ERMA ENVIRONMENTAL RISK MANAGEMENT AUTHORITY DECISION

28 June 2011

Application code	ERMA200472
Application Type	Amendment to a group standard
Purpose of the Amendment	To make amendments to the specified Dental Products Group Standards
Applicants	Ministry of Health, the New Zealand Dental Council
Hearing Date	12 April 2011
Considered by	A Committee of the Authority

1 Summary of decision

1.1 Amendments are made to the *Dental Products (Oxidising, [5.1.1]) Group Standard* 2006 and the *Dental Products (Subsidiary Hazard) Group Standard 2006* (the specified Dental Products Group Standards) in accordance with section 96B of the Hazardous Substances and New Organisms Act 1996 (the Act).

1.2 The Committee's decisions with regard to dental products containing or releasing hydrogen peroxide are as follows:

Precautionary information

1.2.1 Tooth-whitening products containing or releasing less than 7% hydrogen peroxide[1] must be labelled with information that is equivalent to the following precautionary statements:

'If irritation develops, discontinue use. If irritation continues, consult a dentist';
'Use for longer than 14 days is not recommended except under the supervision of a dentist';
'Not recommended for use on children under 16 years of age';
'Avoid swallowing'; and
'Avoid direct contact of the product with gums or eyes'.

1.2.2 Tooth-whitening products containing or releasing 7% or more hydrogen peroxide must be accompanied by information that is equivalent to the precautionary statements set out in 1.2.1.

1.2.3 Oral hygiene products containing or releasing hydrogen peroxide must have on the label, the precautionary statement:

If irritation occurs, discontinue use.

[1] This decision relates to products containing or releasing hydrogen peroxide, including carbamide peroxide. The ratio used for conversion of hydrogen peroxide to carbamide peroxide is 1:3.

1.2.4 The Committee notes that the Group Standards include alternative labelling provisions. Amongst these is the option to comply with the relevant current labelling requirements of Australia or other specified countries as an alternative means of compliance to those set out in the relevant labelling conditions in the Group Standards.

Restrictions on sale

1.2.5 Dental products containing or releasing less than 7% hydrogen peroxide may be sold to members of the public by any person.

1.2.6 Tooth-whitening products containing or releasing between 7% and 12% hydrogen peroxide may only be sold to members of the public by:

- a dentist[2];
- a registered oral health practitioner[2]; or
- a non-registered tooth-whitening practitioner who is under the supervision of a dentist.

1.2.7 Tooth-whitening products containing or releasing more than 12% hydrogen peroxide may only be sold to members of the public by:

- a dentist; or
- a registered oral health practitioner who is under the supervision of a dentist.

Restrictions on commercial application procedures

1.2.8 Tooth-whitening products containing or releasing between 7% and 12% hydrogen peroxide may be applied by:

- a dentist;
- a registered oral health practitioner; or
- a non-registered tooth-whitening practitioner.

1.2.9 Tooth-whitening products containing or releasing more than 12% hydrogen peroxide may only be applied by:

- a dentist;
- a registered oral health practitioner who is under the supervision of a dentist; or
- a non-registered tooth-whitening practitioner who is under the supervision of a dentist.

1.2.10 Table 1 summarises the sale and application restrictions for tooth whitening products containing or releasing 7% or more hydrogen peroxide, relevant to specific parties.

[2] Dentists and registered oral health practitioners are regulated under the Health Practitioners Competence Assurance (HPCA) Act 2003

Table 1: Summary of restrictions

Hydrogen peroxide contained or released	Dentist	Registered oral health practitioner	Non-registered tooth-whitening practitioner
Sale (to the public)			
7 – 12%	✓	✓	✓ UNDER DENTIST SUPERVISION
>12%	✓	✓ UNDER DENTIST SUPERVISION	X
Application procedure			
7-12%	✓	✓	✓
>12%	✓	✓ UNDER DENTIST SUPERVISION	✓ UNDER DENTIST SUPERVISION

1.3 The Committee notes that the Ministry of Health[3] has expressed a willingness to "work with the NZCTWA [New Zealand Cosmetic Teeth Whitening Association] to develop an appropriate Guideline(s) for Tooth Whitening."

1.4 The Committee endorses this approach and **recommends** that the Ministry does develop such Guidelines for non-registered tooth-whitening practitioners. These Guidelines could address matters such as health and safety standards, including hygiene and training, as proposed by the Ministry of Health.

1.5 The amendments that implement these decisions have been incorporated into the group standards as set out in **Appendix 2** and **Appendix 3.**

1.6 The amended group standards will be notified in the *Gazette* and will come into force 24 months from the date of notification in the *Gazette*.

2 Consideration

2.1 The applicants' proposals for amendment to the specified dental products group standards are set out in **Appendix 1**, paragraph A1.3.

2.2 In accordance with section 96C, the Committee considered the relevant matters set out in Part 6A of the Act. Specifically, before amending a group standard, the Committee must:

[3] R. Haisman, Ministry of Health, 13 May 2011. Letter to ERMA New Zealand project team

- be satisfied that the group standard is a more efficient and effective way of managing the risks of all the hazardous substances in the group (96C(1)(a-c));
- be satisfied that all the hazardous substances in the group standard have a similar nature, are of a similar type, or have similar circumstances of use, such that the risks of the substance or products can be effectively managed by one set of conditions (96C(1)(e)(ii)); and
- consider the best international practices and standards for the safe management of hazardous substances (96C(1)(f)); and
- consider the types of controls appropriate for the group in accordance with sections 77, 77A and 77B of the Act (96C(1)(g)).

Efficiency and effectiveness

2.3 The 'efficiency and effectiveness' of regulating dental products under the group standards was established by the Authority in 2006 when the Authority issued the group standards. The Committee considers that, with the amendments detailed in **Appendix 2** and **Appendix 3**, the specified Dental Products Group Standards will continue to represent the most efficient and effective way of managing the risks posed by dental products.

Scope of the group standards

2.4 The Committee considers that the amendments detailed in **Appendix 2** and **Appendix 3** change the scope of the substances covered by these group standards; however, the Authority's earlier conclusion, that the products are of a similar nature, type or use such that they are appropriate for inclusion in one group standard, remains valid.

2.5 The Committee notes that the hazard classification of a product determines the group standard to which a product may be assigned. Products containing or releasing less than 8% hydrogen peroxide fit within the scope of the *Dental Products (Subsidiary Hazard) Group Standard*; whereas substances containing or releasing 8% or more hydrogen peroxide are classified as oxidising (class 5.1.1) substances and therefore meet the scope of the *Dental Products (Oxidising, [5.1.1]) Group Standard*.

2.6 The Committee further notes that the scope of the *Dental Products (Oxidising [5.1.1] Group Standard* has been amended to include skin corrosive, HSNO 8.2B or 8.2C classifications. Thus, if a substance is a dental product containing or releasing more than 20% hydrogen peroxide and the skin corrosivity results solely from the hydrogen peroxide, it will be covered by this group standard.

International considerations

2.7 The Committee reviewed standards established in other jurisdictions relating to dental products containing or releasing hydrogen peroxide. In particular, the Committee gave consideration to international regulations regarding restrictions and mandated label statements. In addition, the Committee considered the desirability of maintaining regulatory consistency with Australia so as to minimise trade barriers without disregarding the need to safeguard public health. The Committee noted that

the use of Australian identification requirements is provided for as an alternative means of compliance in the Group Standards.

2.8 The Committee also took account of Canadian label requirements in its decision regarding identification requirements for products containing or releasing hydrogen peroxide.

3 Controls and recommendations

3.1 The Committee must consider the types of controls appropriate for the group in accordance with sections 77, 77A and 77B of the Act as required by 96C(1)(g).

Information requirements for dental products containing or releasing hydrogen peroxide

3.2 The Committee has taken account of the risks of tooth-whitening products containing or releasing hydrogen peroxide and of international information requirements for tooth-whitening products, particularly those in Canada and Australia.

3.3 Canadian identification requirements include precautionary statements regarding the frequency of product use, risks to children, and risks arising from swallowing, eye and gum contact. The Committee considers adoption of similar precautionary statements appropriate to ensure that the public is informed and the risks associated with unsupervised use of the substance are managed. The Committee notes that in Canada the products are not recommended for use on children under 12 years of age. However, the Committee considers that a more appropriate age limit would be 16 years based on the risks of tooth-whitening products and the age limits proposed by some submitters.

3.4 Accordingly, in order to manage the risks of tooth-whitening products sold to the general public, the Committee determines that tooth-whitening products containing or releasing less than 7% hydrogen peroxide must have on the label, information that is equivalent to the following precautionary statements:

'If irritation develops, discontinue use. If irritation continues, consult a dentist';
'Use for longer than 14 days is not recommended except under the supervision of a dentist';
'Not recommended for use on children under 16 years of age';
'Avoid swallowing'; and
'Avoid direct contact of the product with gums or eyes'.

3.5 The Committee also determines that a person must not supply, offer to supply or advertise a tooth-whitening product containing or releasing more than 7% hydrogen peroxide, unless the product is accompanied by information that is equivalent to the precautionary statements in paragraph 3.4.

3.6 The Committee notes the differences in use pattern between toothpastes and mouthwashes in comparison to products intended solely for tooth whitening; specifically that they are intended for daily use and have a short contact time with the teeth and gums. Therefore, the Committee determines that oral hygiene products containing or releasing hydrogen peroxide do not require all of the precautionary statements set out in paragraph 3.4. However, such products must carry the following warning on the label:

'If irritation occurs, discontinue use.'

Alternative labelling provisions

3.7 The Committee notes that the Group Standards provide for alternative labelling as set out in subclause 2(15)(a)-(d) of the specified group standards. Amongst these provisions, labelling conditions set out in subclauses 2(1) to (14) do not need to be met if a substance complies with the relevant current labelling requirements of Australia, and other specified countries in accordance with subclause 2(15)(d).

3.8 The Committee further notes that parties who elect to label their products in compliance with the New Zealand Hazardous Substances Regulations in accordance with subclause 2(15)(a) of the specified group standards, must nevertheless comply with the precautionary statements required for dental products and oral hygiene products containing or releasing hydrogen peroxide (subclauses 2(3)(c) or 2(3)(d) as the case may be). This requirement is set out in subclause 2(15A) of the relevant group standard.

3.9 In adopting these information requirements, the Committee has considered:

- the need for the controls to be cost effective (section 77A(4)(b));
- the need to allow the benefits of the substances to be retained without significantly increasing the risk (section 77(4)(b)); and
- the desirability of harmonising labelling with Australian requirements.

Restrictions on tooth-whitening products

Products containing or releasing less than 7% hydrogen peroxide

3.10 Based on the systemic toxicity of hydrogen peroxide, the Committee determines that the concentration of hydrogen peroxide contained or released in a dental product that may be sold to the general public must be less than 7% (based on analysis of Dahl and Pallesen, 2003).[4] In addition to risks of systemic toxicity, there is a potential for short-term effects within the oral cavity such as irritancy and sensitivity, even at lower concentrations of hydrogen peroxide. There are potentially greater risks if a product is overused or misused, and when products are used by children.

Products containing or releasing between 7% and 12% hydrogen peroxide

3.11 The Committee notes the risk of irritancy and tooth sensitivity is greater if the person has conditions such as dental caries, receding gums or failing dental work, making the supply and use of higher concentration products under the supervision of a dentist or a registered oral health practitioner desirable.

3.12 Registered oral health practitioners are regulated under the Health Practitioners Competence Assurance (HPCA) Act 2003 and subject to investigation by the Dental Council and the Health and Disability Commissioner (HDC). The Committee therefore considers it appropriate for registered oral health practitioners to supply or apply tooth-whitening products containing or releasing between 7% and 12% hydrogen peroxide in the same capacity as a dentist.

[4] Dahl, JE, Pallesen, U. *Tooth bleaching – A critical review of the biological aspects*. Critical Rev. Oral Biol Med, Vol 14 (4) p292-304, 2003.

3.13 The Committee further notes that tooth-whitening products containing or releasing up to 16% hydrogen peroxide are currently used by commercial tooth-whitening practitioners not registered under the HPCA Act. The Committee notes the submissions from representatives of this industry, concerned that significant adverse effects on their businesses, including potential business closures, would occur should the supply of products containing or releasing more than 3.6% hydrogen peroxide be restricted as originally proposed by the applicants. The Committee notes the single case reported to the HDC, but considers that, overall, insufficient evidence of adverse events occurring due to the actions of non-dental practitioners who are not dentists has been presented to warrant such a severe restriction.

