

## Response ID ANON-UG6B-V6AE-6

Submitted to Application to amend the Poisons Standard  
Submitted on 2023-07-04 12:59:40

### Applicant's details

1 What is your name?

Enter your full name in the text box below:  
Tan Nguyen

2 What is your email address?

Enter your email address in the box below:  
tan.nguyen@deakin.edu.au

3 What is your phone number?

Phone number:  
+61432715420

4 What is the name of the organisation you are representing for this application?

(Only if applicable):  
Public Health Association of Australia Oral Health Special Interest Group

5 Are you the contact person for this application?

Yes. I will skip the 'Contact person's details' page and proceed to the 'Substance details' page.

### Substance details

1 What is the name of the substance?

Enter each substance on a separate line (only if applicable):.

2 What are the alternative names of the substance?

Enter each alternative name on a separate line (only if applicable):.

3 Is the substance a derivative of any currently scheduled poisons?

Not Answered

If yes, please specify each derivative on a separate line below:.

4 What are the CAS numbers of the substance?

Enter each CAS number on a separate line (only if applicable):.

5 Upload an image of the chemical structure of the substance.

Please upload an image:  
No file uploaded

6 What are the known uses of the substance?

Enter each known use on a separate line (only if applicable):.

7 What are the proposed uses of the substance?

Enter each proposed use on a separate line (only if applicable):.

8 What are the pack sizes of products marketed or supplied in Australia that contain the substance?

Enter each pack size on a separate line (only if applicable):.

9 What are the proposed pack sizes for products that contain the substance?

Enter each pack size on a separate line (only if applicable):

10 In what forms do products containing the substance currently appear in Australia?

Enter each form on a separate line (only if applicable):

11 What are the proposed forms for products containing the substance?

Enter each form on a separate line (only if applicable):

## Purpose of application

1 What title would you like to give to this application?

Enter the main title of your application in the text box below:

Amendment to Schedule 3 for FLUORIDES for human topical use.

2 What type of change to the Poisons Standard are you requesting in this application?

Amend or add entries for a substance already included in the Poisons Standard

3 Provide an overview of your application in plain English (500 words or less).

Enter the description of your proposed request in the text box below:

We are seeking the amendment of Schedule 3 with reference to FLUORIDES for human topical use.

We are seeking an amendment to replace the term "dental" with "health", so that it reads as:

"(iii) in preparations for supply to registered health professionals or by approval of an appropriate authority."

To date, there are long processes to amend authorisations for registered non-dental health practitioners to have obtain and administer fluorides considered Schedule 4 under the Poisons Standards.

Specific to the Victorian context, Aboriginal communities, including children, experience low culturally safe services, racism, fear, and complex administrative process when accessing mainstream services that includes oral healthcare. These barriers are potentially resulting in a relatively low number of Aboriginal children accessing timely preventive and early intervention dental treatment across Victoria in particular communities.

Aboriginal and Torres Strait Islander health practitioners are primary health care professionals who provide high-quality, culturally safe, clinical care services to Aboriginal communities. They have a high level of clinical skills and are trained to work autonomously alongside general practitioners, nurses, midwives, allied health and oral health practitioners in a range of settings.

On 22 February 2022 the Drugs, Poisons and Controlled Substances Amendment (Registered Aboriginal and Torres Strait Islander Health Practitioners) Regulations 2022 were made (1). This was advocated by the community through the Loddon Mallee Aboriginal Reference Group, which was supported by Dental Health Services Victoria and the Victorian Department of Health since 2017.

The above amendment enables suitably trained and registered health practitioners to access to fluorides currently considered Schedule 4 under the Poisons Standard. This will enable broader opportunities to support oral disease prevention at a population health level.

Research has shown it demonstrated effectiveness (2) and cost-effectiveness (3) for the Australian context, when applied to the surfaces of teeth. Some registered non-dental health practitioners already have access including general practitioners, nurse practitioners (NT and WA jurisdictions), and Aboriginal and Torres Strait Islander health practitioners (NT, WA and VIC). Alongside the proposed amendments, registered health practitioners would need to adhere to their scope of practice, including training requirements to expand their scope of practice.

