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Dentistry — Toothpastes — Requirements, test methods and marking

*Produits et matériel pour l'art dentaire — Dentifrice — Prescriptions,
méthodes d'essai et marquage*



Reference number
ISO 11609:1995(E)

Foreword

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Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 11609 was prepared by Technical Committee ISO/TC 106, *Dentistry*, in collaboration with the International Dental Federation (FDI).

Annex A forms an integral part of this International Standard. Annexes B and C are for information only.

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Dentistry — Toothpastes — Requirements, test methods and marking

1 Scope

This International Standard specifies requirements and test methods for physical and chemical properties, and for the marking and/or labelling of toothpastes for daily use by the public with a toothbrush to promote oral hygiene.

NOTE 1 It is anticipated that guidelines on claimed or implied efficacy of toothpastes for the prevention or control of oral conditions will be published as an FDI Technical Report.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 1942:1989, *Dental vocabulary*.

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods*.

BS 5136:1981, *Specification for toothpastes*.

CTFA, *International Cosmetic Ingredients Dictionary*.¹⁾

SHELLIS, R.P. A synthetic saliva for cultural studies of dental plaque. *Archives Oral Biol.*, **23**, pp. 485-489, 1978.

1) See note 4, clause 6.

POPE, D.G. Accelerated stability testing for production of drug product stability. *Drugs and Cosmetics*, pp. 54-62, 1980.

3 Definitions

For the purposes of this International Standard, the definitions given in ISO 1942 and the following definitions apply.

3.1 dentifrice: Any substance or combination of substances specially prepared for the public for cleaning the accessible surfaces of teeth.

3.1 toothpaste: Any semi-solid dentifrice preparation presented in the form of a paste, cream or gel.

NOTE 2 The product's main constituents generally are an abrasive, humectants, a binder, a surfactant and a flavouring. Secondly, the product may contain agents for oral health maintenance.

4 Requirements

4.1 Total fluoride

The total fluoride concentration shall not exceed the limits set by national laws and regulations and in no case shall the total fluoride concentration exceed 0,15 % (*m/m*). When using containers, for example dispensing systems of various sorts, the total fluoride content per single unit shall not exceed 300 mg.

Test in accordance with one of the procedures given in annex B or the EEC method^[22]. Other validated methods of similar sensitivity and accuracy may be used (see references [20] and [21]).

4.2 Heavy metals

The maximum concentration shall not exceed the limits set by national laws and regulations. In no case shall the total heavy metal concentration in the toothpaste be greater than 20 mg/kg.

Test in accordance with reference [10], [11] or [12], or other validated method of similar sensitivity and accuracy.

4.3 Alkalinity

When tested in accordance with 5.2.1, the toothpaste shall have a pH below 10,5.

4.4 Demineralization

Toothpastes having a pH of less than 5,5 shall be tested for demineralization in accordance with 5.2.2. The enamel lost from teeth exposed to the test shall not exceed that lost from teeth exposed to the control treatment or shall comply with the requirements of the enamel abrasion test (5.2.2.2).

4.5 Compatibility with oral tissues

The toothpaste should not cause irritation or damage to the oral tissue when used as intended by the manufacturer.

Test in accordance with 5.2 and 5.3.

NOTE 3 Specific qualitative and quantitative requirements for freedom from biological hazards are not included in this International Standard, but it is recommended that reference should be made to ISO/TR 7405^[1] and ISO 10993-1^[2] when assessing possible biological or toxicological hazards.

4.6 Microbiology

Testing for microbiological contamination shall be carried out according to reference [9] or references [3], [4] and [5].

4.7 Abrasivity

The abrasivity of the toothpaste shall not exceed the following limits for dentin:

- 2,5 times, if using the procedure specified in annex A, or
- 2 times, if using the procedure specified in BS 5136,

that of the primary reference material.

Test in accordance with 5.3 or any other validated method of similar sensitivity and accuracy.

4.8 Stability

The toothpaste shall show no signs of deterioration which may affect compliance with this International Standard after being subjected to the ageing procedure specified in 5.4.

4.9 Readily fermentable carbohydrates

The toothpaste shall not contain readily fermentable carbohydrates. Compliance shall be established by the absence of such compounds in the complete formula or by performing tests in accordance with commonly used analytical methods.

5 Test methods

5.1 Visual inspection

The toothpaste shall show no signs of deterioration (e.g. separation, discoloration, viscosity/extension difficulties) after being stored according to the accelerated ageing procedures specified in 5.4.1. This attests to its compliance with this International Standard. Examine under a bright light with normal visual acuity without magnification.

5.2 Determination of pH and enamel demineralization

5.2.1 Determination of pH

Suspend one part by mass of the toothpaste into three parts by mass of water for analytical laboratory use complying with ISO 3696 (grade 2). Determine the pH of the suspension within 10 min, using a pH-meter with a glass and calomel electrode assembly.

5.2.2 Determination of enamel demineralization or abrasion (low pH compositions)

The toothpaste shall comply with the requirements of either 5.2.2.1 or 5.2.2.2.

5.2.2.1 Enamel demineralization

For toothpaste with a pH below 5,5, use the following procedure.

Prepare radioactive human enamel (see annex A or B) in a manner that will provide a uniform surface area on all specimens. Perform the irradiation of the specimens in accordance with the procedure for radioactive abrasion tests. Cover the remainder of the enamel with an acid-resistant varnish.

Immerse the specimens in artificial saliva for 1 h to promote a slight protein film simulating oral condi-



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