3.14 The Committee considers that stipulating the maximum allowable concentration of hydrogen peroxide contained or released in a dental product that may be applied by non-registered practitioners would be more effective in managing the risks of higher concentration products than the controls in the group standards (no existing restriction). The Committee considers that allowing non-registered tooth-whitening practitioners to apply products containing or releasing 12% or less hydrogen peroxide would minimise the potential impact on these businesses in comparison to the 3.6% restriction originally proposed by the applicants.

3.15 The Committee notes the support of the Ministry of Health and the Dental Council in enabling non-registered tooth-whitening practitioners to provide cosmetic procedures providing they have received adequate training and the procedure is provided in a hygienic manner and in hygienic premises. The Committee notes the express willingness of the Ministry of Health to work with the New Zealand Cosmetic Teeth Whitening Association to develop appropriate Guidelines for Tooth Whitening.

3.16 Taking account of the risks of tooth-whitening products containing or releasing hydrogen peroxide when applied in an unsupervised environment, the Committee considers it appropriate that, only when operating under the supervision of a dentist may non-registered practitioners sell dental products containing or releasing between 7 and 12% hydrogen peroxide to members of the general public.

3.17 Thus the Committee determines that a person (person A) may only **supply** a tooth-whitening product containing or releasing between 7% and 12% 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; or
    ii) a registered oral health practitioner; or
    iii) a non-registered tooth-whitening practitioner who is under the supervision of a dentist.

3.18 A person (Person A) may only **apply** a tooth-whitening product containing or releasing between 7% and 12% 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.

Products containing or releasing more than 12% hydrogen peroxide

3.19 In order to manage the risks of dental products containing or releasing more than 12% hydrogen peroxide, the Committee considers it appropriate for sale and application, performed by specified practitioners, to be undertaken only under the supervision of a dentist. The Committee notes that dental supervision may address appropriate tools, procedures and advice provided during the application or sale of products to a member of the public. In addition, dentists are regulated under the HPCA Act 2003 and subject to investigation by the Dental Council and the Health and Disability Commissioner (HDC).

3.20 Thus the Committee determines that a person (Person A) may only **supply** a tooth-whitening product containing or releasing more than 12% hydrogen peroxide to:

a) a person who obtains the product for the purpose of supplying:
    i) a dentist;
    ii) a registered oral health practitioner who is under the supervision of a dentist; or
b) a non-registered tooth-whitening practitioner who is under the supervision of a dentist;any other person, but only if person A is:
    i) a dentist; or
    ii) a registered oral health practitioner who is under the supervision of a dentist.

3.21 A person (person A) may only **apply** a tooth-whitening product containing or releasing more than 12% hydrogen peroxide to another person, if person A is:

a) a dentist;
b) a registered oral health practitioner who is under the supervision of a dentist; or
c) a non-registered tooth-whitening practitioner who is under the supervision of a dentist.

3.22 The Committee notes that tooth-whitening products containing or releasing more than 20% hydrogen peroxide are classified as skin corrosive (8.2B) and do not therefore meet the scope of the specified group standards. The Committee further notes that intra-coronal bleaching and other significant dentistry procedures carried out in New Zealand rely on dental products containing or releasing higher concentrations of hydrogen peroxide and such procedures reflect international best practice. Therefore, the Committee considers it is appropriate to make a consequential amendment to the scope of the *Dental Products Group Standard (Oxidising, [5.1.1]) 2006* to include a skin corrosive, HSNO 8.2B or 8.2C classification, if the substance is a dental product containing or releasing more than 20% hydrogen peroxide and the skin corrosivity results solely from the hydrogen peroxide. Appropriate changes to the conditions of the Group Standard to address the corrosivity hazard (8.2) have been made where necessary.

Delayed implementation period

3.23 The applicants proposed that a 12 month period be provided for importers and manufacturers before they must comply with the new requirements.

3.24 The Committee noted the submissions by industry requesting a longer time period of up to 24 months to allow changes to be implemented in an orderly and cost-effective manner; and to give suppliers time to allow 'stock in trade' to work through the supply chain.

3.25 The Committee considers that the change is substantial and a longer period is appropriate to repackage products and where necessary to adjust product formulations so they comply with the new requirements. It is recognised that these products have been available for some time and many are supplied from overseas. Therefore it is appropriate to provide a longer phase- in period for the new requirements.

3.26 Taking into account the considerations above, the Committee determines that a 24 month delayed implementation period is appropriate.

4 Decision

4.1 The Committee, in accordance with sections 96B and 96C of the Act, approves the amendments to the *Dental Products Group Standard (Oxidising, [5.1.1]) 2006* and the *Dental Products Group Standard (Subsidiary Hazard) 2006* set out in **Appendices 2** and **3** respectively and directs that the amendments be made by notice in the *Gazette* as required under the Act.

4.2 These amendments come into force 24 months from the date of notification in the *Gazette*.

In addition, the Committee directs that the amendments be published and that the amended group standards be available for inspection free of charge and on the website and that notice is given of where the amended group standard may be inspected or purchased.

Valerie Orchard (Chair) **28 June 2011**

Appendix 1: Application and consideration process

A1.1. This application related to proposals by the Ministry of Health and the Dental Council to amend the specified Dental Products Group Standards was considered in accordance with section 96C of the Act.

A1.2. On 8 December 2010, the Authority publicly notified[5]–

- the proposal to amend the group standards; and
- its assessment of the matters required under subsections 96C(1)(a), (b), (c), (d), and (e) in relation to the *g*roup standards as proposed to be amended.[6]

A1.3. Four proposals were outlined in the application and consultation document. These proposals were:

Proposal 1	That an amendment is made to the Schedule 1 of the relevant Dental Products Group Standards covering products containing or releasing >0.1% - ≤ 3.6% hydrogen peroxide to require the following precautionary statement to be provided on a leaflet provided with the product: ***"This product releases hydrogen peroxide. Avoid repeated use (more than 3 applications per month). If irritation develops consult a dentist."***
Proposal 2	That amendments are made to the Schedule 1 of the relevant Dental Products Group Standards covering products containing or releasing >3.6% hydrogen peroxide to require that a member of the public needs to obtain the product from a dentist (person registered with the Dental Council under the Health Practitioners Competence Assurance Act 2003).
Proposal 3:	That an amendment is made to the Schedule 1 of the relevant Dental Products Group Standards covering dental products containing or releasing > 3.6% hydrogen peroxide to require the following precautionary statement to be provided on a leaflet provided with the product: ***"This product releases more than 3.6% hydrogen peroxide. Only permitted for supply to members of the public by a dentist."***
Proposal 4:	That a 12 month period be provided for importers and manufacturers before they must comply with the new requirements.

[5] On the ERMA New Zealand website and by way of notices in 4 major daily newspapers

[6] Subsection 96C(1)(d) was included amongst the considerations for consultation. However the Committee notes that subsection (d) is not applicable. The original group standards were made under subsections 96B(2)(a) – (c) only, whereas 96C(1)(d) is only relevant to a group standard made under subsection 96B(2)(d).

A1.4. The submission period prescribed under the Act is 30 working days from the date of notification for the receipt of submissions, and was thus due to close on 16 February 2011. However, in response to requests, the submission period was extended by a total of 10 working days until 2 March 2011.

A1.5. Sixteen submissions were received. Six submitters requested to be heard at a public hearing.

A1.6. The Agency[7] prepared an update paper to aid the Committee in its decision making process. The update paper contained a summary of submissions received and the Agency's response to the issues raised.

A1.7. A public hearing was held on 12 April 2011 at ERMA New Zealand, Wellington.

A1.8. The proposed amendments were considered by a Committee of the Authority (under delegation from the Authority (section 19(2)(b)) comprising Dr Valerie Orchard (Chair), Mr Richard Woods and Dr Deborah Read. The Committee commenced its consideration on 12 April 2011 and held subsequent consideration meetings on 16 May 2011, 2 June 2011 and 23 June 2011.

A1.9. In accordance with section 96C, the Committee considered the relevant matters set out in Part 6A of the Act.

A1.10. The information available to the Committee comprised:

- the consultation paper;
- full copies of all submissions;
- the Agency's update paper; and
- presentations and comments made by submitters at the hearing.

A1.11. Four proposals were outlined in the application and consultation document.

A1.12. Following the hearing, on 12 April 2011 the Committee requested further information be provided. The Agency sourced the following information and provided this to the Committee on 29 April 2011:

- Specific articles from the scientific literature;
- Further information on international regulatory requirements;
- A summary of submitters requests regarding cut-offs and identification statements.

A1.13. In addition, the Committee requested the full case report regarding the case "Teeth whitening supplied by an unregistered non-dentist whitening practitioner (09HDC02164)" from the Health and Disability Commissioner (HDC). In response to an Agency request the HDC replied on 29 April 2011 that "HDC did not investigate this case and it was closed under section 38 of the Health and Disability

[7] The Agency is the executive arm of ERMA New Zealand which provides support to the Authority.

Commissioner Act 1994". The Agency supplied the HDC response and case summary to the Committee.

A1.14. Following consideration of all the information available, the Committee developed an alternative scenario which allowed for non-registered practitioners to provide tooth-whitening procedures.

A1.15. The committee invited the applicants, to comment on the alternative scenario. In response, the applicants commented:

"Ministry and DCNZ are generally supportive of enabling non-registered practitioners to provide [in chair tooth-whitening procedures], provided that they have received adequate training and the procedure is provided in a hygienic manner and in hygienic premises....health and safety standards must be met to protect both the tooth-whitening practitioner and the person on which the procedure is being performed given that tooth-whitening is an intra-oral procedure involving bodily fluids".

A1.16. The Ministry also expressed a willingness to "work with the NZCTWA to develop an appropriate Guideline(s) for Tooth-Whitening."

A1.17. The Committee took account of the response of the Ministry of Health in their consideration of the application.

Appendix 2: Dental Products (Oxidising, [5.1.1]) Group Standard 2006 as amended

Amended as at 8 September 2010
Amended as at 1 July 2010
Amended as at 30 June 2013

Hazardous Substances and New Organisms Act 1996

Dental Products (Oxidising [5.1.1]) Group Standard 2006

Pursuant to section 96B of the Hazardous Substances and New Organisms Act 1996 (**the Act**), the Environmental Risk Management Authority, on its own initiative, issues this Group Standard.

Contents

5 Title

Dental Products (Oxidising [5.1.1]) Group Standard 2006

HSNO Approval Number

The HSNO Approval Number for this Group Standard is HSR002557.

6 Commencement

This Group Standard comes into force on 1 July 2006 and applies to substances under section 96B(2)(a), (b) and (c) of the Act.

7 Interpretation

(1) In this Group Standard, unless the context otherwise requires, words and phrases shall have the meanings given to them in Schedule 3.

(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) Regulations 2001.

8 Scope of Group Standard

Substances covered by Group Standard

(1) This Group Standard applies to substances that are imported or manufactured for use as a dental product.

(2) A substance referred to in subclause (1) must be—

(a) an oxidising solid or liquid of medium hazard, HSNO 5.1.1B classification; or

(b) an oxidising solid or liquid of low hazard, HSNO 5.1.1C classification.

(3) In addition to the hazard referred to in subclause (2), a substance may have any of the following (but only the following) hazards:

(a) acute toxicity, HSNO 6.1D or 6.1E classification (including aspiration hazard);

(b) skin irritancy, HSNO 6.3A or 6.3B classification;

(c) eye corrosivity, HSNO 8.3A classification;

(d) eye irritancy, HSNO 6.4A classification;

(e) respiratory sensitisation, HSNO 6.5A classification;

(f) contact sensitisation, HSNO 6.5B classification;

(g) mutagenicity, HSNO 6.6A or 6.6B classification;

(h) reproductive toxicity, HSNO 6.8A, 6.8B or 6.8C classification;

(i) target organ toxicity, HSNO 6.9A or 6.9B classification;

(ia) a skin corrosive, HSNO 8.2B or 8.2C classification, if the substance is a tooth-whitening product containing or releasing more than 20% hydrogen peroxide and the skin corrosivity results solely from the hydrogen peroxide; and

(j) ecotoxicity, HSNO class 9.

History Explanatory Note
Clause (ia) was added via the Dental Products Group Standards (Amendment) Notice 2011 – New Zealand Gazette 30 June 2011. The clause comes into force on 30 June 2013.

Substances excluded from Group Standard

(4) This Group Standard excludes cosmetic products.

(5) No substance shall be permitted under this Group Standard if it 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; and

(c) clause 21 of Schedule 1 is complied with.

