other matters that the Secretary considers necessary to protect public health;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); and
- The Scheduling handbook: Guidance for amending the Poisons Standard; and
- A medicines safety update on the risk of venous thromboembolism associated with oral contraceptive use.

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

I have made a final decision to confirm my interim decision to not amend the current Poisons Standard with respect to the eleven oral contraceptive substances that were the subject of the two applications. In making my final decision, I have taken into account the material detailed in the interim decision and the 24 public submissions received in response to the call for further submissions published on 30 September 2021 under regulation 42ZCZP of the Regulations. I note that the majority of written submissions were in opposition to the interim decision. Twenty (20) written responses were received, three supportive and 17 opposed.

I note that many public submissions expressed concern that the interim decision not to down-schedule these oral contraceptive substances from Schedule 4 to Schedule 3 would ban, increase restrictions, or otherwise reduce access to oral contraceptives, which would greatly impact the mental health of many women. I would like to reiterate that the decision to confirm my interim decision not to down-schedule these substances will not alter the current scheduling, restrictions or access to these substances from their current availability.

I have carefully considered the public health issues raised by professional peak bodies involved in women's health and I agree with their view that the benefits of oral contraceptives were not fully characterised in the interim decision. I acknowledge that oral contraceptives provide additional health benefits to women by lowering the risk of ovarian, endometrial and colorectal cancer[1,2,3]. In my consideration of this proposal, I have taken into account section 52E(1)(a) and (b) of the Act, and in doing so I reaffirm my position that, on balance, these benefits to individual and public health do not outweigh the seriousness and frequency of adverse effects and interactions that occur with the use of the oral contraceptive substances.

I agree that timely and appropriate access to contraception forms an integral part of a woman's right to reproductive and sexual health. Several written responses raised concerns regarding barriers in the access of oral contraceptives at the current scheduling level, and the relationship between these barriers to access and the high rate of unplanned or unintended pregnancy in Australia. In accordance with section 52E(1)(a) of the Act, and to reiterate my statement in the interim decision, I consider that while the proposed changes would address some barriers affecting access to ongoing supply of oral contraceptives, I do not feel the benefits of supply from a pharmacist outweigh the risks to women's health when supplied without consultation from a medical practitioner. In considering section 52E(1)(b) of the Act, I also note that timely access to emergency supply provisions of oral contraceptive substances are currently available to women in the absence of a medical practitioner or prescription via pharmacies. The National Health Continued Dispensing Determination 2012[4] allows for supply of oral contraceptives at a subsidised cost via the Pharmaceutical Benefits Scheme (PBS) and state and territory legislation allows for emergency ongoing supply of oral contraceptives by a pharmacist. Alternative mechanisms suggested to increase access to oral contraceptives, such as the extending of prescribing rights to nurse practitioners or prolonging the validity of prescriptions beyond 12 months, fall outside the remit of the Poisons Standard.

I refer to the submissions made by the Pharmacy Guild of Australia (the **Guild**) and Pharmaceutical Society of Australia (PSA) in which these peak bodies detailed their experience in creating national professional guidance documentation for the supply of other Schedule 3 substances. This experience was presented to address the concerns regarding a lack of clarity

[1] Wentzensen N & Berrington de Gonzalez A (2015). The Pill's gestation: from birth control to cancer prevention, The Lancet Oncology, 16(9): 1004-1006

[2] https://www.canceraustralia.gov.au/cancer-types/endometrial-cancer/awareness/medical-history-and-medications/oral-contraceptive-pill

[3] https://www.canceraustralia.gov.au/affected-cancer/cancer-types/ovarian-cancer/what-are-risk-factors-ovarian-cancer

[4] National Health (Continued Dispensing) Determination 2012 www.legislation.gov.au/Details/F2020C00918

surrounding the implementation and enforcement of the proposed Appendix M entry outlined in the interim decision. I have carefully considered the Guild's argument that the proposed Appendix M entry (stipulating a maximum supply of 3-4 months) would mitigate concerns about risk factors changing over time by increasing the frequency of clinical review and follow-up. I acknowledge the clinical capabilities of pharmacists, who have provided emergency progesterone-only contraception since 2004 and have performed an important role in ensuring public health through provision of vaccination services. However, regular reassessment by a medical practitioner allows routine preventive health screening (such as cervical smears, pelvic exams, clinical breast exams and screening for sexually transmitted infections) as well as regular review of the suitability of continued oral contraception compared to other forms of long-acting reversible contraception, which are not available without a prescription. I have weighed the severity and frequency of adverse effects, alongside the seriousness of potential drug-drug and drug-condition interactions without medical practitioner intervention and follow-up against the benefits of increased access. In doing so, I remain of the firm view that medical practitioner involvement is required and the current scheduling of oral contraceptive substances under Schedule 4 remains appropriate.

