

BS EN ISO 11609:2010



BSI Standards Publication

Dentistry — Dentifrices — Requirements, test methods and marking (ISO 11609:2010)

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The UK participation in its preparation was entrusted to Technical Committee CH/106/7, Oral hygiene products.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Compliance with a British Standard cannot confer immunity from legal obligations.

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English Version

Dentistry - Dentifrices - Requirements, test methods and
marking (ISO 11609:2010)

Médecine bucco-dentaire - Dentifrices - Exigences,
méthodes d'essai et marquage (ISO 11609:2010)

Zahnheilkunde - Zahnputzmittel - Anforderungen,
Prüfverfahren und Kennzeichnung (ISO 11609:2010)

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Foreword

The text of **ISO 11609:2010** has been prepared by Technical Committee ISO/TC 106 "Dentistry" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 11609:2010 by Technical Committee CEN/TC 55 "Dentistry" the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2011, and conflicting national standards shall be withdrawn at the latest by March 2011.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 11609:1998.

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Endorsement notice

The text of ISO 11609:2010 has been approved by CEN as a EN ISO 11609:2010 without any modification.

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Requirements relative to the physical and chemical properties of dentifrices	2
4.1 Total fluoride	2
4.1.1 Total fluoride concentration	2
4.1.2 Total fluoride in a single-unit container	2
4.2 Heavy metals	2
4.3 pH	2
4.4 Microbiology	2
4.5 Abrasivity	2
4.6 Stability	3
4.7 Readily fermentable carbohydrates	3
5 Test methods	3
5.1 Determination of pH	3
5.2 Determination of dentine abrasivity	3
5.3 Determination of enamel abrasivity	3
5.4 Determination of stability	3
6 Marking and labelling	4
7 Packaging	4
Annex A (informative) Abrasivity test procedure — American Dental Association (ADA) method	5
Annex B (informative) Determination of relative dentifrice abrasivity to enamel and dentine by a surface profile method	12
Annex C (informative) Testing of total fluoride in dentifrices	16
Bibliography	19

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

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ISO 11609 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 7, *Oral care products*.

This second edition of ISO 11609 cancels and replaces the first edition (ISO 11609:1995), which has been technically revised.

Introduction

Dentifrices should not cause any adverse reactions to the oral soft tissues when used in accordance with the manufacturer's recommendation for frequency and duration of use, nor cause any known side effects.

Guidelines on assessing the claimed or implied efficacy of dentifrices for the prevention or control of oral conditions can be found through the US Food and Drug Administration^[3], the American Dental Association^[4] and the Commission Work Project (8-95) of the FDI World Dental Federation^[16].

Dentistry — Dentifrices — Requirements, test methods and marking

1 Scope

This International Standard specifies requirements for the physical and chemical properties of dentifrices and provides guidelines for suitable test methods. It also specifies requirements for the marking, labelling and packaging of dentifrices.

This International Standard applies to dentifrices, including toothpastes, destined to be used by the public on a daily basis with a toothbrush to promote oral hygiene.

Specific qualitative and quantitative requirements for freedom from biological and toxicological hazards are not included in this International Standard. These are covered in ISO 7405^[1] and ISO 10993-1^[2].

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 1942, *Dentistry — Vocabulary*

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

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

International Nomenclature of Cosmetic Ingredients (INCI), in *International Cosmetic Ingredient Dictionary and Handbook*¹⁾

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and the following apply.

3.1

dentifrice

any substance or combination of substances specially prepared for the public for hygiene of the accessible surfaces of teeth and surrounding tissues

3.2

toothpaste

any semi-solid dentifrice preparation presented in the form of a paste, cream or gel

NOTE The products' common constituents are abrasives, humectants, binders, surfactants, flavourings, fluorides and other agents for oral health benefits.

1) Nomenclature developed by the Personal Care Products Council (Formerly CTFA). Available at: <http://www.ctfa.org/council-bookstore>.

3.3

single-unit container

container of dentifrice marketed to individual consumers

3.4

primary container

container that is in contact with the product

4 Requirements relative to the physical and chemical properties of dentifrices

4.1 Total fluoride

4.1.1 Total fluoride concentration

The total fluoride concentration shall not exceed a mass fraction of 0,15 % when tested in accordance with one of the procedures given in Annex C.

Other validated methods of similar sensitivity and accuracy may be used (see References [5] to [12], [28] and [29]).

4.1.2 Total fluoride in a single-unit container

The amount of total fluoride in a single-unit container shall not exceed 300 mg.

This requirement does not apply to containers of dentifrice to be dispensed under supervised conditions in community-based caries prevention programmes such as school tooth brushing programmes.

4.2 Heavy metals

The total maximum concentration shall not exceed 20 mg/kg.

Test in accordance with References [13], [14] or [15], or another validated method of similar sensitivity and accuracy.

4.3 pH

When tested in accordance with 5.1, the dentifrice shall have a pH below 10,5.

4.4 Microbiology

Testing for microbiological contamination shall be carried out according to References [17] to [22] and [31] to [38] or any other validated method of equivalent sensitivity, accuracy and specificity.

4.5 Abrasivity

The abrasivity of the dentifrice shall not exceed the following limits for dentine:

- 2,5 times that of the primary reference material, if using the procedure specified in Annex A; or
- 2 times that of the primary reference material, if using the procedures specified in Annex B.