(6) Despite clause 21 of Schedule 1, no substance shall be permitted under this Group Standard if it is a hazardous chemical that is not listed on the Inventory of Chemicals.

(7) For the purposes of subclause (6), "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 change its composition.

9 Conditions of Group Standard

The obligations and restrictions set out in Schedules 1 and 2 to the Group Standard apply to the substances by way of conditions.

Schedule 1
Conditions of Group Standard

Part 1
Information Requirements

1 General information

(1) Any information (including advertising) provided or required to be made available or supplied under this Part (Information Requirements) must be readily understandable and if provided in words (whether written or oral) be in the English language. Where written information is provided, it must also be legible and durable.

(2) Any information provided must not include any statement, expression, device, trade name or description that—

(a) contradicts or modifies any expression required by this Group Standard to be on the label; or

(b) is false or misleading in relation to the safety of the substance or any of its ingredients; or

(c) misrepresents the composition of the substance; or

(d) misrepresents any property of the substance, including information that suggests the substance belongs to a class or sub-class that it does not in fact belong to.

2 Labelling

Duties of suppliers

(2) A person must not sell or supply a substance to another person unless the substance is labelled in accordance with the following requirements.

Hazard information required on each label

(3) A label must provide the following general information about a substance:

(a) the product name; and

(b) enough information to enable the New Zealand importer, supplier or manufacturer to be contacted, either in person or by telephone; and

(c) in the case of a HSNO 6.1D, 6.1E, 6.3A, 6.3B, 6.4A, 6.5A, 6.5B or 8.3A substance, a 24 hour emergency telephone number.

(4) Where a substance is available to the general public—

(a) for a HSNO 6.1D, 6.1E or 8.3A substance, there must be—

(i) on the main label, the general precautionary statement **'Keep out of reach of children'**; and

(ii) on the label, the general precautionary statement **'If medical advice is needed: Have product container or label at hand'**; and

(b) for all substances, there must be on the label, the general precautionary statement **'Read label before use'**.

(c) A person must not supply, offer to supply, or advertise a tooth-whitening product containing or releasing 8% or more hydrogen peroxide, unless the substance is accompanied by information that is equivalent to the following precautionary statements:

(i) '**If irritation develops, discontinue use. If irritation continues, consult a dentist'**; and

(ii) '**Use for longer than 14 days is not recommended except under the supervision of a dentist**'; and

(iii) '**Not recommended for use on children under 16 years of age**'; and

(iv) '**Avoid swallowing**'; and

(v) '**Avoid direct contact of the product with gums or eyes**'.

History Explanatory Note
Clause 2(3)(c) was added via the Dental Products Group Standards (Amendment) Notice 2011 – New Zealand Gazette 30 June 2011. The clause comes into force on 30 June 2013.

(5) A label must provide the following hazard information about the substance:

(a) pictogram, signal word and hazard statements for HSNO class 5.1.1 substances to appear on the main label—

(i) the pictogram for a HSNO class 5.1.1 substance; and

(ii) the applicable signal word, either:

(I) **'danger'** in the case of a HSNO 5.1.1B, 8.2B, or 8.2C substance; or

(II) **'warning'** in the case of a HSNO 5.1.1C substance, unless the substance is a HSNO 6.5A, 6.6A, 6.8A, 6.9A or 8.3A substance in which case, the signal word **'danger'** is required**;** and

(iii) the oxidising hazard statement **'may intensify fire, oxidiser'**; and

(iv) for a HSNO 8.2B or 8.2C substance, the corrosivity hazard statement **'causes severe skin burns and eye damage'**.

History Explanatory Note
The amendment to Clause 2(4)(a) (ii) (I) was made via the Dental Products Group Standards (Amendment) Notice 2011 – New Zealand Gazette 30 June 2011.
The addition of Clause 2(4)(a) (iv) was made via the Dental Products Group Standards (Amendment) Notice 2011 – New Zealand Gazette 30 June 2011.

These changes come into force on 30 June 2013.

(b) where a substance has any of the hazards permitted under clause 4(3) of this Group Standard (Scope of Group Standard), the corresponding pictograms and hazard statements as listed in Tables 1 and 2 of the document *Labelling of Hazardous Substances: Hazard and Precautionary Information* published by the Authority, July 2006 must appear on the label, subject to the principles of precedence as set out in the above-named document; and

(c) for all hazards, the label must provide the applicable precautionary (prevention, storage and response) statements as listed in Tables 3 to 5 of the document *Labelling of Hazardous Substances: Hazard and Precautionary Information* published by the Authority, July 2006.

(6) A single indication may be used if it is capable of conveying two or more of the items of hazard information required by subclause (4).

Disposal information required on each label

(7) A label must provide a description of one or more appropriate and achievable methods for the disposal of a substance in accordance with clause 18 of this Schedule, which may also include any method of disposal that must be avoided.

Identification of components on label

(8) Subject to subclause (8), a label must provide—

(a) the common or chemical name and concentration of every ingredient that would, independently of any other ingredient, give the substance a HSNO 6.5, 6.6, 6.8, 6.9 or 8.3 classification; and

(b) the name of every ingredient (other than an ingredient referred to in subclause (a)) that would, independently of any other ingredient, give the substance a HSNO 6.1D classification, and the concentration of the ingredient that would contribute the most to that classification.

(9) In the case of a HSNO 6.5, 6.6, 6.8 or 6.9 classification, the identification of any component on the label is only required if the concentration of that component is at or above the concentration specified in Table 1.

Table 1. Concentration values triggering identification of components on label

HSNO Classification	Cut-off, %
6.5A, 6.5B, 6.6A	0.1
6.6B	1

6.8A, 6.8C	0.3
6.8B	3
6.9A, 6.9B	10

(10) For the purposes of complying with subclause (7)—

(a) a generic name may be used to identify a group of ingredients in accordance with the provisions of regulation 26 of the Hazardous Substances (Identification) Regulations 2001; and

(b) the concentration of an ingredient in a substance may be stated as a range in accordance with the provisions of regulation 27 of the Hazardous Substances (Identification) Regulations 2001.

Multiple packages

(11) Where a substance is labelled in compliance with subclauses (1) to (9), but some or all of the required information is obscured by outer packaging, the outer packaging of the substance must bear the labelling or marking required by—

(a) subclauses (4)(a) and (b); or

(b) the Land Transport Rule; or

(c) the Civil Aviation Rule; or

(d) the Maritime Rule.

Exemption from specific labelling requirements for ecotoxic substances

(12) For a substance with an ecotoxic hazard of—

(a) HSNO 9.1C or 9.1D classification, the corresponding hazard statement required by subclause (4)(b) is not required;

(b) HSNO 9.2, 9.3 or 9.4 classification, the corresponding pictogram, and hazard, prevention and response statements required by subclauses (4)(b) and (c) are not required.

Exemption from specific labelling requirements for small packages

(13) When a substance is contained in a package with a capacity of **5 L or 5 kg** or less, the label for that package does not need to provide the following information:

(a) any pictogram required by subclauses (4)(a) and (b); and

(b) the signal word, hazard and response statements for any HSNO class 9 hazards, as required by subclauses (4)(b) and (c).

Exemption from specific labelling requirements for imported and exported packages

(14) Where a substance has been imported into New Zealand in a closed package or in a freight container (and for any reasonable period after it arrives that is necessary to arrange compliance with the requirements of subclauses (1) to (9)) and where that substance is being carried from the place of importation to the destination stated in its importation documentation without having been removed from that package or container, subclauses (1) to (9) are complied with if the package or container concerned complies with the requirements of—

(a) subclauses (4)(a) and (b); or

(b) the Land Transport Rule; or

(c) the Civil Aviation Rule; or

(d) the Maritime Rule.

(15) Where a substance is exported from New Zealand, subclauses (1) to (9) are complied with if the substance is labelled or marked as required by—

(a) subclauses (4)(a) and (b); or

(b) the Land Transport Rule; or

(c) the Civil Aviation Rule; or

(d) the Maritime Rule.

Alternative compliance measures for labelling

(16) Subject to subclause (15A), the requirements of subclauses (1) to (14) do not need to be met if a substance complies with—

(a) the relevant identification provisions in the Hazardous Substances (Identification) Regulations 2001, the Hazardous Substances (Emergency Management) Regulations 2001 and the Hazardous Substances (Disposal) Regulations 2001; or

(b) a code of practice approved by the Authority under section 78 of the Act that specifies requirements equivalent to those set out in subclauses (1) to (14); or

(c) the UN Globally Harmonised System of Classification and Labelling of Chemicals (GHS) and the requirements of subclause (2); or

(d) the relevant current labelling requirements of Australia, USA, Canada, the European Union or any other country as approved by the Authority, as if the substances were for sale or supply in those countries, and the requirements of subclause (2).

(15A) A person who relies on subclause (15)(a) must still comply with subclause (3)(c).

History Explanatory Note
Clause 2(15A) was added via the Dental Products Group Standards (Amendment) Notice 2011 – New Zealand Gazette 30 June 2011. Clause 2(15) was amended to reflect the added clause (15A). The changes come into force on 30 June 2013.

(17) [*Omitted*]

History Explanatory Note
Clause 2(16) was omitted as at 1 July 2010 via the Labelling Requirements in Group Standards (Amendment) Notice 2010 – New Zealand Gazette 3 June 2010. The omitted words are as follows:

"Subclause (15)(d) expires with the close of 31 December 2010."

Substances transported in bulk

(18) Where a substance is transported in bulk, subclauses (1) to (9) do not apply provided the substance is transported in compliance with—

(a) the Land Transport Rule; or

(b) the Civil Aviation Rule; or

(c) the Maritime Rule.

(19) For the purposes of subclause (17), "bulk" means—

(a) a liquid substance in a container in an undivided quantity exceeding **450 L**; or

(b) a solid substance in a container in an undivided quantity exceeding **400 kg**.

3 Safety data sheets

(1) A person, when selling or supplying a substance at any quantity shall provide a safety data sheet for the substance supplied to the recipient if—

(a) the substance is likely to be used in a place of work; and

(b) they have not previously supplied a safety data sheet for that substance to the recipient.

(2) In each place of work where the substance is manufactured, stored or used, the person in charge of the place must ensure that every person handling the substance has access to a safety data sheet for that substance.

(3) The safety data sheet must be available to a person handling the substance within 10 minutes, and be readily understandable by any fully trained worker required to have access to it.

(4) A person who manufactures or supplies a substance in New Zealand or imports a substance into New Zealand must, if asked to do so by any person in charge of a place of work where a substance is stored or used, give that person the required safety data sheet.

(5) Information required on a safety data sheet must be provided under the following general headings in the order listed below, and must include the information referred to under those headings:

(a) **Identification of the substance and supplier—**

(i) product name; and

(ii) recommended uses; and

(iii) name of the supplier, New Zealand contact details including an emergency contact;

(b) **Hazards identification—**

(i) a description of the hazards of the substance, which may include its HSNO hazard classification; and

(ii) hazard information, including signal words, hazard statement(s) and precautionary statement(s);

(c) **Composition/information on ingredients—**

(i) in the case of single component substances, their chemical identity, including common names and synonyms, CAS number and any impurities that are themselves hazardous; or

(ii) in the case of substances that are mixtures, the chemical identity of each hazardous ingredient, their CAS number and their concentration ranges;

(d) **First aid measures—**

(i) first aid instructions according to each relevant route of exposure; and

(ii) whether medical attention is required, and its urgency; and

(iii) information on the most important symptoms and effects, acute and delayed, from exposure;

(e) **Fire fighting measures—**

(i) information on the appropriate type of extinguishers or fire-fighting agents, including extinguishers that may not be appropriate for a particular situation; and

(ii) any advice on hazards that may arise from combustion products; and

(iii) precautions for fire fighters and protective clothing requirements;

(f) **Accidental release measures—**

(i) advice on protective clothing requirements and emergency procedures; and

(ii) any environmental precautions from accidental spills and release; and

(iii) advice on how to contain and clean up a spill or release;

(g) **Handling and storage—**

(i) precautions for safe handling; and

(ii) conditions for safe storage, including any incompatibilities;

(h) **Exposure controls/personal protection—**

(i) exposure limits set for the substance or any of its components, or in their absence, relevant overseas exposure limits; and

(ii) engineering controls; and

(iii) individual protection measures, including personal protective equipment;

(i) **Physical and chemical properties—**

(i) a description of relevant physical and chemical properties for the substance, including units of measurement and reference conditions where appropriate; and

(ii) where necessary for interpretation of data reported, the method of determination;

(j) **Stability and reactivity—**

(i) an indication of the chemical stability of the substance under normal and anticipated storage and handling conditions; and

(ii) a list of conditions to avoid to prevent a hazardous situation; and

(iii) information on incompatible substances or materials;

(k) **Toxicological information—**

(i) a full description of the toxicological (health) effects, including the symptoms or signs of injury or ill health associated with each likely route of exposure; and

(ii) the dose, concentration or conditions of exposure likely to cause injury or ill health; and

(iii) a summary of the data used to identify the health effects;

(l) **Ecological information—**

(i) ecotoxicity; and

(ii) persistence and degradability; and

(iii) mobility;

(m) **Disposal considerations—**

(i) disposal methods, including disposal of packaging; and

(ii) special precautions to be taken during disposal; and

(iii) any method of disposal that should not be used;

(n) **Transport information—**

If relevant;

(i) the UN number; and

(ii) the proper shipping name; and

(iii) the UN Dangerous Goods class and subsidiary risk; and

(iv) the UN Packing Group;

(o) **Regulatory information—**

(i) HSNO approval number and/or title of the Group Standard; and

(ii) information on the conditions of the Group Standard, and any other regulatory requirements;

(p) **Other information—**

(i) date of preparation or revision of the safety data sheet; and

(ii) a key/legend to abbreviations and acronyms used.

