

Dental Products (Subsidiary Hazard) Group Standard 2020

HSR002558

GROUP STANDARD

UNDER THE HAZARDOUS SUBSTANCES AND NEW ORGANISMS ACT 1996

Dental Products (Subsidiary Hazard) Group Standard 2020

Pursuant to [section 96B](#) of the Hazardous Substances and New Organisms Act 1996 (the Act), the Environmental Protection Authority issues this Group Standard.

Pursuant to [section 96B](#) of the Act, the Environmental Protection Authority amended this Group Standard on 23 March 2021.

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1. Name of Group Standard

Dental Products (Subsidiary Hazard) Group Standard 2020

HSNO Approval Number

The HSNO Approval Number for this Group Standard is HSR002558.

2. Commencement

This Group Standard comes into force on 30 April 2021.

3. Interpretation

- (1) In this Group Standard, unless the context otherwise requires, words and phrases shall have the meanings given to them in Schedule 2. Any words or phrases that are used but not defined in this Group Standard but that are [defined in the Act](#) have the same meaning as in the Act.
- (2) In this Group Standard, reference to a hazard classification means a reference to the specified hazard classification as set out in the Hazardous Substances (Hazard Classification) [Notice](#) 2020.

4. Scope of Group Standard

Substances covered by Group Standard

- (1) This Group Standard applies to hazardous substances under [section 96B\(2\)\(a\), \(b\) and \(c\)](#) of the Act.
- (2) This Group Standard applies to solid or liquid substances that are imported or manufactured for use as a dental product.
- (3) A substance referred to in subclause (2) must have one or more of the following (but only the following) hazard classifications:
 - (a) acute oral toxicity Category 4:
 - (b) acute dermal toxicity Category 4:
 - (c) acute inhalation toxicity Category 4:
 - (d) skin irritation Category 2:
 - (e) serious eye damage Category 1:
 - (f) eye irritation Category 2:
 - (g) respiratory sensitisation Category 1:
 - (h) skin sensitisation Category 1:
 - (i) germ cell mutagenicity Category 1 or Category 2:

- (j) reproductive toxicity Category 1 or Category 2:
- (k) effects on or via lactation:
- (l) specific target organ toxicity – single exposure Category 1, Category 2 or Category 3:
- (m) specific target organ toxicity – repeated exposure Category 1 or Category 2:
- (n) aspiration hazard Category 1:
- (o) hazardous to the aquatic environment acute Category 1:
- (p) hazardous to the aquatic environment chronic Category 1, Category 2, Category 3 or Category 4.

Substances excluded from Group Standard

- (4) This Group Standard excludes any substance if it contains—
 - (a) asbestos; or
 - (b) a chemical that:
 - (i) is a persistent organic pollutant within the definition in [section 2](#) of the Act; or
 - (ii) exhibits the characteristics of a persistent organic pollutant as set out in paragraph 1 of Annex D to [Schedule 1AA](#) of the Act.
- (5) This Group Standard excludes cosmetic products.
- (6) This Group Standard excludes any substance that contains a chemical that is a mutagen or reproductive toxicant that is not listed on the [Inventory of Chemicals](#), unless—
 - (a) the new mutagen or reproductive toxicant is used to completely replace an existing mutagen or reproductive toxicant in the substance; and
 - (b) the new mutagen or reproductive toxicant has a lower hazard classification than the existing mutagen or reproductive toxicant.
- (7) This Group Standard excludes any substance that is a hazardous chemical not listed on the [Inventory of Chemicals](#).
- (8) For the purposes of subclause (7), “chemical” means any element or compound in its natural state or obtained by any production process, including any impurities and any additive necessary to preserve the stability of the chemical but excluding any solvent which may be separated without affecting the stability of the chemical or changing its composition.

5. Conditions of Group Standard

The conditions that specify the obligations and restrictions for substances covered by this Group Standard are set out in Schedule 1.

Advisory Note: In addition to requirements specified in this document, people who are undertaking work in a workplace involving hazardous substances covered by this Group Standard have obligations under the [Health and Safety at Work Act 2015](#).