## Amendments to the Schedules of the Poisons Standard

1 In what Schedules of the current Poisons Standard is the substance included?

Schedule 3

2 What is the current text for the substance as it appears in the Schedules of the Poisons Standard?

(If you have only selected 'Not in any Schedule' in the previous question, you do not have to answer this question):

FLUORIDES for human topical use:

(a) in liquid preparations containing 5500 mg/kg or less of fluoride ion, in a container with a child-resistant closure except when included in or expressly excluded from Schedule 2; or

(b) in non-liquid preparations containing 5500 mg/kg or less of fluoride ion except:

(i) in preparations for therapeutic use containing 1500 mg/kg or less of fluoride ion and, when containing more than 1000 mg/kg fluoride ion, compliant with the requirements of the required advisory statements for medicine labels; or

(ii) in preparations for non-therapeutic use containing 1500 mg/kg or less of fluoride ion and, when containing more than 1000 mg/kg fluoride ion, labelled with warnings to the following effect:

(A) Do not swallow; and

(B) Do not use [this product/name of product] in children six years of age or less; or

(iii) in preparations for supply to registered dental professionals or by approval of an appropriate authority.

3 In what Schedules of the Poisons Standard do you propose the substance to be included?

## Schedule 3

### 4 What text are you proposing for the substance in the Schedules and Index of the Poisons Standard?

(Only if applicable):

Schedule 3 - Amend Entry

FLUORIDES for human topical use:

(a) in liquid preparations containing 5500 mg/kg or less of fluoride ion, in a container with a child-resistant closure except when included in or expressly excluded from Schedule 2; or

(b) in non-liquid preparations containing 5500 mg/kg or less of fluoride ion except:

(i) in preparations for therapeutic use containing 1500 mg/kg or less of fluoride ion and, when containing more than 1000 mg/kg fluoride ion, compliant with the requirements of the required advisory statements for medicine labels; or

(ii) in preparations for non-therapeutic use containing 1500 mg/kg or less of fluoride ion and, when containing more than 1000 mg/kg fluoride ion, labelled with warnings to the following effect:

(A) Do not swallow; and

(B) Do not use [this product/name of product] in children six years of age or less; or

(iii) in preparations for supply to registered health professionals or by approval of an appropriate authority.

### Detailed claims against the requirements of the scheduling criteria

a What are the risks and benefits associated with the use of the substance?

Risk and Benefits (52E):

b What are the purposes for which the substance is to be used and the extent of use of the substance?

Purpose and extent of substance use:

c What is the toxicity of the substance?

Toxicity of the substance:

d What is the dosage, formulation, labelling, packaging and presentation of the substance?

dosage, formulation, labelling, packaging and presentation:

e What is the potential for the substance to be misused or abused?

Potential for misuse/abuse:

f Are there any other matters that may be necessary to protect public health?

other matters that may be necessary to protect public health:

Would you like to provide any other information to support your application to amend the Poisons Standard?

Further information:

### Claims against the Scheduling Policy Framework (SPF) - scheduling factors

1 How does your proposed amendment of the Poisons Standard align with the scheduling factors?

(Only if applicable):

Consistent with the scheduling factors, the amendment does not enable higher strength fluoride for human topical use to be accessed by the general public. Public protection is enforced through the relevant health practitioner registration standard and guidelines, if the use of higher strength fluoride for human topical use is relevant to their scope of practice.

2 Have you read and understood the scheduling factors and Scheduling Policy Framework?

Yes

### Related documents

### References

Please enter a list of your references in the text box below::

#### References

1. Department of Health. Victoria A. Medicines and poisons – Secretary approvals [Internet]. State Government of Victoria, Australia; [cited 2022 Oct 6]. Available from: <https://www.health.vic.gov.au/drugs-and-poisons/medicines-and-poisons-secretary-approvals>
2. Marinho VCC, Worthington HV, Walsh T, Clarkson JE. Fluoride varnishes for preventing dental caries in children and adolescents. Cochrane Database Syst Rev. 2013 Jul 11;(7):CD002279.
3. Nguyen TM, Tonmukayakul U, Warren E, Cartwright S, Liew D. A Markov cost-effective analysis of biannual fluoride varnish for preventing dental caries in permanent teeth over a 70-year time horizon. Health Promot J Austr. 2020 Apr;31(2):177–83.

#### References:

TGA 2023.zip was uploaded

#### Bibliography and supporting data

Please enter a list of the bibliography or supporting data in the text box below::

#### Bibliography:

No file uploaded

#### Confidentiality including personal information and declaration

##### Confidentiality including personal information

My application contains no material that is confidential.

#### Declaration

Yes:

Yes