(6) Where a substance is being transported, a safety data sheet is not required if—

(a) there is in the vehicle concerned documentation complying with the Land Transport Rule whilst being transported by land; or

(b) there is in the ship concerned documentation complying with the Maritime Rule whilst being transported by sea; or

(c) there is in the aircraft concerned documentation complying with the Civil Aviation Rule whilst being transported by air.

4 Advertising

Where a substance with an acute toxic hazard (HSNO 6.1D or 6.1E classification), and/or a corrosivity hazard (HSNO 8.2 or 8.3A classification) is advertised to members of the public, and the person to whom the advertising is directed is not provided with a reasonable opportunity to read and consider the information required to be on the product label prior to

purchase of the substance, any advertising (whether written, screen or audio) must include in readily understandable form the following information:

(a) an indication that the substance is acutely toxic and/or corrosive (whatever the case may be); and

(b) the need to restrict access by children to the substance.

History Explanatory Note
Clause 4 was amended via the Dental Products Group Standards (Amendment) Notice 2011 – New Zealand Gazette 30 June 2011. The amendment comes into force on 30 June 2013.

Part 2
Site and Storage

5 Compliance with site and storage requirements

(1) Any location at which a substance is manufactured or stored in quantities that exceed those set out in Table 2 must comply with the relevant conditions for HSNO class 5.1.1 substances as set out in the document entitled *Site and Storage Conditions for Class 5.1.1 Oxidising Substances and Class 5.2 Organic Peroxides* published by the Authority, July 2006.

Table 2. Trigger quantities beyond which site and storage conditions apply for HSNO class 5.1.1 substances

	Trigger Quantity	
Location and transit depot test certification – where package to be kept closed at all times	500 L or 500 kg	(for a HSNO 5.1.1B substance)
	1,000 L or 1,000 kg	(for a HSNO 5.1.1C substance)
Location and transit depot test certification – where substances manufactured or used	50 L or 50 kg	(for a HSNO 5.1.1B substance)
	100 L or 100 kg	(for a HSNO 5.1.1C substance)
Fire extinguishers	200 L or 200 kg	(for a HSNO 5.1.1B substance)
	500 L or 500 kg	(for a HSNO 5.1.1C substance)
Response plans and secondary containment	100 L or 100 kg	(for a HSNO 9.1A substance)
	500 L or 500 kg	(for a HSNO 5.1.1B substance)
	1,000 L or 1,000 kg	(for a HSNO 6.1D, 6.5A, 6.5B, 9.1B, 9.1C substance)
	5,000 L or 5,000 kg	(for a HSNO 5.1.1C substance)
Signage	100 L or 100 kg	(for a HSNO 9.1A substance)
	250L or 250kg	(for a HSNO 8.2B substance)
	500 L or 500 kg	(for a HSNO 5.1.1B substance)
	1,000L or 1,000 kg	(for a HSNO 5.1.1C substance)

(2) The trigger quantities referred to in Table 2 must take into account any other hazardous substance that is present at that location.

History Explanatory Note

The signage trigger quantity for a HSNO 8.2B substance was added to Table 2 via the Dental Products Group Standards (Amendment) Notice 2011 – New Zealand Gazette 30 June 2011. The change comes into force on 30 June 2013.

Stationary container systems

(3) Any stationary container system that contains, or is intended to contain, a substance must comply, to the extent applicable, with the controls for stationary container systems as set out in Parts 1 to 19 of Schedule 8 of the Hazardous Substances (Dangerous Goods and Scheduled Toxic Substances) Transfer Notice 2004, notwithstanding clause 1(1) of that Schedule.

Part 3
Approved Handler

6 Approved handler requirement for HSNO class 5.1.1 substances

When present in quantities greater than those listed in Table 3, a HSNO class 5.1.1 substance must be—

(a) under the personal control of an approved handler who holds a current test certificate to manage HSNO class 5 substances; or

(b) secured so that a person cannot gain access to the substance without tools, keys, or any other device used for operating locks.

Table 3. Quantities that trigger approved handler requirements for HSNO class 5.1.1 substances

HSNO classification	Trigger Quantity
5.1.1B	500 kg or 500 L
5.1.1C	1,000 kg or 1,000 L

7 Exclusions to approved handler requirements

Despite clause 6 of this Schedule, a substance may be handled by a person who is not an approved handler if—

(a) the approved handler has provided guidance to the person in respect of the handling; and

(b) the approved handler is available at all times to provide assistance, if necessary, to the person while the substance is being handled by the person.

8 Exception to approved handler requirement for transportation of packaged substances

(1) The approved handler requirement is deemed to be complied with if—

(a) in the case of a substance being transported on land—

(i) in the case of a substance being transported by rail, the person who drives the rail vehicle that is transporting the substance is fully trained in accordance with an approved safety system under section 6D of the Transport Services Licensing Act 1989 or a safety system which is referred to in an approved safety case under the Railways Act 2005; and

(ii) in every other case, the person who drives, loads, and unloads the vehicle that is transporting the substance—

(I) for hire or reward, or in quantities which exceed those set out in Schedule 1 of the Land Transport Rule, has a current dangerous goods endorsement on his or her driver licence; or

(II) in every other case, the Land Transport Rule is complied with; or

(b) in the case of a substance being transported by sea, one of the following is complied with:

(i) Maritime Rule; or

(ii) International Maritime Dangerous Goods Code; or

(c) in the case of a substance being transported by air, the Civil Aviation Rule is complied with.

(2) Subclause (1)(a)—

(a) does not apply to a tank wagon or a transportable container to which the Hazardous Substances (Tank Wagons and Transportable Containers) Regulations 2004 applies; but

(b) despite paragraph (a), does apply to an intermediate bulk container that complies with Chapter 6.5 of the UN Model Regulations.

(3) Subclause (1)(c)—

(a) applies to pilots, aircrew, and airline ground personnel loading and handling substances within an aerodrome; but

(b) does not apply to the storage and handling of a substance in any place that is not within an aerodrome, or within an aerodrome by non-airline ground personnel.

Part 4
Packaging

9 General packaging requirements

Every person who packs a substance must—

(a) select packaging that when filled and closed—

(i) does not leak any substance under normal working conditions; and

(ii) maintains its ability to retain its contents, if part of the contents are removed and the package resealed; and

(iii) does not react with a substance in any way as to weaken the package; and

(b) ensure that, if a substance is being packed into a package that has previously contained another substance—

(i) both substances are compatible; or

(ii) all practicable steps are taken to remove all residues of the original substance.

10 Specific packaging requirements for substances with certain hazards

Specific packaging requirement for HSNO 5.1.1 substances

(2) Packaging for a HSNO 5.1.1 substance must, when closed, exclude any other substance that may cause the substance to spontaneously combust.

Specific packaging requirement for certain HSNO 6.1 substances

(3) Any packaging containing a liquid substance with a HSNO 6.1D classification must be permanently identified as containing a toxic substance unless the substance as packaged is restricted to a place of work.

(4) The requirement of subclause (2) does not need to be met if the substance container meets the container requirements for that substance of Australia, the European Union or any other country as approved by the Authority.

11 Compliance with UN Packing Group requirements

(1) Where allowed for by the UN Model Regulations, large packaging may be used to contain a substance if it has been constructed, marked, and tested as a large package as provided in Chapter 6.6 of the UN Model Regulations.

(2) When a substance is packaged in quantities less than or equal to **450 L or 400 kg**, the packaging must comply with the requirements of—

(a) UN Packing Group II for a HSNO 5.1.1B substance; or

(b) UN Packing Group III for a HSNO 5.1.1C substance.

Variation to UN Packing Group II requirements

(3) Despite subclause (2)(a), a HSNO 5.1.1B substance may, as a minimum, be packaged in packaging that complies with Schedule 4 of the Hazardous Substances (Packaging) Regulations 2001 when in quantities less than or equal to **1.0 L** or **1.0 kg**.

Variation to UN Packing Group III requirements

(4) Despite subclause (2)(b), a HSNO 5.1.1C substance may, as a minimum, be packaged in packaging that complies with Schedule 4 of the Hazardous Substances (Packaging) Regulations 2001 when in quantities less than or equal **5.0 L** or **5.0 kg**.

Marking of Packaging

(5) No manufacturer or importer of packaging designed and constructed for use with a substance may mark the packaging as specified in paragraphs 6.1.2 and 6.1.3 of the UN Model Regulations unless—

(a) the markings comply with the corresponding elements of those paragraphs, including the codes for packaging type, UN Packing Group, and the UN packaging symbol; and

(b) the codes marked for UN Packing Group II or UN Packing Group III are marked on packaging that complies with the tests set out in Schedule 2 or Schedule 3 respectively of the Hazardous Substances (Packaging) Regulations 2001; and

(c) the design of the packaging has also been test certified as complying with the tests set out in Schedule 2 or Schedule 3 respectively of the Hazardous Substances (Packaging) Regulations 2001.

(6) Subclause (5) does not apply to a substance that is not required to be packaged in UN Packing Group II or UN Packing Group III.

12 Child resistant packaging

(1) In the case of a HSNO 6.1D, 6.1E, 8.2 or 8.3A substance, when that substance is packaged in quantities of less than **2.5 L** or **2.5 kg**, that package must be child resistant, unless being sold or supplied to a place of work where children do not have access and the substance is for use in that place of work.

(2) The requirements of subclause (1) do not need to be met if—

(a) the substance complies with the requirements for child resistant packaging (if any) of Australia, USA or the European Union or any other country as approved by the Authority; and

(b) the substance is not—

(i) a HNSO 6.1D or 8.2 substance; or

(ii) an aspiration hazard. `

History Explanatory Note
Clause 12(1) and 12(2) (b) (i) were amended via the Dental Products Group Standards (Amendment) Notice 2011 – New Zealand Gazette 30 June 2011. These amendments come into force on 30 June 2013.

Part 5
Equipment

13 Personal protective equipment

(1) A person who handles a substance in a place of work must use protective clothing or equipment when the substance is expected, or likely, to—

(a) come into contact with an ignition source or an incompatible substance or material, or

(b) be exposed to a greater temperature than the limit specified in clause 5(2) of the document entitled *Site and Storage Conditions for Class 5.1.1 Oxidising Substances and Class 5.2 Organic Peroxides* published by the Authority, 2006.

(2) Despite subclause (1), a person who handles a substance with a hazard equivalent to a HSNO 6.1D, 6.3A, 6.5A, 6.5B, 6.6A, 6.6B, 6.8A, 6.8B, 6.8C, 6.9A, 6.9B, 8.2B, 8.2C, or 8.3A classification in a place of work must use protective clothing or equipment at all times.

(3) The protective clothing or equipment must—

(a) be designed, constructed, and operated so as to—

(i) prevent the substance making direct contact with the wearer or user; and

(ii) prevent the wearer or user being exposed to more than the level of heat radiation specified in clause 14(2) of the document entitled *Site and Storage Conditions for Class 5.1.1 Oxidising Substances and Class 5.2 Organic Peroxides* published by the Authority, 2006; and

(iii) where relevant, ensure that the person is not exposed to a concentration of the substance that is greater than the workplace exposure standard for the substance, or any component of the substance.