I acknowledge the submission provided by Family Planning NSW that over-the-counter access to oral contraceptives occurs elsewhere than in New Zealand. In July 2021 desogestrel-only containing contraceptive products were made available without a prescription in the UK[5] and some United States (US) jurisdictions to allow pharmacist-only dispensing of oral contraceptives[6]. In most comparable overseas jurisdictions such as the UK, the US[7], Canada[8], and the EU[9],[10] all other oral contraceptive substances are formally designated as prescription only.

Creation of a Schedule 3 entry for oral contraceptive substances carries with it requirements for not only clinical screening, assessment, and follow-up, but record-keeping and information sharing between doctors and pharmacists. I consider that benefits are not available in the general community pharmacy setting. In making my final decision I must consider under section 52E(1)(f) the potential impacts to public health of the application. I reiterate that the Poisons Standard is adopted by states and territories through jurisdictional legislation, which may differ in enactment and scope. In the case of oral contraceptive substances, I feel that several factors outweigh the benefits of access to oral contraceptives without the requirement for a prescription at this time. These factors are the clear requirement for adequate training and accreditation programs that can be accessed readily by pharmacists without a cost imposition, taken together with the risks to health of inconsistent communication between medical practitioners and pharmacists.

In conclusion, having taken into account the interim decision submissions, my consideration of the Scheduling Policy Framework and the matters under section 52E(1) remain unchanged from my interim decision. I find that the requirement for medical practitioner intervention in the prescribing of oral contraceptive substances remains consistent with the Scheduling Factors for Schedule 4 at this time.

[5] Medicines and Healthcare Products Regulatory Agency (MHRA), https://www.gov.uk/government/news/first-progesterone-only-contraceptive-pills-to-be-available-to-purchase-from-pharmacies

[6] American College of Obstetricians and Gynaecologists, https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2019/10/over-the-counter-access-to-hormonal-contraception

[7] US Food and Drug Administration (FDA) https://www.accessdata.fda.gov/scripts/cder/daf/

[8] Health Canada, https://health-products.canada.ca/dpd-bdpp/index-eng.jsp

[9] Ibis Reproductive Health, Oral Contraceptives Over-the-Counter Working Group, https://ocsotc.org/world-map/

[10] Grindlay K et al. (2013). Prescription requirements and over-the-counter access to oral contraceptives: a global review, Contraception, 88: 91-96

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

3.1 Final decision in relation to ethanol and isopropanol in hand sanitisers

Proposal

The applicant(s) proposed the creation of new Schedule 6 entries for ethanol and isopropanol when present in hand sanitiser preparations at concentrations greater than 50%, with exceptions when meeting certain requirements for packaging, labelling, formulation and physical properties.

Neither substance is currently captured by any Schedule entry, although ethanol is listed in Appendix B (substances considered not to require control by scheduling) under the alternative name ethyl alcohol.

Final decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has, in relation to the proposed amendment, made a final decision to not amend the scheduling for ethanol and isopropanol in hand sanitisers in the current Poisons Standard.

Materials considered

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

- The applications to amend the current Poisons Standard with respect to ethanol and isopropanol;
- The six 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, including one written submission, 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 Australian Health Ministers' Advisory Council's 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 confirm my interim decision not to amend the current Poisons Standard in relation to ethanol (ethyl alcohol) and isopropanol. My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the material detailed in the interim decision and the responses received after the second call for public submissions, published on 13 October 2021 under regulation 42ZCZP of the Regulations. I note that the written public submission received during the second round of consultation was fully supportive of the interim decision.

3.2 Final decision in relation to methanol in hand sanitisers

Proposal

The applicant proposed the creation of a new Schedule 10 entry for methanol when used in hand sanitiser preparations at concentrations greater than 2%. The substance is currently captured in Schedule 6 at concentrations greater than 10%, Schedule 5 at concentrations between 2% and 10%, and is not included in a schedule at concentrations below 2%.

Final decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has, in relation to the proposed amendment, made a final decision to amend the scheduling for methanol and create a new definition for hand sanitisers in the current Poisons Standard as follows:

Schedule 10 – New Entry

METHANOL in hand sanitiser preparations containing more than 5 per cent methanol.

Schedule 6 – Amend Entry

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

a) when included in Schedule 5; or

b) when included in Schedule 10; or

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

Schedule 5 – Amend Entry

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

a) when included in Schedule 10; or

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

c) when methanol is present only as a denaturant of ethanol.

