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Zobozdravstvo - Zobne paste - Zahteve, preskusne metode in označevanje (ISO/DIS 11609:2024)

Dentistry - Dentifrices - Requirements, test methods and marking (ISO/DIS 11609:2024)

Zahnheilkunde - Zahnreinigungsmittel - Anforderungen, Prüfverfahren und Kennzeichnung (ISO/DIS 11609:2024)

Médecine bucco-dentaire - Dentifrices - Exigences, méthodes d’essai et marquage (ISO/DIS 11609:2024)

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ISO/DIS 11609

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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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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.

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 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*

ISO 19448, *Dentistry — Analysis of fluoride concentration in aqueous solutions by use of fluoride ion-selective electrode*

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 https://www.electropedia.org/

— ISO Online browsing platform: available at https://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

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.

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.

3.3
single-unit container
container of dentifrice marketed to individual consumers

3.4
primary container
container that is in direct 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 professionally supervised conditions or in community-based caries prevention programmes such as school toothbrushing programmes.

4.2 Heavy metals

The total maximum concentration of heavy metals 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 limit for dentine:

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

The abrasivity of the dentifrice shall not exceed the following limit for enamel:

— four times that of the primary reference material, if using the procedure specified in Annex A or B.

NOTE Abrasivity values below the limits specified in this standard are not intended to be used to rank the safety of dentifrices. All dentifrices beneath the abrasivity limits are recognized as safe with respect to their abrasion of human hard tissues.

Test in accordance with 5.2 or 5.3 or any other validated method of similar sensitivity and accuracy.

NOTE If an alternative abrasivity reference to the primary reference material (calcium pyrophosphate) is used, traceability to the primary reference material must be maintained by the testing laboratory. Results must always be reported with respect to the original primary reference material (calcium pyrophosphate) if any alternative abrasivity reference is used.

4.6 Stability

The dentifrice shall show no deterioration that may affect compliance with this document or could result in toxicological hazards after being subjected to one of the ageing procedures specified in 5.4 or after 30 months of storage at room temperature. If deterioration is detected, the dentifrice shall be labelled with an expiry date.

4.7 Readily fermentable carbohydrates

The dentifrice 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 Determination of pH

Suspend one part by mass of the dentifrice into three parts by mass of water for analytical laboratory use complying with ISO 3696 (grade 3). Determine the pH of the suspension within 10 min, using a pH-meter and electrode assembly.

5.2 Determination of dentine abrasivity

Determine the mean relative abrasivity compared to the primary reference sample, or any other reference material calibrated to the primary reference sample for human dentine, using one of the methods specified in Annex A or B.

Other validated measurement methods on dentine of similar sensitivity and accuracy may be used, conforming to practices and principles found in References[39] to.[44] For other references see, for example, References [23] and [24].

5.3 Determination of enamel abrasivity

Determine the mean relative abrasivity compared to the primary reference sample, or any other reference material calibrated to the primary reference sample for human enamel, using one of the methods specified in Annex A or B.

Other validated measurement methods on enamel of similar sensitivity and accuracy may be used, conforming to practices and principles found in References[39] to.[44] For other references see, for example, References [23] and [24].

5.4 Determination of stability

For the accelerated ageing procedure, the dentifrice shall be stored in its original container at 40 °C ± 2 °C at 75 % ± 5 % relative humidity for 3 months or at such conditions of time and temperature as will simulate storage at room temperature for 30 months[25]. Following storage, test the product according to this document.