(b) be designed and constructed of materials that, in the circumstances in which the substance is being used or handled—

(i) cannot be degraded, attacked, or combusted by the substance; or

(ii) are resistant to such degradation, attack, or combustion for the time specified by the supplier of the equipment or clothing; and

(4) In relation to the "circumstances" described in subclause (3)(b), relevant matters include the range of temperatures and pressures and the presence of other substances likely to be encountered when used as described in the documentation referred to in subclause (5).

(5) The protective clothing or equipment must be accompanied by documentation that gives sufficient instruction on use and maintenance of the equipment or clothing to enable it to be maintained and used in a manner that meets the requirements of this clause.

(6) The documentation referred to in subclause (5) must be available to a person handling the substance within 10 minutes, and be readily understandable by any fully trained worker required to have access to it.

(7) This clause does not apply to a substance that is contained in a closed package that complies with the requirements of Part 4 (Packaging).

History Explanatory Note
Clause 13(2) was amended via the Dental Products Group Standards (Amendment) Notice 2011 – New Zealand Gazette 30 June 2011. These amendments come into force on 30 June 2013.

14 Equipment or clothing used to handle a substance

(1) The person in charge of a substance must ensure that—

(a) any equipment used to handle the substance—

(i) retains the substance, without leakage at all temperatures and pressure for which the equipment is intended to be used; and

(ii) dispenses or applies the substance, without leakage, at a rate and in a manner that the equipment is designed for.

(b) any equipment or clothing that is directly used to handle the substance is designed, constructed, and operated in such a way that the substance—

(i) does not make direct contact with any incompatible substance or material; and

(ii) does not accumulate in or on the equipment or clothing beyond any accumulation that is directly associated with its intended design and use, as indicated in the documentation referred to under clause 13(5); and

(iii) is not exposed to sufficient energy to cause combustion—

unless the contact or exposure is intended or anticipated, in which case, the conditions of clauses 13(1) and (2) must be met.

(2) The equipment or clothing must meet the requirements specified in clauses 13(3)(b) and 13(4) to (6).

Part 6
Transportation

15 Tank wagons and transportable containers

Tank wagons and transportable containers of any capacity used to carry a substance must comply with the Hazardous Substances (Tank Wagons and Transportable Containers) Regulations 2004.

16 Fire extinguishers

Where a motor vehicle is transporting a substance in quantities greater than those listed in Table 4, there must be present, in or on the vehicle, the number of fire extinguishers listed in Table 4.

Table 4. Trigger quantities for provision of fire extinguishers in vehicles

HSNO Classification	Trigger Quantity	No of fire extinguishers
5.1.1B	200 L or 200 kg	1
5.1.1C	500 L or 500 kg	2

17 Passenger service vehicle restrictions

When a substance is carried on a passenger service vehicle, the substance must—

(a) be packaged in a sealed container; and

(b) not exceed—

(i) **0.5 kg** per package for a HSNO 5.1.1B substance; or

(ii) **1 kg** per package for a HSNO 5.1.1C substance.

Part 7
Disposal

18 Disposal of substance

(1) A substance must be disposed of by—

(a) exporting the substance from New Zealand as waste; or

(b) treating the substance so that it is no longer a hazardous substance.

(2) In subclause 1(b), "treating the substance" does not include depositing the substance in a sewage facility but does include—

(a) detonation, deflagration, or controlled combustion, provided the detonation, deflagration, or controlled combustion is managed to the performance requirements of regulation 7(3)(b) of the Hazardous Substances (Disposal) Regulations 2001 in relation to blast overpressure, heat radiation and access by persons; or

(b) depositing the substance in a landfill provided the landfill is managed to ensure that—

(i) the substance will not at any time come into contact with an explosive or flammable substance (equivalent to HSNO class 1, 2, 3 or 4); and

(ii) there is no ignition source in the vicinity of the disposal site that is capable of igniting the substance; and

(iii) if the substance were to combust, or cause or contribute to combustion, no person or place where a person may legally be, would be exposed to more blast overpressure or heat radiation than that described in regulation 7(3)(b) of the Hazardous Substances (Disposal) Regulations 2001; and

(iv) the concentration of the substance in any discharge from the landfill does not, after reasonable mixing, exceed any relevant tolerable exposure limit and/or environmental exposure limit set for the substance or any of its component(s).

(3) This clause does not apply to a substance that is intended for recycling.

19 Disposal of packaging

(1) The conditions of this clause apply to a package that—

(a) contained a substance; and

(b) was in direct contact with the substance; and

(c) is no longer to be used to contain the substance and is intended for disposal.

(2) A package must—

(a) be rendered incapable of containing any substance; and

(b) be disposed of in a manner that is consistent with that of the substance it contained, taking into account the nature and type of the packaging.

(3) Packaging (that may or may not contain any residual substance) that is lawfully disposed of by householders or other consumers through a public or commercial waste collection service is a means of compliance with subclause (2).

(4) Notwithstanding subclause (2), a package may be reused or recycled if—

(a) it has been treated to remove any residual contents of the substance; or

(b) the residual contents of the package have been rendered non-hazardous.

Part 8
Exposure Limits

20 Compliance with exposure limits

(1) Exposure limits are adopted for a substance or component(s) of a substance (as the case may be) to the extent (if at all) that they are set out on the register of exposure limits.

(2) In the case of WES values, where a WES value does not exist on the register of exposure limits but is listed in the document referred to in subclause (3), the value or values specified in that document shall apply to the substance or any component of the substance.

(3) The document referred to in subclause (2) is the document entitled *Workplace Exposure Standards* published by the Occupational Safety and Health Service, Department of Labour, January 2002, ISBN 0-477-03660-0.

Part 9
Notification to the Authority

21 Inventory of Chemicals

(1) Where a substance is imported into, or manufactured in, New Zealand after 30 June 2006, 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 has a deemed approval; 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.

(2) Subclause (1) applies subject to clauses 4(5) to (7) of this Group Standard (Scope of Group Standard).

Part 10
Other Matters

22 Assigning a substance to a Group Standard

(1) The manufacturer or importer of a substance who determines, or is otherwise independently advised, that the substance complies with clause 4 of this Group Standard (Scope of Group Standard) must keep a record of that determination or advice and have that record available for inspection.

(2) The record must contain sufficient information to allow for independent verification that the substance complies with clause 4 of this Group Standard (Scope of Group Standard).

Part 11
Restrictions on tooth-whitening products

23 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 8% and up to (and including) 12% 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 8% and up to (and including) 12% 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.

(3) A person (Person A) may only supply a tooth-whitening product covered by this group standard containing or releasing more than 12% hydrogen peroxide to:

(a) a person who obtains the product for the purpose of supplying:

(i) a dentist;

(ii) a registered oral health practitioner who is under the supervision of a dentist; or

(iii) a non-registered tooth-whitening practitioner who is under the supervision of a dentist;

(b) any other person, but only if Person A is:

(i) a dentist; or

(ii) a registered oral health practitioner who is under the supervision of a dentist.

(4) A person (Person A) may only apply a tooth-whitening product covered by this group standard containing or releasing more than 12% hydrogen peroxide to another person if Person A is:

(a) a dentist;

(b) a registered oral health practitioner who is under the supervision of a dentist; or

(c) a non-registered tooth-whitening practitioner who is under the supervision of a dentist.

History Explanatory Note
Part 11 was added via the Dental Products Group Standards (Amendment) Notice 2011 – New Zealand Gazette 30 June 2011. The part comes into force on 30 June 2013.

Schedule 2
Transitional Conditions

History Explanatory Note

The transitional provisions were deleted via the Dental Products Group Standards (Amendment) Notice 2011 – New Zealand Gazette 30 June 2011, as the transitional provisions had expired.

Schedule 3
Interpretation

approved handler means a person who holds a current test certificate certifying that they have met the requirements of the Hazardous Substances and New Organisms (Personnel Qualifications) Regulations 2001 as an approved handler in relation to one or more hazard classifications or hazardous substances

aspiration hazard means the potential for a liquid or solid substance to cause chemical pneumonitis if it enters the trachea and lower respiratory system

CAS number means Chemical Abstract Services Registry number

child resistant in relation to packaging, means that—

10 80% of children aged 42 months or over but less than 51 months would be unable to gain access to the contents of the packaging, or would be unlikely to obtain a toxic dose from packaging that is or contains a dispensing device within a period of 5 minutes; and

11 90% of adults aged 50 years or over but under 70 years would be able to open and re-close any child-resistant closure in the packaging

Civil Aviation Rule means the Civil Aviation Rule – Part 92 – Carriage of Dangerous Goods made under the Civil Aviation Act 1990

compatible means that the substance—

is chemically inert if brought into contact with any other substance for the range of temperatures and pressures at which the substances are brought into contact; or

if it is chemically reactive when brought into contact with any other substance, it does not—

cause combustion; or

generate an explosion; or

generate a new hazardous substance of a different class, subclass or category

condition means any obligation or restriction imposed upon a substance by a Group Standard

cosmetic product means any substance that is covered by the Cosmetic Products Group Standard 2006

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 a dental specialist under the Health Practitioners Competence Assurance Act 2003 and who 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 and includes tooth-whitening substances and oral hygiene products

exposure limit means an environmental exposure limit (EEL), a tolerable exposure limit (TEL), or a workplace exposure standard (WES) as those terms are defined in section 77B(6) of the Act

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

Land Transport Rule means the Land Transport Rule 45001/1: Dangerous Goods 2005 made under the Land Transport Act 1998

large packaging means packaging consisting of an outer packaging that contains articles or inner packaging, and that—

is designed for mechanical handling; and

can contain a net mass of contents of more than **400 kg** or has a capacity of more than **450 L**; but

has a volume of **3 m^3** or less

main label means, where there are two or more labels on a container or a label is divided into two or more portions—

that label or portion of the label on which the name of the product is most prominently shown and which is primarily designed to attract attention; or

where the name of the product is equally prominent on two or more labels or portions of a label, each of those labels or portions of the label on which the name of the product is equally prominent

Maritime Rule means the Maritime Rule: Part 24A – Carriage of Cargoes – Dangerous Goods made under the Maritime Transport Act 1994

non-registered tooth-whitening practitioner means a person who provides a commercial tooth-whitening service

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

package, packaging, inner packaging and outer packaging have the same meanings as in regulation 3 of the Hazardous Substances (Packaging) Regulations 2001

passenger service vehicle has the same meaning as in the Transport Services Licensing Act 1989

person in charge in relation to a place, a hazardous substance location, a transit depot, or a place of work, means a person who is—

the owner, lessee, sublessee, occupier, or person in possession of the place, location, or depot, or any part of it; or

12 any other person who, at the relevant time, is in effective control or possession of the relevant part of the place, location, or depot

pictogram means a graphical composition intended to convey specific information, in accordance with either—

the relevant pictograms contained in Annex 1 of the first revised edition of *The Globally Harmonized System of Classification and Labelling of Chemicals (GHS)*, published in 2005 by the United Nations (as reproduced in Table 1 of *Labelling of Hazardous Substances: Hazard and Precautionary Information* published by the Authority, July 2006); or

where a hazard class and/or category specified in (a) is covered as a pictogram under the UN Model Regulations, the assigned corresponding pictogram as defined in paragraph 5.2.2 of the UN Model Regulations (as reproduced in Table 1 of *Labelling of Hazardous Substances: Hazard and Precautionary Information* published by the Authority, July 2006)

place of work has the same meaning as in section 2(1) and (3) of the Health and Safety in Employment Act 1992

register of exposure limits means the register of exposure limits for substances with toxic or ecotoxic properties kept and maintained by the Authority pursuant to section 20A of the Act

registered oral health practitioner means a person who is registered under the Health Practitioners Competence Assurance Act 2003 who holds a current Annual Practising Certificate and whose scope of practice includes tooth-whitening procedures

substance means any 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

UN Manual of Tests and Criteria means the fourth revised edition of the *Recommendations on the Transport of Dangerous Goods Manual of Tests and Criteria*, published in 2003 by the United Nations

UN Model Regulations means the 14th revised edition of the *Recommendations on the Transport of Dangerous Goods Model Regulations*, published in 2005 by the United Nations

UN Packing Group relates to a standard of packaging that indicates the level of hazard inherent to dangerous goods defined by the United Nations. Packing Group I indicates high danger; Packing Group II, medium danger; Packing Group III, low danger

History Explanatory Note

Interpretation wording for:

dental industry
dentist
non-registered tooth-whitening practitioner
oral hygiene product
registered oral health practitioner
tooth-whitening product
tooth-whitening service

was added, and the interpretation wording for:

cosmetic product
dental product

was amended via the Dental Products Group Standards (Amendment) Notice 2011 – New Zealand Gazette 30 June 2011.

