

Therapeutic Goods Administration

Consultation on the proposed amendments to the Poisons Standard referred to the Advisory Committee on Chemicals Scheduling (ACCS #27): Arbutin, Picramic Acid

Submission of the Australasian College of Dermatologists

January 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.

Executive summary

The Therapeutic Goods Administration (TGA) has called for public submissions on scheduling proposals referred to the March 2020 meeting of the Advisory Committee on Chemicals Scheduling (ACCS #27). The ACD welcomes the opportunity to put forward this submission on:

1. The addition of arbutin, a naturally occurring β -D glucopyranoside, found in foods, over-the-counter drugs, herbal and dietary supplements and most commonly, an active ingredient in skincare and cosmetic products as a lightening agent for the prevention of melanin formation.
2. The addition of picramic acid (including its salts), reported to be used in hair dyes in Australia.

In summary, the College supports the addition of arbutin and picramic acid (including its salts) to the Poisons Standard as proposed.

1. Arbutin

Arbutin is not specifically scheduled in the Poisons Standard but is cross referenced to hydroquinone in the index of the Poisons Standard. The risks and benefits of the use of arbutin in cosmetic and topical dermal therapeutic products have not been considered by the Australian regulatory system but have been considered by the European Commission's Scientific Committee on Consumer Safety (SCCS).

The proposed amendments to the Poisons Standard are:

Schedule 6 - New entries

ARBUTIN (ALPHA) except:

- a. in cosmetic face creams containing 2 per cent or less alpha-arbutin; or
- b. in cosmetic body lotions containing 0.5 per cent or less alpha-arbutin.

ARBUTIN (BETA) except:

- a. when included in Schedule 4; or
- b. in oral herbal preparations containing 500 mg or less beta-arbutin per recommended daily dose;
or
- c. in cosmetic face creams containing 7 per cent or less beta-arbutin with hydroquinone levels 1 ppm or less.

ARBUTIN (DEOXY OR OTHER DERIVATIVES).

Schedule 4 - New entry

ARBUTIN (BETA) except:

- a. in oral herbal preparations containing 500 mg or less beta-arbutin per recommended daily dose;
or
- b. in cosmetic face creams containing 7 per cent or less beta-arbutin with hydroquinone levels 1 ppm or less.

College response

The College supports the addition of arbutin to the Poisons Standard.

Certain agents such as hydroquinone are used clinically to treat hyperpigmentation conditions and as such, are appropriately scheduled to reflect their safety and tolerability profile and their role in medical management. While skin whitening is common practice in a number of cultures, many other agents used for depigmentation are found in cosmetic products and have not been clinically tested, potentially posing a health risk. An increased regulatory focus to prevent the availability of toxic and/or untested skin whitening ingredients in Australia is supported.

As noted by the NICNAS, arbutin does not meet the definition of a cosmetic due to its inhibitory effect on melanin production.¹ There is insufficient clinical evidence to support its safety and efficacy;² despite this, it is available in Australia in a range of consumer products. The TGA notes that the European Commission's Scientific Committee on Consumer Safety (SCCS) has deemed lower concentrations of arbutin to be safe for cosmetic use. Aligning Australian scheduling to the SCCS is reasonable, in that higher dose preparations which pose greater risks of adverse events, such as contact dermatitis, will be regulated as Schedule 6 or 4 agents as described.

1. Australian Government National Industrial Chemicals Notification and Assessment Scheme. Cosmetics and therapeutic goods. <https://www.nicnas.gov.au/cosmetics-and-soaps/cosmetics-and-therapeutic-goods>. Accessed Jan 2020

2. Hollinger JC; Angra K, Halder RM. Are Natural Ingredients Effective in the Management of Hyperpigmentation? A Systematic Review. J Clin Aesthet Dermatol. 2018 Feb; 11(2): 28–37.

2. Picramic acid (including its salts)

Background

Picramic acid (including its salts) is not specifically scheduled in the current Poisons Standard. These chemicals, reported to be used in hair dyes in Australia, are skin sensitisers and the EU and ASEAN have restricted their use to a concentration of 0.6% to mitigate skin sensitisation risk.

The proposed amendments to the Poisons Standard are:

Schedule 6 - New Entry

PICRAMIC ACID (including its salts) except when used in hair dye products at a concentration of 0.6 per cent or less of picramic acid after mixing under oxidative conditions for use when the immediate container and primary pack are labelled with the following statements:

KEEP OUT OF REACH OF CHILDREN, and

WARNING – This product contains ingredients which may cause skin allergy 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 1.5 mm in height.

Appendix E, Part 1 - New Entry

Standard Statements:

- 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); and
- E1** If in eyes wash out immediately with water.

Appendix F, Part 2 - New Entry

Safety Directions - General:

- 5** Wear protective gloves when mixing or using.

College response

The College supports the addition of picramic acid (including its salts) to the Poisons Standard. The assessment undertaken by NICNAS with regards to the safety and toxicity of this agent is compelling, as is the fairly consistent international regulatory approach. Whilst the prevalence of adverse effects directly attributed to this ingredient in Australia is unknown, its reported presence in hair dyes has implications on consumer safety. Its inclusion in the Poison Schedule and accompanying safety directions are appropriate and supported.



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