

Dentistry - Dentifrices - Requirements, test methods and marking

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EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 11609:2010 sisaldab Euroopa standardi EN ISO 11609:2010 ingliskeelset teksti.

Standard on kinnitatud Eesti Standardikeskuse 31.10.2010 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.

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Standard on kättesaadav Eesti standardiorganisatsioonist.

This Estonian standard EVS-EN ISO 11609:2010 consists of the English text of the European standard EN ISO 11609:2010.

This standard is ratified with the order of Estonian Centre for Standardisation dated 31.10.2010 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.

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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)

This European Standard was approved by CEN on 31 August 2010.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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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of an identical text or by endorsement, at the latest by March 2011, and conflicting national standards shall be withdrawn at the latest by March 2011.

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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.

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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>.