The new and modified interpretations come into force on 30 June 2013.

Explanatory note

This note is not part of the Group Standard, but is intended to provide guidance to users of the Group Standard.

(1) Clause 4 of this Group Standard (Scope of Group Standard) sets out the parameters that determine whether a substance is covered by this Group Standard. It is the responsibility of the manufacturer or importer of a substance to determine whether the substance complies with these parameters. The means of complying may not necessarily require product testing as this may be achieved in a variety of ways, for example, an analysis of the constituent components' hazards. For more information contact ERMA New Zealand.

(2) Codes of practice that have been approved by ERMA New Zealand are a means of complying with the conditions of this Group Standard. A list of approved codes is available from the ERMA New Zealand web site.

(3) Typical substances covered by this Group Standard include—

- whitening materials

Availability and publication of Group Standard and Reference Materials

(4) This Group Standard, and any materials incorporated into it by reference that are published by ERMA New Zealand may be—

(a) viewed on the ERMA New Zealand web site; or

(b) inspected free of charge during normal business hours at the ERMA New Zealand office; or

(c) purchased from ERMA New Zealand, Public Awareness Group, Email publicationinfo@ermanz.govt.nz.

(5) Any regulations incorporated by reference into a Group Standard may be—

(a) inspected free of charge during normal business hours at the ERMA New Zealand office; or

(b) purchased from Bennetts at http://www.bennetts.co.nz/legislation.htm; or

(c) viewed at http://www.legislation.govt.nz.

(6) Any materials incorporated by reference into a Group Standard that are published by the United Nations may be—

(a) inspected free of charge during normal business hours at the ERMA New Zealand office; or

(b) viewed on or ordered from the UN website, http://www.unece.org/trans/danger/publi/order.htm; or

(c) ordered from the New Zealand distributor: Legislation Direct, PO Box 12 418, Wellington, Ph 0064 4 495 2882, Fax 0064 4 495 2880, Email ldorders@legislationdirect.co.nz, or http://www.legislationdirect.co.nz.

(7) Any materials incorporated by reference into a Group Standard that are published by Standards New Zealand or Standards Australia may be—

(a) inspected free of charge during normal business hours at the ERMA New Zealand office; or

(b) ordered from Standards New Zealand, Ph 0800 735 656, Fax 0064 4 498 5994, Email snz@standards.co.nz or http://www.standards.co.nz/purchase-standards/default.htm or, in the case of Australian standards, from SAI Global Limited, Ph 00612 8206 6010, Fax 00612 8206 6020 or Email sales@sai-global.com as appropriate.

(8) Any materials incorporated by reference into a Group Standard that are published by any other party or organisation may be inspected free of charge during normal business hours at the ERMA New Zealand office.

ERMA New Zealand Contact Details

PO Box 131, Wellington
Ph: 0064 4 916 2426
Fax: 0064 4 914 0433
Email: info@ermanz.govt.nz
Website: http://www.ermanz.govt.nz

Appendix 3: Dental Products (Subsidiary Hazard) Group Standard 2006 as amended

Amended as at 8 September 2010
Amended as at 1 July 2010
Amended as at 30 June 2013

Hazardous Substances and New Organisms Act 1996

Dental Products (Subsidiary Hazard) Group Standard 2006

Pursuant to section 96B of the Hazardous Substances and New Organisms Act 1996 (**the Act**), the Environmental Risk Management Authority, on its own initiative, issues this Group Standard.

Contents

1 Title

Dental Products (Subsidiary Hazard) Group Standard 2006

HSNO Approval Number

The HSNO Approval Number for this Group Standard is HSR002558.

2 Commencement

This Group Standard comes into force on 1 July 2006 and applies to substances under section 96B(2)(a), (b) and (c) of the Act.

3 Interpretation

(1) In this Group Standard, unless the context otherwise requires, words and phrases shall have the meanings given to them in Schedule 3.

(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) Regulations 2001.

4 Scope of Group Standard

Substances covered by Group Standard

(9) This Group Standard applies to solid or liquid substances that are imported or manufactured for use as a dental product.

(2) A substance referred to in subclause (1) must have one or more of the following (but only the following) hazards:

(a) acute toxicity, HSNO 6.1D or 6.1E classification (including aspiration hazard);

(b) skin irritancy, HSNO 6.3A or 6.3B classification;

(c) eye corrosivity, HSNO 8.3A classification;

(d) eye irritancy, HSNO 6.4A classification;

(e) respiratory sensitisation, HSNO 6.5A classification;

(f) contact sensitisation, HSNO 6.5B classification;

(g) mutagenicity, HSNO 6.6A or 6.6B classification;

(h) reproductive toxicity, HSNO 6.8A, 6.8B or 6.8C classification;

(i) target organ toxicity, HSNO 6.9A or 6.9B classification;

(j) ecotoxicity, HSNO class 9.

Substances excluded from Group Standard

(3) This Group Standard excludes cosmetic products.

(4) No substance shall be permitted under this Group Standard if it 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; and

(c) clause 18 of Schedule 1 is complied with.

(5) Despite clause 18 of Schedule 1, no substance shall be permitted under this Group Standard if it is a hazardous chemical that is not listed on the Inventory of Chemicals.

(6) For the purposes of subclause (5), "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 change its composition.

5 Conditions of Group Standard

The obligations and restrictions set out in Schedules 1 and 2 to the Group Standard apply to the substances by way of conditions.

Schedule 2
Conditions of Group Standard

Part 1
Information Requirements

1 General information

(1) Any information (including advertising) provided or required to be made available or supplied under this Part (Information Requirements) must be readily understandable and if provided in words (whether written or oral) be in the English language. Where written information is provided, it must also be legible and durable.

(2) Any information provided must not include any statement, expression, device, trade name or description that—

(a) contradicts or modifies any expression required by this Group Standard to be on the label; or

(b) is false or misleading in relation to the safety of the substance or any of its ingredients; or

(c) misrepresents the composition of the substance; or

misrepresents any property of the substance, including information that suggests the substance belongs to a class or subclass that it does not in fact belong to.

2 Labelling

Duties of suppliers

(1) A person must not sell or supply a substance to another person unless the substance is labelled in accordance with the following requirements.

Hazard information required on each label

(2) A label must provide the following general information about a substance:

(a) the product name; and

(b) enough information to enable the New Zealand importer, supplier or manufacturer to be contacted, either in person or by telephone; and

(c) in the case of a HSNO 6.1D, 6.1E, 6.3A, 6.3B, 6.4A, 6.5A, 6.5B or 8.3A substance, a 24 hour emergency telephone number.

(3) Where a substance is available to the general public—

(a) for a HSNO 6.1D, 6.1E or 8.3A substance, there must be—

(i) on the main label, the general precautionary statement **'Keep out of reach of children'**; and

(ii) on the label, the general precautionary statement **'If medical advice is needed: Have product container or label at hand**'; and

(b) for all substances, there must be on the label, the general precautionary statement **'Read label before use'**.

(c) 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:

(i) '**If irritation develops, discontinue use. If irritation continues, consult a dentist'**;

(ii) '**Use for longer than 14 days is not recommended except under the supervision of a dentist**';

(iii) '**Not recommended for use on children under 16 years of age**';

(iv) '**Avoid swallowing**'; and

(v) '**Avoid direct contact of the product with gums or eyes**'.

(d) for oral hygiene products containing or releasing hydrogen peroxide, there must be on the label the precautionary statement '**If irritation occurs, discontinue use.'**

(3A) A person must not supply, offer to supply, or advertise a tooth-whitening product containing or releasing between 7% and less than 8% hydrogen peroxide, unless the product is accompanied by information that is equivalent to the precautionary statements in clause 3(c) above.

History Explanatory Note
Clauses 2(3)(c) and 2(3)(d)and 2(3A) were added via the Dental Products Group Standards (Amendment) Notice 2011 – New Zealand Gazette 30 June 2011. The clauses come into force on 30 June 2013.

(4) For each of the hazards listed under clause 4(2) of this Group Standard (Scope of Group Standard), the corresponding pictograms, signal word, hazard statements and precautionary (prevention, storage and response) statements as listed in Tables 1 to 5 of the document *Labelling of Hazardous Substances: Hazard and Precautionary Information* published by the Authority, July 2006 must appear on the label, subject to the principles of precedence as set out in the above-named document.

(5) A single indication may be used if it is capable of conveying two or more of the items of hazard information required by subclause (4).

Disposal information required on each label

(6) A label must provide a description of one or more appropriate and achievable methods for the disposal of a substance in accordance with clause 15 of this Schedule, which may also include any method of disposal that must be avoided.

Identification of components on label

(7) Subject to subclause (8), a label must provide—

(a) the common or chemical name and concentration of every ingredient that would, independently of any other ingredient, give the substance a HSNO 6.5, 6.6, 6.8, 6.9 or 8.3 classification; and

(b) the name of every ingredient (other than an ingredient referred to in subclause (a)) that would, independently of any other ingredient, give the substance a HSNO 6.1D classification, and the concentration of the ingredient that would contribute the most to that classification.

(8) In the case of a HSNO 6.5, 6.6, 6.8 or 6.9 classification, the identification of any component on the label is only required if the concentration of that component is at or above the concentration specified in Table 1.

Table 1. Concentration values triggering identification of components on label

HSNO Classification	Cut-off, %
6.5A, 6.5B, 6.6A	0.1
6.6B	1
6.8A, 6.8C	0.3
6.8B	3
6.9A, 6.9B	10

(9) For the purposes of complying with subclause (7)—

(a) a generic name may be used to identify a group of ingredients in accordance with the provisions of regulation 26 of the Hazardous Substances (Identification) Regulations 2001; and

(b) the concentration of an ingredient in a substance may be stated as a range in accordance with the provisions of regulation 27 of the Hazardous Substances (Identification) Regulations 2001.

Multiple packages

(10) Where a substance is labelled in compliance with subclauses (1) to (9), but some or all of the required information is obscured by outer packaging, the outer packaging of the substance must bear the labelling or marking required by—

(a) subclause (4) with respect to the appropriate signal word, pictogram(s) and hazard statement(s); or

(b) the Land Transport Rule; or

(c) the Civil Aviation Rule; or

(d) the Maritime Rule.

Exemption from specific labelling requirements for ecotoxic substances

(11) For a substance with an ecotoxic hazard of—

(a) HSNO 9.1C or 9.1D classification, the corresponding hazard statement required by subclause (4) is not required;

(b) HSNO 9.2, 9.3 or 9.4 classification, the corresponding pictogram, signal word, and hazard, prevention and response statements required by subclause (4) are not required.

Exemption from specific labelling requirements for small packages

(12) When a substance is contained in a package with a capacity of **5 L** or **5 kg** or less, the label for that package does not need to provide the following information:

(a) any pictogram required by subclause (4); and

(b) the signal word, hazard and response statements for any HSNO class 9 hazards, as required by subclause (4).

Exemption from specific labelling requirements for imported and exported packages

(13) Where a substance has been imported into New Zealand in a closed package or in a freight container (and for any reasonable period after it arrives that is necessary to arrange compliance with the requirements of subclauses (1) to (9)) and where that substance is being carried from the place of importation to the destination stated in its importation documentation without having been removed from that package or container, subclauses (1) to (9) are complied with if the package or container concerned complies with the requirements of—

(a) subclause (4) with respect to the appropriate signal word, pictogram(s) and hazard statement(s); or

(b) the Land Transport Rule; or

(c) the Civil Aviation Rule; or

(d) the Maritime Rule.

(14) Where a substance is exported from New Zealand, subclauses (1) to (9) are complied with if the substance is labelled or marked as required by—

(a) subclause (4) with respect to the appropriate signal word, pictogram(s) and hazard statement(s); or

(b) the Land Transport Rule; or

(c) the Civil Aviation Rule; or

(d) the Maritime Rule.

Alternative compliance measures for labelling

(15) Subject to subclause (15A), the requirements of subclauses (1) to (14) do not need to be met if a substance complies with—

(a) the relevant identification provisions in the Hazardous Substances (Identification) Regulations 2001, the Hazardous Substances (Emergency Management) Regulations 2001 and the Hazardous Substances (Disposal) Regulations 2001; or

(b) a code of practice approved by the Authority under section 78 of the Act that specifies requirements equivalent to those set out in subclauses (1) to (14); or

(c) the UN Globally Harmonised System of Classification and Labelling of Chemicals (GHS) and the requirements of subclause (2); or

(d) the relevant current labelling requirements of Australia, USA, Canada, the European Union or any other country as approved by the Authority, as if the substances were for sale or supply in those countries, and the requirements of subclause (2)

(15A) A person who relies on subclause (15)(a) must still comply with subclause (3)(c).

