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Irish Standard
I.S. EN ISO 11609:2017

Dentistry - Dentifrices - Requirements, test methods and marking (ISO 11609:2017)

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11609

June 2017

ICS 97.170

Supersedes EN ISO 11609:2010

English Version

Dentistry - Dentifrices - Requirements, test methods and marking (ISO 11609:2017)

Médecine bucco-dentaire - Dentifrices - Exigences, méthodes d'essai et marquage (ISO 11609:2017)

Zahnheilkunde - Zahnreinigungsmittel - Anforderungen, Prüfverfahren und Kennzeichnung (ISO 11609:2017)

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European foreword

This document (EN ISO 11609:2017) has been prepared by Technical Committee ISO/TC 106 “Dentistry” in collaboration with 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of an identical text or by endorsement, at the latest by December 2017 and conflicting national standards shall be withdrawn at the latest by December 2017.

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INTERNATIONAL STANDARD

ISO 11609

Third edition
2017-06

Dentistry — Dentifrices — Requirements, test methods and marking

Médecine bucco-dentaire — Dentifrices — Exigences, méthodes d'essai et marquage

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

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

This third edition cancels and replaces the second edition (ISO 11609:2010), which has been technically revised.

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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].

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Dentistry — Dentifrices — Requirements, test methods and marking

1 Scope

This document 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 document applies to dentifrices, including toothpastes, destined to be used by the consumers 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 document. These are covered in ISO 7405[1] and ISO 10993-1[2].

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

3.1
dentifrice
any substance or combination of substances specially prepared for the consumers 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 1 to entry: The product's 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: https://access.personalcarecouncil.org/eweb/DynamicPage.aspx?Site=pcpc&WebKey=4513b14e-2f75-4857-85b4-b3697be5d5d9.

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