Schedule 1: Conditions of Group Standard

Part 1 - Compliance with EPA Notices

1. Labelling and advertising

- (1) Substances covered by this Group Standard must comply with the relevant provisions of the Hazardous Substances (Labelling) [Notice](#) 2017.
- (2) In addition to the requirements in subclause (1), for tooth-whitening products containing or releasing less than 7% hydrogen peroxide, the label must have information that is equivalent to the following precautionary statements—
 - (a) **“If irritation develops, discontinue use. If irritation continues, consult a dentist”**;
 - (b) **“Use for longer than 14 days is not recommended except under the supervision of a dentist”**;
 - (c) **“Not recommended for use on children under 16 years of age”**;
 - (d) **“Avoid swallowing”**; and
 - (e) **“Avoid direct contact of the product with gums or eyes”**.
- (3) In addition to the requirements in subclause (1), for oral hygiene products containing or releasing hydrogen peroxide, there must be on the label the precautionary statement—**“If irritation occurs, discontinue use.”**

2. Safety data sheets

Substances covered by this Group Standard must comply with the relevant provisions of the Hazardous Substances (Safety Data Sheets) [Notice](#) 2017.

3. Packaging

Substances covered by this Group Standard must comply with the relevant provisions of the Hazardous Substances (Packaging) [Notice](#) 2017.

4. Disposal

Substances covered by this Group Standard must comply with the relevant provisions of the Hazardous Substances (Disposal) [Notice](#) 2017.

5. Restriction on supply, storage and use

Substances covered by this Group Standard must comply with the relevant provisions of the Hazardous Substances (Hazardous Property Controls) [Notice](#) 2017.

Part 2 - Notification to the Authority

6. Inventory of Chemicals

- (1) When a substance is imported into, or manufactured in, New Zealand after 30 June 2006, the importer or manufacturer must ensure that all hazardous chemicals contained in the substance are listed on the [Inventory of Chemicals](#).
- (2) If that substance contains a hazardous chemical that is not listed on the [Inventory of Chemicals](#), then the importer or manufacturer of the substance must at the time they first import or manufacture the substance, notify the Authority in writing of—
 - (a) the name of the substance; and
 - (b) the HSNO approval number and/or title of the group standard under which the substance is deemed to have been approved; and
 - (c) the name and CAS number of the chemical not listed on the [Inventory of Chemicals](#) that is present in the substance; and
 - (d) the concentration of that chemical in the substance; and
 - (e) the hazardous properties of the chemical, including the provision of the relevant hazard data used to assign the substance to the group standard; and
 - (f) the proposed use of the substance.
- (3) Subclause (2) applies subject to clause 4(6) - (8) of this Group Standard (Scope of Group Standard).

Part 3 - Other Matters

7. Assigning a substance to a group standard

- (1) If an importer or manufacturer considers that this Group Standard applies to the importation or manufacture of a substance, then the importer or manufacturer is responsible for assigning the substance to this Group Standard.
- (2) In order to assign the substance to this Group Standard, the importer or manufacturer must—
 - (a) ensure that the substance complies with clause 4 of this Group Standard (Scope of Group Standard); and
 - (b) keep a record of how it was determined the substance complies with clause 4 of this Group Standard.
- (3) The importer or manufacturer must—
 - (a) ensure that the record contains sufficient information to allow for independent verification that the substance complies with clause 4 of this Group Standard (Scope of Group Standard); and
 - (b) have that record available for inspection.

Part 4 - Restrictions on tooth-whitening products

8. Supply and application of tooth-whitening products

- (1) A person (Person A) may only supply a tooth-whitening product covered by this Group Standard containing or releasing between 7% and less than 8% hydrogen peroxide to—
 - (a) a dentist;
 - (b) a registered oral health practitioner;
 - (c) a non-registered tooth-whitening practitioner;
 - (d) a person who obtains the product for the purpose of supplying the persons in (a) to (c) above; or
 - (e) any other person but only if Person A is:
 - (i) a dentist;
 - (ii) a registered oral health practitioner; or
 - (iii) a non-registered tooth-whitening practitioner who is under the supervision of a dentist.