History Explanatory Note
Clause 2(15A) was added via the Dental Products Group Standards (Amendment) Notice 2011 – New Zealand Gazette 30 June 2011. Clause 2(15) was amended to reflect the added clause (15A). The clause comes into force on 30 June 2013.

(16) [*Omitted*]

History Explanatory Note
Clause 2(16) was omitted as at 1 July 2010 via the Labelling Requirements in Group Standards (Amendment) Notice 2010 – New Zealand Gazette 3 June 2010. The omitted words are as follows:

"Subclause (15)(d) expires with the close of 31 December 2010."

Substances transported in bulk

(17) Where a substance is transported in bulk, subclauses (1) to (9) do not apply provided the substance is transported in compliance with—

(a) the Land Transport Rule; or

(b) the Civil Aviation Rule; or

(c) the Maritime Rule.

(18) For the purposes of subclause (17), "bulk" means—

(a) a liquid substance in a container in an undivided quantity exceeding **450** L; or

(b) a solid substance in a container in an undivided quantity exceeding **400 kg**.

3 Safety data sheets

(1) A person, when selling or supplying a substance at quantities that exceed those set out in Table 2 shall provide a safety data sheet for the substance supplied to the recipient if—

(a) the substance is likely to be used in a place of work; and

(b) they have not previously supplied a safety data sheet for that substance to the recipient.

Table 2. Trigger quantities for provision of safety data sheet

13 Hazardous Property	14 Trigger Quantity
15 HSNO 6.1D, 6.5A, 6.5B, 6.6A, 6.6B, 6.8A, 6.8B, 6.8C, 6.9A, 6.9B, 8.3A, 9.1A, 9.1B or 9.1C or any combinations thereof	16 Any quantity
17 HSNO 6.1E, 6.3A, 6.3B, 6.4A, 9.1D, 9.2A, 9.2B, 9.2C, 9.2D, 9.3A, 9.3B, 9.3C, 9.4A, 9.4B or 9.4C or any combinations thereof but excluding any of the hazards listed in the preceding row	18 50 L or 50 kg aggregate quantity

(2) If subclause (1) applies—

(a) in each place of work where the substance is manufactured, stored or used, the person in charge of the place must ensure that every person handling the substance has access to a safety data sheet for that substance; and

(b) the safety data sheet must be available to a person handling the substance within 10 minutes, and be readily understandable by any fully trained worker required to have access to it.

(3) A person who manufactures or supplies a substance in New Zealand or imports a substance into New Zealand must, if asked to do so by any person in charge of a place of work where a substance is stored or used, give that person the required safety data sheet.

(4) Information required on a safety data sheet must be provided under the following general headings in the order listed below, and must include the information referred to under those headings:

(a) **Identification of the substance and supplier—**

(i) product name; and

(ii) recommended uses; and

(iii) name of the supplier, New Zealand contact details including an emergency contact;

(b) **Hazards identification—**

(i) a description of the hazards of the substance, which may include its HSNO hazard classification; and

(ii) hazard information, including signal words, hazard statement(s) and precautionary statement(s);

(c) **Composition/information on ingredients—**

(i) in the case of single component substances, their chemical identity, including common names and synonyms, CAS number and any impurities that are themselves hazardous; or

(ii) in the case of substances that are mixtures, the chemical identity of each hazardous ingredient, their CAS number and their concentration ranges;

(d) **First aid measures—**

(i) first aid instructions according to each relevant route of exposure; and

(ii) whether medical attention is required, and its urgency; and

(iii) information on the most important symptoms and effects, acute and delayed, from exposure;

(e) **Fire fighting measures—**

(i) information on the appropriate type of extinguishers or fire-fighting agents, including extinguishers that may not be appropriate for a particular situation; and

(ii) any advice on hazards that may arise from combustion products; and

(iii) precautions for fire fighters and protective clothing requirements;

(f) **Accidental release measures—**

(i) advice on protective clothing requirements and emergency procedures; and

(ii) any environmental precautions from accidental spills and release; and

(iii) advice on how to contain and clean up a spill or release;

(g) **Handling and storage—**

(i) precautions for safe handling; and

(ii) conditions for safe storage, including any incompatibilities;

(h) **Exposure controls/personal protection—**

(i) exposure limits set for the substance or any of its components, or in their absence, relevant overseas exposure limits; and

(ii) engineering controls; and

(iii) individual protection measures, including personal protective equipment;

(i) **Physical and chemical properties—**

(i) a description of relevant physical and chemical properties for the substance, including units of measurement and reference conditions where appropriate; and

(ii) where necessary for interpretation of data reported, the method of determination;

(j) **Stability and reactivity—**

(i) an indication of the chemical stability of the substance under normal and anticipated storage and handling conditions; and

(ii) a list of conditions to avoid to prevent a hazardous situation; and

(iii) information on incompatible substances or materials;

(k) **Toxicological information—**

(i) a full description of the toxicological (health) effects, including the symptoms or signs of injury or ill health associated with each likely route of exposure; and

(ii) the dose, concentration or conditions of exposure likely to cause injury or ill health; and

(iii) a summary of the data used to identify the health effects;

(l) **Ecological information—**

(i) ecotoxicity; and

(ii) persistence and degradability; and

(iii) mobility;

(m) **Disposal considerations—**

(i) disposal methods, including disposal of packaging; and

(ii) special precautions to be taken during disposal; and

(iii) any method of disposal that should not be used;

(n) **Transport information—**

If relevant,

(i) the UN number; and

(ii) the proper shipping name; and

(iii) the UN Dangerous Goods class and subsidiary risk; and

(iv) the UN Packing Group;

(o) **Regulatory information—**

(i) HSNO approval number and/or title of the Group Standard; and

(ii) information on the conditions of the Group Standard, and any other regulatory requirements;

(p) **Other information—**

(i) date of preparation or revision of the safety data sheet; and

(ii) a key/legend to abbreviations and acronyms used.

(5) Where a substance is being transported, a safety data sheet is not required if—

(a) there is in the vehicle concerned documentation complying with the Land Transport Rule whilst being transported by land; or

(b) there is in the ship concerned documentation complying with the Maritime Rule whilst being transported by sea; or

(c) there is in the aircraft concerned documentation complying with the Civil Aviation Rule whilst being transported by air.

4 Advertising

Where a substance with an acute toxic hazard (HSNO 6.1D or 6.1E classification) and/or a corrosive hazard (HSNO 8.3A classification) is advertised to members of the public, and the person to whom the advertising is directed is not provided with a reasonable opportunity to read and consider the information required to be on the product label prior to purchase of the substance, any advertising (whether written, screen or audio) must include in readily understandable form the following information:

(a) an indication that the substance is acutely toxic and/or corrosive (whatever the case may be); and

(b) the need to restrict access by children to the substance.

Part 2
Site and Storage

5 Compliance with site and storage requirements

(1) Any location at which a substance is manufactured or stored in quantities that exceed those set out in Table 3 must comply with the relevant conditions as set out in the document entitled *Site and Storage Conditions for Toxic, Corrosive and Ecotoxic Substances* published by the Authority, July 2006.

Table 3. Trigger quantities beyond which site and storage conditions apply

	Trigger quantity

Response plans and secondary containment	100 L or 100 kg	(for a HSNO 9.1A substance); or
	1,000 L or 1,000 kg	(for a HSNO 6.1D, 6.5A, 6.5B, 9.1B or 9.1C substance); or
	10,000 L or 10,000 kg	(for a HSNO 9.1D, 8.3A, 6.6A, 6.8A or 6.9A substance)
Signage	100 L or 100 kg	(for a HSNO 9.1A substance); or
	1,000 L or 1,000 kg	(for a HSNO 8.3A, 9.1B or 9.1C substance); or
	10,000 L or 10,000 kg	(for a HSNO 6.1D or 9.1D substance)

(2) The trigger quantities referred to in Table 3 must take into account any other hazardous substance that is present at that location.

Stationary container systems

(3) Any stationary container system that contains, or is intended to contain, a substance must comply, to the extent applicable, with the controls for stationary container systems as set out in Parts 1 to 19 of Schedule 8 of the Hazardous Substances (Dangerous Goods and Scheduled Toxic Substances) Transfer Notice 2004, notwithstanding clause 1(1) of that Schedule.

Part 3
Approved Handler

6 Approved handler requirements

(1) Substances covered under this Group Standard will not require an approved handler.

Part 4
Packaging

7 General packaging requirements

Every person who packs a substance must—

(a) select packaging that when filled and closed—

(i) does not leak any substance under normal working conditions; and

(ii) maintains its ability to retain contents, if part of the contents are removed and the package resealed; and

(iii) does not react with a substance in any way as to weaken the package; and

(b) ensure that, if a substance is being packed into a package that has previously contained another substance—

(i) both substances are compatible; or

(ii) all practicable steps are taken to remove all residues of the original substance.

8 Compliance with UN Packing Group requirements

(1) Where allowed for by the UN Model Regulations, large packaging may be used to contain a substance if it has been constructed, marked, and tested as a large package as provided in Chapter 6.6 of the UN Model Regulations.

(2) When a substance is packaged in quantities less than or equal to **450 L** or **400 kg**, the packaging must comply with the requirements of—

(a) UN Packing Group III for a HSNO 9.1A or 9.1B substance; or

(b) Schedule 4 of the Hazardous Substances (Packaging) Regulations 2001 for all other substances.

Variation to UN Packing Group III requirements

(3) Despite subclause (2)(a), a HSNO 9.1A or 9.1B substance may, as a minimum, be packaged in packaging that complies with Schedule 4 of the Hazardous Substances (Packaging) Regulations 2001 when in quantities less than or equal to **5 L** or **5 kg.**

Marking of Packaging

(4) No manufacturer or importer of packaging designed and constructed for use with a substance may mark the packaging as specified in paragraphs 6.1.2 and 6.1.3 of the UN Model Regulations unless—

(a) the markings comply with the corresponding elements of those paragraphs, including the codes for packaging type, UN Packing Group, and the UN packaging symbol; and

(b) the codes marked for UN Packing Group III are marked on packaging that complies with the tests set out in Schedule 3 of the Hazardous Substances (Packaging) Regulations 2001; and

(c) the design of the packaging has also been test certified as complying with the tests set out in Schedule 3 of the Hazardous Substances (Packaging) Regulations 2001.

(5) Subclause (4) does not apply to a substance that is not required to be packaged in UN Packing Group III.

9 Child resistant packaging

(1) In the case of a HSNO 6.1D, 6.1E or 8.3A substance, when that substance is packaged in quantities of less than **2.5 L** or **2.5 kg**, that package must be child resistant, unless being sold or supplied to a place of work where children do not have access and the substance is for use in that place of work.

(1) The requirements of subclause (1) do not need to be met if—

(a) the substance complies with the requirements for child resistant packaging (if any) of Australia, USA or the European Union or any other country as approved by the Authority; and

(b) the substance is not—

(i) a HNSO 6.1D substance; or

(ii) an aspiration hazard.

10 Specific packaging requirement for certain HSNO 6.1 substances

(1) Any packaging containing a liquid substance with a HSNO 6.1D classification must be permanently identified as containing a toxic substance unless the substance as packaged is restricted to a place of work.

(2) The requirement of subclause (1) does not need to be met if the substance container meets the container requirements for that substance of Australia, the European Union or any other country as approved by the Authority.

Part 5
Equipment

11 Personal protective equipment

(1) A person who handles a HSNO 6.1D, 6.3A, 6.5A, 6.5B, 6.6A, 6.6B, 6.8A, 6.8B, 6.8C, 6.9A, 6.9B or 8.3A substance in a place of work must use protective clothing or protective equipment that is designed, constructed, and operated to ensure that the person—

(a) does not come into contact with the substance; and

(b) is not exposed to a concentration of the substance that is greater than the workplace exposure standard for the substance, or any component of the substance.

(2) Subclause (1) does not apply to a substance that is contained in a closed package that complies with the requirements of Part 4 (Packaging).

(3) The supervisor of a place of work must ensure that protective clothing or protective equipment used to handle a substance is accompanied by documentation containing information specifying—

(a) the circumstances in which the clothing or equipment may be used; and

(b) the requirements for maintaining the clothing or equipment.

(4) In subclause (3)(a), "circumstances" include, if relevant, the presence of other substances, and the temperatures and pressures in or at which the clothing or equipment may be used.

