

Australian Standard[®] 2827—1985

TOOTHPASTES

For referenced documents see Clause 2
" " " see p.21 + p.5

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Australian Consumers Association
Australian Federation of Consumer Organizations
Australian Dental Association
Australian Dental Standards Laboratory
Australian Dental Trade Association
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Confederation of Australian Industry
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AUSTRALIAN STANDARD

TOOTHPASTES

AS 2827—1985

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PREFACE

This standard was prepared by the Association's Committee on Oral Hygiene Agents and Devices under the direction of the Dental Materials and Equipment Standards Committee, and is one of a series intended for use in assessing the quality of dental goods used in Australia.

In the preparation of this standard, account was taken of BS 5136:1981, Toothpastes, and the Council of the European Communities Directive relating to cosmetic products.

Chemical and other test methods that are required for this standard but not specified in Appendices should be recognized techniques which are subject to agreement between the manufacturer and the testing authority.

Some facilities required for the testing of materials for compliance with this standard are available at the Australian Dental Standards Laboratory, 240 Langridge Street, Abbotsford, Victoria, 3067.

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STANDARDS ASSOCIATION OF AUSTRALIA

Australian Standard
for
TOOTHPASTES

1 SCOPE. This standard specifies requirements for toothpastes intended for use with a brush for the cleaning of natural teeth. Such toothpastes may contain therapeutic additives.

NOTES:

1. Dentifrices presented in powder or liquid form may be the subject of separate Australian standards.
2. Advisory information on sampling and assessing compliance with this standard is given in Appendix F.

2 REFERENCED DOCUMENTS. The following documents are referred to in this standard:

- AS 1032 Toothbrushes
- AS 1152 Test Sieves
- BS 2006 Metal Collapsible Tubes
- BS 2625 Chemically Pure Glycerol
- BS 2942 Formaldehyde Solution
- BS 3984 Sodium Silicates
- ✓ Proposed Australian Approved Names and Other Names for Therapeutic Substances 615.1
4
- British Pharmacopoeia
- European Pharmacopoeia
- United States Pharmacopoeia—National Formulary
- Approved Food Standards and Approved Food Additives
- Standard for Cosmetics
- British Pharmaceutical Codex
- Food Chemicals Codex
- World Health Organization Food Additive Series
- Food and Agriculture Organization Nutrition Reports
- United States Code of Federal Regulations

3 DEFINITIONS. For the purpose of this standard, the following definitions apply:

3.1 Unit pack—pack (generally a carton) containing a complete primary container.

3.2 Primary container—the container (generally a collapsible tube) which is actually in contact with the toothpaste.

4 COMPOSITION

4.1 Basic requirements. The composition of the toothpaste shall be such that—

- (a) no toxic or irritant reaction is caused in the mouth;
- (b) allowing that amounts may be inadvertently ingested, no harmful effects will result from normal use; and
- (c) the toothpaste will comply with relevant Commonwealth and State legislation governing health, safety and therapeutic claims.

NOTE: Appendix A gives an interim list of substances which are used, or may be used, in the manufacture of toothpastes. These, and other substances which may be added to the list, must comply with the relevant Commonwealth and State legislation governing health and safety, and the other requirements set out in Clause 4.1.

Substances not on the list may also be used provided that their chemical identity is disclosed to the Commonwealth Department of Health and in confidence to the testing authority. The proposed National Health and Medical Research Council Cosmetics Standard will provide further guidance to manufacturers.

4.2 Therapeutic additives.

4.2.1 Additives other than fluorine derivatives. Toothpastes having additives claimed to impart clinical effectiveness to the toothpaste shall maintain their clinical effectiveness during the normal life of the product (see Clauses 7.2 (d) and 7.3 (d)). At the time of manufacture, the amount of such additives shall be not more than 115 percent or less than 85 percent of the amount stated on the label.

4.2.2 Fluorine derivatives as additives. When determined in accordance with one of the two methods described in Appendix D, the total fluorine content shall not exceed 1000 µg/g (tolerance limits 90 percent to 110 percent). The water soluble fluorine derivative determined as fluoride ion shall be not less than 600 µg/g within one year of manufacture (see Clause 7.1(d)).

4.3 Heavy metals. Toxic or heavy metals shall not be present in quantities greater than those shown in Table 1.

TABLE 1
LIMITS FOR METALS

Toxic or heavy metals	Content µg/g max
Antimony	1.5
Arsenic	2
Cadmium	1
Copper	10
Lead	5
Mercury	0.5
Selenium	1
Tin	50
Zinc	150

NOTE: For the purpose of this standard, antimony, arsenic and selenium are deemed to be metals. The restrictions for metals, added for a specific purpose do not apply if a value higher than that shown in Table 1 can be demonstrated to comply with the requirements of Clause 4.1.

5 PHYSICOCHEMICAL PROPERTIES.

5.1 pH value. When determined in accordance with Appendix B, the pH value of the toothpaste shall be within the range 4.2 to 10.5.

5.2 Abrasive properties. When the toothpaste is tested in accordance with Appendix C, its abrasivity calculated by the statistical treatment provided shall not exceed the following limits when measured by either the radio-tracer or the surface profile method:

- (a) For dentine, 2 times the reference paste.
- (b) For enamel, 4 times the reference paste.