Appendix E, Part 2

Poison	First Aid Instructions
METHANOL • above 10 per cent • 10 per cent or less	 **A, G3** **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)

Index – Amend Entry

METHANOL

Schedule 10
Schedule 6
Schedule 5
Appendix E, Part 2
Appendix F, Part 3

PART 1 (INTERPRETATION) – New Entry

"**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.

Materials considered

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

- The application to amend the current Poisons Standard with respect to methanol;

- The five 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, including one written submission, 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 Australian Health Ministers' Advisory Council's 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 methanol and the creation of a definition for hand sanitiser preparations in the Poisons Standard. In making my final decision, I have taken into account the material detailed in the interim decision and the responses received after the second call for public submissions, published on 13 October 2021 under regulation 42ZCZP of the Regulations.

I note that the written public submission received during the second round of consultation from Accord Australasia was supportive of the interim decisions regarding a Schedule 10 entry for hand sanitiser preparations containing more than 5% methanol, as this guards against the high methanol content hand sanitisers that are found in USA, EU and Mexico. Furthermore, Accord was supportive of the new definition for 'Hand sanitiser preparation'.

I have considered the submission from Accord to include an exception when methanol is present only as a denaturant of ethanol as an amendment to the Schedule 5 entry. As stated by the Centre for Disease Control in their first aid instructions for methanol poisoning,[11] ethanol can be used to limit the toxicity of methanol. To recognise the potential benefit, low risk and legitimate mitigation of methanol toxicity by ethanol in combination products, I have decided to implement an additional amendment to the Schedule 5 entry for methanol to exempt methanol from Schedule 5 when present in a preparation only as a denaturant of ethanol.

Implementation date

1 February 2022

3.3 Final decision in relation to eugenol

Proposal

A Delegate of the Secretary of the Commonwealth Department of Health (the Delegate) proposed to amend the Schedule 6 entry for eugenol to reduce concentration cut-offs for cosmetic preparations intended for skin contact.

[11] https://www.cdc.gov/niosh/ershdb/emergencyresponsecard_29750029.html

Final decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has, in relation to the proposed amendment, made a final decision to not amend the scheduling for eugenol in the current Poisons Standard.

Materials considered

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

- A human health tier II assessment for eugenol, published by AICIS (30 June 2020);
- The 11 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, including one written submission, 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; and (f) any other matters that the Secretary considers necessary to protect public health;
- The Australian Health Ministers' Advisory Council's 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 confirm my interim decision to not amend the current Poisons

Standard in relation to eugenol. My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the material detailed in the interim decision and the responses received after the second call for public submissions, published on 13 October 2021 under regulation 42ZCZP of the Regulations. I note that the written public submission received during the second round of consultation was fully supportive of the interim decision.

4 Final decisions in relation to proposed amendments referred to the Advisory Committee on Chemicals Scheduling (ACCS #31, June 2021)

4.1 Final decisions in relation to 2-amino-5-methylphenol

Final decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has made a final decision to confirm the interim decision and amend the current Poisons Standard in relation to 2-amino-5-methylphenol as follows:

Schedule 10 – New Entry

2-AMINO-5-METHYLPHENOL in preparations for cosmetic use.

Schedule 7 – New Entry

2-AMINO-5-METHYLPHENOL **except** when included in Schedule 10.

Index – New Entry

2-AMINO-5-METHYLPHENOL

Schedule 10
Schedule 7

Materials considered

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

- A human health tier II assessment for 2-amino-5-methylphenol, published by AICIS (26 October 2018);
- The two public submissions, both 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 Chemicals Scheduling (ACCS #31);
- The public submission 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; and (c) the toxicity of a substance;
- The Australian Health Ministers' Advisory Council's 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 confirm my interim decision to amend the current Poisons Standard with respect to 2-amino-5-methylphenol. My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the

material detailed in the interim decision and the one public submission received before the second closing date in response to the call for further submissions published on 13 October 2021 under regulation 42ZCZP of the Regulations.

I note that the only written public submission received in response to the interim decision was from Accord Australasia, who did not oppose the interim decision.

Implementation date

1 February 2022

4.2 Final decision in relation to 6-methoxy-N2-methyl-2,3-pyridinediamine

Final decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has made a final decision to confirm the interim decision and amend the current Poisons Standard in relation to 6-methoxy-N2-methyl-2,3-pyridinediamine as follows:

Schedule 6 – New Entry

6-METHOXY-N2-METHYL-2,3-PYRIDINEDIAMINE **except** when used in oxidative or non-oxidative hair dyes at a concentration of 1.0% or less when the immediate container and primary pack are labelled:

KEEP OUT OF REACH OF CHILDREN, and

WARNING – This product contains ingredients that may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye.

written in letters not less than 1.5mm in height.

