

Therapeutic Goods Administration

Consultation on the proposed amendments to the Poisons Standard referred to the June 2020 meetings of ACMS #31 and Joint ACMS-ACCS #25

Submission of the Australasian College of Dermatologists

May 2020

About the Australasian College of Dermatologists

The Australasian College of Dermatologists (ACD) is the sole medical college accredited by the Australian Medical Council for the training and continuing professional development of medical practitioners in the specialty of dermatology. As the national peak membership organisation, the College represents over 550 specialist dermatologist Fellows (FACD) and 100 trainees across the country.

The College is the leading authority in Australia for dermatology, providing information, advocacy and advice to individuals, communities, government and other health stakeholders on dermatological practice.

ACD Response

The Therapeutic Goods Administration (TGA) has called for public submissions on scheduling proposals referred to the June 2020 meeting of the Advisory Committee on Medicines Scheduling (ACMS #31) and Joint Advisory Committee on Medicines and Chemical Scheduling (Joint ACMS-ACCS #25).

The ACD welcomes the opportunity to put forward this submission on the proposed amendments to scheduling of:

- 1.3 Clotrimazole, an antifungal medication
- 2.3 Methylisothiazolinone and Methylchloroisothiazolinone, preservatives used in e.g. paints, cosmetics and household products.
- 2.4 Isothiazolinones, a group of synthetic biocides/preservatives found in many skin and hair products as well as industrial products.

The ACD **supports** the amendments to the Poisons Standard, as proposed, for clotrimazole, methylisothiazolinone and methylchloroisothiazolinone and isothiazolinones.

Appendix: Scheduling proposals for clotrimazole, methylisothiazolinone and methylchloroisothiazolinone and isothiazolinones group

1.3 Clotrimazole

Clotrimazole is an antifungal medication currently listed under Schedule 6, Schedule 4, Schedule 3, Appendix F, Part 3 and Appendix H of the Poisons Standard.

The Applicant proposes to make clotrimazole 1% vaginal cream directly available to consumers from pharmacies without the need to consult a doctor or pharmacist.

Proposed scheduling:

Schedule 3 - Amend Entry

CLOTRIMAZOLE in preparations for vaginal use **except when included in Schedule 2.**

Schedule 2 - Amend Entry

CLOTRIMAZOLE for human use:

- a) in preparations for vaginal use containing 1 per cent or less of clotrimazole; or
- b) in dermal preparations; and
- c) for application to the nails.

except in preparations for the treatment of tinea pedis.

Appendix F, Part 3

CLOTRIMAZOLE in vaginal preparations when included in **Schedule 2 or Schedule 3** – Warning statements - 54,63,64,66

2.3 Methylothiazolinone and methylchloroithiazolinone

Methylothiazolinone and Methylchloroithiazolinone are preservatives currently listed under Schedule 6 and Appendix F, Part 3 of the Poisons Standard. They are isothiazolinones which are known skin sensitisers and there is a high skin sensitisation incidence and prevalence around the world.

The proposed cut-off value of 0.05 per cent for preparations not intended for direct application to the skin, takes into account the minimum patch test concentrations used to elicit sensitisation reactions in patients with allergies to isothiazolinones. The proposed warning statement is intended to allow persons who know they have previously been sensitised to isothiazolinones to avoid elicitation by taking additional care or by choosing a different product.

Proposed scheduling:

Schedule 6 - Amend Entry

METHYLISOTHIAZOLINONE **except:**

- a. in rinse-off cosmetic preparations or therapeutic goods intended for topical rinse-off application containing 0.0015 per cent or less of methylothiazolinone; or
- b. in other preparations that are not intended for direct application to the skin containing ~~0.1~~ 0.05 per cent or less of ~~methylothiazolinone~~ isothiazolinones in total when labelled with the statements:

CONTAINS ISOTHIAZOLINONES

REPEATED EXPOSURE MAY CAUSE SENSITISATION

(written in letters not less than 1.5 mm in height)

Schedule 6 - Amend Entry

METHYLCHLOROISOTHIAZOLINONE **except:**

- a. in rinse-off cosmetic preparations or therapeutic goods intended for topical rinse-off application containing 0.0015 per cent or less of methylchloroithiazolinone and methylothiazolinone in total; or
- b. in other preparations that are not intended for direct application to the skin containing ~~0.1~~ 0.05 per cent or less of ~~methylchloroithiazolinone and methylothiazolinone in total.~~ isothiazolinones in total when labelled with the statements:

CONTAINS ISOTHIAZOLINONES

REPEATED EXPOSURE MAY CAUSE SENSITISATION

(written in letters not less than 1.5 mm in height)

2.4 Isothiazolinones

An isothiazolinones group entry does not exist in the current Poisons Standard. Five isothiazolinones are separately scheduled in the current Poison Standard. These are:

- Methylisothiazolinone, currently listed in: Schedule 6; Appendix F, Part 3
- Methylchloroisothiazolinone, currently listed in: Schedule 6; Appendix F, Part 3
- 4,5-dichloro-2-n-octyl-3(2H)-isothiazolone, currently listed in: Schedule 6
- Octhilione, currently listed in Schedule 6
- Benzisothiazolinone and 2-methyl-1,2-benzisothiazol-3-one, not specifically scheduled in the current Poisons Standard.

Proposed scheduling

Schedule 6 - New Entry

ISOTHIAZOLINONES not elsewhere specified in these Schedules, **except** in preparations that are not intended for direct application to the skin containing 0.05 per cent or less of isothiazolinones in total and labelled with the statements:

CONTAINS ISOTHIAZOLINONES

REPEATED EXPOSURE MAY CAUSE SENSITISATION

(written in letters not less than 1.5 mm in height)

Schedule 6 - Delete Entry

~~OCTHILINONE except in paints, jointing compounds and sealants containing 1 per cent or less of octhilione calculated on the non-volatile content.~~

Schedule 6 - Delete Entry

~~4,5-DICHLORO-2-N-OCTYL-3(2H)-ISOTHIAZOLONE.~~



THE AUSTRALASIAN COLLEGE OF DERMATOLOGISTS

PO Box 3785 Rhodes NSW 2138 Australia
Suite 2A Level 2 9 Blaxland Road Rhodes NSW 2138 Australia
Telephone +61 2 8765 0242 | Australia Only 1300 361 821
Facsimile +61 2 9736 2194 | Email admin@dermcoll.edu.au
Website www.dermcoll.edu.au