12 Equipment used to handle a substance

(1) A person in charge of a substance must ensure that equipment used to handle the substance—

(a) retains the substance, without leakage at all temperatures and pressure for which the equipment is intended to be used; and

(b) dispenses or applies the substance, without leakage, at a rate and in a manner that the equipment is designed for.

(2) The equipment must be accompanied by documentation containing information about the use and maintenance of the equipment to enable the equipment to be used and maintained in a manner that complies with subclause (1).

Part 6
Transportation

13 Tank wagons and transportable containers

Tank wagons and transportable containers of any capacity used to carry a substance must comply with the Hazardous Substances (Tank Wagons and Transportable Containers) Regulations 2004.

14 Passenger service vehicle restrictions

When a substance is carried on a passenger service vehicle, the substance must—

(a) be packaged in a sealed container; and

(b) not exceed—

(i) **1 L** or **2 kg** per package for a HSNO 8.3A substance; or

(ii) **2.5 L** or **5 kg** per package for all other substances.

Part 7
Disposal

15 Disposal of substance

(1) A substance must be disposed of by—

(a) exporting the substance from New Zealand as waste; or

(b) treating the substance so that it is no longer a hazardous substance; or

(c) discharging the substance into the environment so that, after reasonable mixing, the concentration of the substance in an environmental medium does not exceed any relevant tolerable exposure limit and/or environmental exposure limit set for the substance or any of its component(s).

(2) In subclause 1(b), "treating the substance" includes depositing the substance in a landfill, incinerator or sewage facility providing—

(a) the landfill, incinerator or sewage facility renders the substance non-hazardous by a means other than dilution; or

(b) the concentration of the substance in any discharge from the landfill, incinerator or sewage facility does not, after reasonable mixing, exceed any relevant tolerable exposure limit and/or environmental exposure limit set for the substance or any of its component(s).

(3) Notwithstanding subclause (1)(c), if the substance or one or more of its components is bioaccumulative and not rapidly degradable the substance must be treated before discharge into the environment to reduce the percentage by volume of the substance in the discharge to 1% or less.

(4) A substance with no ecotoxic (HSNO class 9) hazard may be discharged into the environment without complying with subclause (1)(c) if it is rapidly degradable and the products of degradation are not hazardous.

(5) This clause does not apply to a substance that is intended for recycling.

16 Disposal of packaging

(1) The conditions of this clause apply to a package that—

(a) contained a substance; and

(b) was in direct contact with the substance; and

(c) is no longer to be used to contain the substance and is intended for disposal.

(2) A package must—

(a) be rendered incapable of containing any substance; and

(b) be disposed of in a manner that is consistent with that of the substance it contained, taking into account the nature and type of the packaging.

(3) Packaging (that may or may not contain any residual substance) that is lawfully disposed of by householders or other consumers through a public or commercial waste collection service is a means of compliance with subclause (2).

(4) Notwithstanding subclause (2), a package may be reused or recycled if—

(a) it has been treated to remove any residual contents of the substance; or

(b) the residual contents of the package have been rendered non-hazardous.

Part 8
Exposure Limits

17 Compliance with exposure limits

(1) Exposure limits are adopted for a substance or component(s) of a substance (as the case may be) to the extent (if at all) that they are set out on the register of exposure limits.

(2) In the case of WES values, where a WES value does not exist on the register of exposure limits but is listed in the document referred to in subclause (3), the value or values specified in that document shall apply to the substance or any component of the substance.

(3) The document referred to in subclause (2) is the document entitled *Workplace Exposure Standards* published by the Occupational Safety and Health Service, Department of Labour, January 2002, ISBN 0-477-03660-0.

Part 9
Notification to the Authority

18 Inventory of Chemicals

(1) Where a substance is imported into, or manufactured in, New Zealand after 30 June 2006, 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 has a deemed approval; 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.

(2) Subclause (1) applies subject to clauses 4(4) to (6) of this Group Standard (Scope of Group Standard).

Part 10
Other Matters

19 Assigning a substance to a Group Standard

(1) The manufacturer or importer of a substance who determines, or is otherwise independently advised, that the substance complies with clause 4 of this Group Standard (Scope of Group Standard) must keep a record of that determination or advice and have that record available for inspection.

(2) The record must contain sufficient information to allow for independent verification that the substance complies with clause 4 of this Group Standard (Scope of Group Standard).

Part 11
Restrictions on tooth-whitening products

20 Supply and application of tooth-whitening products

(2) 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;

(a) a person who obtains the product for the purpose of supplying the persons in (a) to (c) above; or

(b) 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.

(3) 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.

History Explanatory Note
Part 11 was added via the Dental Products Group Standards (Amendment) Notice 2011 – New Zealand Gazette 30 June 2011. The part comes into force on 30 June 2013.

Schedule 2Transitional Conditions

History Explanatory Note

The transitional provisions were deleted as at 30 June 2011 via the Dental Products Group Standards (Amendment) Notice 2011 – New Zealand Gazette 30 June 2011, as the transitional provisions had expired.

19

20

Schedule 3
Interpretation

approved handler means a person who holds a current test certificate certifying that they have met the requirements of the Hazardous Substances and New Organisms (Personnel Qualifications) Regulations 2001 as an approved handler in relation to one or more hazard classifications or hazardous substances

aspiration hazard means the potential for a liquid or solid substance to cause chemical pneumonitis if it enters the trachea and lower respiratory system

CAS number means Chemical Abstract Services Registry number

child resistant in relation to packaging, means that—

21 80% of children aged 42 months or over but less than 51 months would be unable to gain access to the contents of the packaging, or would be unlikely to obtain a toxic dose from packaging that is or contains a dispensing device within a period of 5 minutes; and

22 90% of adults aged 50 years or over but under 70 years would be able to open and re-close any child-resistant closure in the packaging

Civil Aviation Rule means the Civil Aviation Rule – Part 92 – Carriage of Dangerous Goods made under the Civil Aviation Act 1990

compatible means that the substance—

is chemically inert if brought into contact with any other substance for the range of temperatures and pressures at which the substances are brought into contact; or

if it is chemically reactive when brought into contact with any other substance, it does not—

cause combustion; or

generate an explosion; or

generate a new hazardous substance of a different class, subclass or category

condition means any obligation or restriction imposed upon a substance by a Group Standard

cosmetic product means any substance that is covered by the Cosmetic Products Group Standard 2006

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 who 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 and includes tooth-whitening substances and oral hygiene products

exposure limit means an environmental exposure limit (EEL), a tolerable exposure limit (TEL), or a workplace exposure standard (WES) as those terms are defined in section 77B(6) of the Act

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

Land Transport Rule means the Land Transport Rule 45001/1: Dangerous Goods 2005 made under the Land Transport Act 1998

large packaging means packaging consisting of an outer packaging that contains articles or inner packaging, and that—

(a) is designed for mechanical handling; and

(b) can contain a net mass of contents of more than **400 kg** or has a capacity of more than **450 L**; but

(c) has a volume of **3 m^3** or less

main label means, where there are two or more labels on a container or a label is divided into two or more portions—

that label or portion of the label on which the name of the product is most prominently shown and which is primarily designed to attract attention; or

where the name of the product is equally prominent on two or more labels or portions of a label, each of those labels or portions of the label on which the name of the product is equally prominent

Maritime Rule means the Maritime Rule: Part 24A – Carriage of Cargoes – Dangerous Goods made under the Maritime Transport Act 1994

non-registered tooth-whitening practitioner means a person who provides a commercial tooth-whitening service

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

package, packaging, inner packaging and outer packaging have the same meanings as in regulation 3 of the Hazardous Substances (Packaging) Regulations 2001

passenger service vehicle has the same meaning as in the Transport Services Licensing Act 1989

person in charge in relation to a place, a hazardous substance location, a transit depot, or a place of work, means a person who is—

the owner, lessee, sublessee, occupier, or person in possession of the place, location, or depot, or any part of it; or

any other person who, at the relevant time, is in effective control or possession of the relevant part of the place, location, or depot

pictogram means a graphical composition intended to convey specific information, in accordance with either—

(a) the relevant pictograms contained in Annex 1 of the first revised edition of *The Globally Harmonized System of Classification and Labelling of Chemicals (GHS)*, published in 2005 by the United Nations (as reproduced in Table 1 of *Labelling of Hazardous Substances: Hazard and Precautionary Information*, published by the Authority July 2006); or

(b) where a hazard class and/or category specified in (a) is covered as a pictogram under the UN Model Regulations, the assigned corresponding pictogram as defined in paragraph 5.2.2 of the UN Model Regulations (as reproduced in Table 1 of *Labelling of Hazardous Substances: Hazard and Precautionary Information* published by the Authority, July 2006)

place of work has the same meaning as in section 2(1) and (3) of the Health and Safety in Employment Act 1992

register of exposure limits means the register of exposure limits for substances with toxic or ecotoxic properties kept and maintained by the Authority pursuant to section 20A of the Act

registered oral health practitioner means a person who is registered under the Health Practitioners Competence Assurance Act 2003 who holds a current Annual Practising Certificate and whose scope of practice includes tooth-whitening procedures

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

UN Manual of Tests and Criteria means the fourth revised edition of the *Recommendations on the Transport of Dangerous Goods Manual of Tests and Criteria*, published in 2003 by the United Nations

UN Model Regulations means the 14th revised edition of the *Recommendations on the Transport of Dangerous Goods Model Regulations*, published in 2005 by the United Nations

UN Packing Group relates to a standard of packaging that indicates the level of hazard inherent to dangerous goods defined by the United Nations. Packing Group I indicates high danger; Packing Group II, medium danger; Packing Group III, low danger

History Explanatory Note

Interpretation wording for:

dental industry
dentist
non-registered tooth-whitening practitioner
oral hygiene product
registered oral health practitioner
tooth-whitening product
tooth-whitening service

was added, and the interpretation wording for:

cosmetic product
dental product

was amended via the Dental Products Group Standards (Amendment) Notice 2011 – New Zealand Gazette 30 June 2011.

The interpretations come into force on 30 June 2013.

Explanatory note

This note is not part of the Group Standard, but is intended to provide guidance to users of the Group Standard.

(1) Clause 4 of this Group Standard (Scope of Group Standard) sets out the parameters that determine whether a substance is covered by this Group Standard. It is the responsibility of the manufacturer or importer of a substance to determine whether the substance complies with these parameters. The means of complying may not necessarily require product testing as this may be achieved in a variety of ways, for example, an analysis of the constituent components' hazards. For more information contact ERMA New Zealand.

(2) Codes of practice that have been approved by ERMA New Zealand are a means of complying with the conditions of this Group Standard. A list of approved codes is available from the ERMA New Zealand web site.

(3) Typical substances covered by this Group Standard include—

- whitening materials

Availability and publication of Group Standard and Reference Materials

(4) This Group Standard, and any materials incorporated into it by reference that are published by ERMA New Zealand may be—

(a) viewed on the ERMA New Zealand web site; or

(b) inspected free of charge during normal business hours at the ERMA New Zealand office; or

(c) purchased from ERMA New Zealand, Public Awareness Group, Email publicationinfo@ermanz.govt.nz.

(5) Any regulations incorporated by reference into a Group Standard may be—

(a) inspected free of charge during normal business hours at the ERMA New Zealand office; or

(b) purchased from Bennetts at http://www.bennetts.co.nz/legislation.htm; or

(c) viewed at http://www.legislation.govt.nz.

(6) Any materials incorporated by reference into a Group Standard that are published by the United Nations may be—

(a) inspected free of charge during normal business hours at the ERMA New Zealand office; or

(b) viewed on or ordered from the UN website, http://www.unece.org/trans/danger/publi/order.htm; or

(c) ordered from the New Zealand distributor: Legislation Direct, PO Box 12 418, Wellington, Ph 0064 4 495 2882, Fax 0064 4 495 2880, Email ldorders@legislationdirect.co.nz, or http://www.legislationdirect.co.nz.

(7) Any materials incorporated by reference into a Group Standard that are published by Standards New Zealand or Standards Australia may be—

(a) inspected free of charge during normal business hours at the ERMA New Zealand office; or

(b) ordered from Standards New Zealand, Ph 0800 735 656, Fax 0064 4 498 5994, Email snz@standards.co.nz or http://www.standards.co.nz/purchase-standards/default.htm or, in the case of Australian standards, from SAI Global Limited, Ph 00612 8206 6010, Fax 00612 8206 6020 or Email sales@sai-global.com as appropriate.

(8) Any materials incorporated by reference into a Group Standard that are published by any other party or organisation may be inspected free of charge during normal business hours at the ERMA New Zealand office.

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