Index – New Entry

6-METHOXY-N2-METHYL-2,3-PYRIDINEDIAMINE

Schedule 6

Materials considered

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

- A human health tier II assessment for 6-methoxy-N2-methyl-2,3-pyridinediamine, published by AICIS (8 March 2019);
- The European Chemicals Agency (ECHA) substance infocard for 6-methoxy-N2-methylpyridine-2,3-diamine dihydrochloride;
- The two public submissions, both 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 Chemicals Scheduling (ACCS #31);

- The public submission 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; and (f) any other matters that the Secretary considers necessary to protect public health;
- The Australian Health Ministers' Advisory Council's 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 confirm my interim decision to amend the current Poisons Standard with respect to 6-methoxy-N2-methyl-2,3-pyridinediamine. My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the material detailed in the interim decision and the one public submission received before the second closing date in response to the call for further submissions published on 13 October 2021 under regulation 42ZCZP of the Regulations.

I note that the only written public submission received in response to the interim decision was from Accord Australasia, who did not oppose the interim decision. A longer transition period has been implemented to allow time for reformulation and labelling changes.

Implementation date

1 June 2022

4.3 Final decisions in relation to lead acetates

Final decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has made a final decision to confirm the interim decision and amend the current Poisons Standard in relation to lead acetates as follows:

Schedule 10

LEAD COMPOUNDS in paints, tinters, inks or ink additives **except** in preparations containing 0.009 per cent or less of lead calculated on the non-volatile content of the paint, tinter, ink or ink additive.

Schedule 6 – Amend Entry

LEAD COMPOUNDS **except**:

a) when included in Schedule 4 ~~or 5~~;

b) in paints, tinters, inks or ink additives;

c) in preparations for cosmetic use containing 100 mg/kg or less of lead;

d) in pencil cores, finger colours, showcard colours, pastels, crayons, poster paints/colours or coloured chalks containing 100 mg/kg or less of lead; or

e) in ceramic glazes when labelled with the warning statement:

CAUTION – Harmful if swallowed. Do not use on surfaces which contact food or drink.

written in letters not less than 1.5 mm in height.

Schedule 5 – Delete Entry

~~LEAD COMPOUNDS in preparations for use as hair cosmetics.~~

Appendix E, Part 2

Poison	Standard statements
LEAD COMPOUNDS	
• in hair cosmetics	A
• in other preparations	A, S1
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). **S1** – If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water.	

Appendix F, Part 3

Poison	Warning statements	Safety direction
Glazing preparations containing LEAD COMPOUNDS.	**50** - Unless adequately fired, utensils glazed with this preparation must not be used as containers for food or beverages; to do so may cause lead poisoning.	
LEAD COMPOUNDS		
c) in hair cosmetics.	**25** - Do not use on broken skin. Wash hands thoroughly after use.	
d) when in Schedule 6.		**1** - Avoid contact with eyes. **4** - Avoid contact with skin. **8** - Avoid breathing dust (or) vapour (or) spray mist.

Index – Amend Entry

LEAD COMPOUNDS
cross reference: GLAZING PREPARATIONS, PRINTING INKS or INK ADDITIVES, SELENIUM

Schedule 10
Schedule 6
~~Schedule 5~~
Appendix E, Part 2
Appendix F, Part 3
Appendix F, Part 3 (glazing preparations)

Materials considered

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

- A human health tier III assessment for lead acetates, published by AICIS (28 June 2020);
- The three public submissions, two 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 Chemicals Scheduling (ACCS #31);
- 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; and (f) any other matters that the Secretary considers necessary to protect public health;
- The Australian Health Ministers' Advisory Council's 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 confirm my interim decision to amend the current Poisons Standard with respect to lead acetates. My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the material detailed in the interim decision and the public submissions received before the second closing date in response to the call for further submissions published on 13 October 2021 under regulation 42ZCZP of the Regulations.

I have noted the submission from the Australian Competition and Consumer Commission (ACCC), who recommended that the final decision in this matter be expanded to further reduce access to, or otherwise completely eliminate the presence of, lead acetates in hair cosmetic products. I acknowledge the concerns raised in this submission, however on consideration of the balance of scheduling factors at this time I have decided to confirm the interim decision. Moreover, the use of lead in a range of products could be addressed in a future application. I have also noted the other written public submission regarding this decision that was received from Accord Australasia, who did not oppose the interim decision.

I have included the term "glazing preparations" in the index entry for clarification of the two Appendix F entries. A longer transition period has been implemented to allow industry time to meet the storage and labelling requirements for a Schedule 6 poison under the Poisons Standard.

Implementation date

1 June 2022