



Environmental
Protection Authority
Te Mana Rauhi Taiao

Dental Products (Toxic [6.7]) Group Standard 2017 - HSR002560



GROUP STANDARD

UNDER THE HAZARDOUS SUBSTANCES AND NEW ORGANISMS ACT 1996

Dental Products (Toxic [6.7]) Group Standard 2017

Pursuant to clause 5 of Schedule 7 of the Hazardous Substances and New Organisms Act 1996 (the Act), the Environmental Protection Authority has reviewed and, for the purpose of updating, reissues this Group Standard.

Table of Contents

1.	Name of Group Standard.....	1
2.	Commencement	1
3.	Interpretation	1
4.	Scope of Group Standard.....	1
5.	Conditions of Group Standard.....	2
	Schedule 1: Conditions of Group Standard.....	3
	Part 1 - Compliance with EPA Notices	3
1.	Labelling and advertising.....	3
2.	Safety Data Sheets.....	3
3.	Packaging	3
4.	Disposal	3
5.	Restrictions on supply, storage and use.....	3
	Part 2 - Notification to the Authority.....	3
6.	Inventory of Chemicals.....	3
	Part 3 - Other Matters.....	4
7.	Assigning a substance to a group standard	4
	Schedule 2: Interpretation	5
	Explanatory note	6

1. Name of Group Standard

Dental Products (Toxic [6.7]) Group Standard 2017

HSNO Approval Number

The HSNO Approval Number for this Group Standard is HSR002560.

2. Commencement

This Group Standard comes into force on 1 December 2017.

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 the Act.
- (2) In this Group Standard, references to a hazardous property of a substance being equivalent to a specified HSNO hazard classification, means a reference to the specified hazard classification as set out in the Hazardous Substances (Classification) Notice 2017.

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 be either a known or presumed human carcinogen (HSNO 6.7A classification) or suspected human carcinogen (HSNO 6.7B classification).
- (4) In addition to the hazard referred to in subclause (3), a substance may have any of the following (but only the following) hazards:
 - (a) acute toxicity, HSNO 6.1D or 6.1E classification;
 - (b) HSNO 6.1E (aspiration hazard) classification;
 - (c) skin irritancy, HSNO 6.3A or 6.3B classification;
 - (d) eye corrosivity, HSNO 8.3A classification;
 - (e) eye irritancy, HSNO 6.4A classification;
 - (f) respiratory sensitisation, HSNO 6.5A classification;
 - (g) contact sensitisation, HSNO 6.5B classification;
 - (h) mutagenicity, HSNO 6.6A or 6.6B classification;
 - (i) reproductive toxicity, HSNO 6.8A, 6.8B or 6.8C classification;
 - (j) target organ toxicity, HSNO 6.9A or 6.9B classification;
 - (k) ecotoxicity, HSNO class 9.

Substances excluded from Group Standard

- (5) 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.
- (6) This Group Standard excludes cosmetic products.
- (7) This Group Standard excludes any substance that contains a chemical that is a CMR that is not listed on the Inventory of Chemicals, unless—
 - (a) the new CMR is used to completely replace an existing CMR in the substance; and
 - (b) the new CMR has a lower hazard classification than the existing CMR.
- (8) This Group Standard excludes any substance that is a hazardous chemical not listed on the Inventory of Chemicals.
- (9) For the purposes of subclause (8), “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

Substances covered by this Group Standard must comply with the relevant provisions of the Hazardous Substances (Labelling) Notice 2017.

2. Safety Data Sheets

Substances covered by this Group Standard must comply with the relevant provisions of the Hazardous Substances (Safety Data Sheet) 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. Restrictions 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(7) - (9) 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.

Schedule 2: Interpretation

asbestos has the same meaning as in 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

CMR means a substance that is a carcinogen, mutagen or reproductive toxicant when assessed against the criteria for carcinogenicity, mutagenicity and reproductive toxicity set out in the Hazardous Substances (Classification) Notice 2017

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 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

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

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

workplace has the same meaning as in 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) 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.
- (2) Any transitional measures that were in this Group Standard immediately prior to 1 December 2017 but have expired have not been included in this reissued Group Standard.
- (3) All amendments made under section 96B to the Group Standard since it was first issued that are still in force have been incorporated into this reissued 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) A person relying on this Group Standard will have four years (until 1 December 2021) to comply with the Labelling, Safety Data Sheet and Packaging Notices. Within that time, a person may comply with the equivalent conditions in the Group Standard in force immediately before 1 December 2017. All other aspects of this Group Standard apply from 1 December 2017.



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