- (2) A person (Person A) may only apply a tooth-whitening product covered by this Group Standard containing or releasing between 7% and less than 8% hydrogen peroxide to another person if Person A is:
 - (a) a dentist;
 - (b) a registered oral health practitioner; or
 - (c) a non-registered tooth-whitening practitioner.

Schedule 2: Interpretation

Act means the [Hazardous Substances and New Organisms Act 1996](#)

asbestos has the same meaning as in [regulation 3\(1\)](#) of the Health and Safety at Work (Asbestos) Regulations 2016 but does not include substances that contain naturally occurring traces of asbestos

CAS number means [Chemical Abstract Services Registry number](#)

condition means any obligation or restriction imposed upon a substance by a group standard

cosmetic product means any product or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition

dental industry includes providing commercial tooth-whitening services and the sale of tooth-whitening products for non-commercial use

dentist means a person who is registered as a dentist or dental specialist under the [Health Practitioners Competence Assurance Act 2003](#) and holds a current annual practising certificate

dental product means any product manufactured for use in the dental industry and includes but is not limited to any substance used or intended to be used in the diagnosis, maintenance, treatment and prevention of any disease, disorder or condition relating to the orofacial complex and associated structures

GHS has the same meaning as in the Hazardous Substances (Hazard Classification) [Notice 2020](#)

Inventory of Chemicals means an [inventory](#) kept and maintained by the Authority of chemicals known to be present in New Zealand

mutagen means a substance that is a mutagen within the meaning of the GHS

non-registered tooth-whitening practitioner means a person who provides a commercial tooth-whitening service and who is not a dentist or a registered oral health practitioner

oral hygiene product means any substance supplied, offered for supply, or advertised as a product that is intended for use for oral hygiene, including toothpaste and mouthwash

registered oral health practitioner means a person who is registered under the [Health Practitioners Competence Assurance Act 2003](#), and holds a current annual practising certificate, and is not a dentist, and whose scope of practice includes tooth-whitening procedures

reproductive toxicant means a substance that is a reproductive toxicant within the meaning of the GHS

substance means any solid or liquid dental product that is within the scope of clause 4 of this Group Standard (Scope of Group Standard)

tooth-whitening product means any substance supplied, offered for supply, or advertised as a product that whitens teeth but excludes oral hygiene products

tooth-whitening service means the oral application of tooth-whitening products by one person to another person

workplace has the same meaning as in [section 20\(1\)](#) of the Health and Safety at Work Act 2015

Explanatory note

This note is not part of the group standard but is intended to provide guidance to users of the group standard.

- (1) Typical substances covered by this Group Standard include—
 - whitening materials.
- (2) Under the Act, [section 96E\(3\)](#) provides that a hazardous substance to which [section 96B\(2\)\(a\)](#) applies is deemed to have been approved by the Authority under [section 29](#).
- (3) All amendments made under [section 96B](#) to the Dental Products (Subsidiary Hazard) Group Standard 2017 since it was first issued that were still in force before 30 April 2021 have been incorporated into this Group Standard.
- (4) In addition to requirements specified in this document, people who are undertaking work in a workplace involving hazardous substances covered by this Group Standard have obligations under the [Health and Safety at Work Act 2015](#).
- (5) Each of the Labelling, Safety Data Sheets and Packaging [Notices](#) provide that a person relying on this Group Standard will have four years (until 30 April 2025) to comply with the relevant controls under those Notices. Within that time, a person must comply with one of the following:
 - (a) the relevant controls under the Labelling, Safety Data Sheets and Packaging [Notices](#); or
 - (b) the equivalent conditions in the Dental Products (Subsidiary Hazard) Group Standard 2017 in force immediately before 30 April 2021; or
 - (c) the equivalent conditions in the Dental Products (Subsidiary Hazard) Group Standard 2006 in force immediately before 1 December 2017.

All other aspects of this Group Standard apply from 30 April 2021.

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