International Standard

ISO 11609

Dentistry — Dentifrices — Requirements, test methods and marking

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

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Foreword

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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 document 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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This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 7, *Oral care products,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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This fourth edition cancels and replaces the third edition (ISO 11609:2017), which has been technically revised.

The main changes are as follows:

— edits and clarifications to align with the ISO directives;

— updates for abrasive availability;

— corrections for contacting the manufacturer of the cross-brushing machine;

— correcting Clause 2 and the Bibliography;

— 4.2 has been modified to suggest ISO 21392 for the analysis of five elemental impurities.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

Dentifrices are not expected to cause adverse reactions to oral soft tissue 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 Reference [19], Reference [20] and Reference [21].

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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 is applicable to dentifrices, including toothpastes, destined to be used by consumers on a daily basis with a toothbrush to promote oral hygiene.

This document does not apply to specific qualitative and quantitative requirements for freedom from biological and toxicological hazards. These are covered in ISO 7405 and ISO 10993-1.

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.

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ISO 1942, *Dentistry — Vocabulary*

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

ISO 8601-1, *Date and time — Representations for information interchange — Part 1: Basic rules*

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ISO 8601-2, *Date and time — Representations for information interchange — Part 2: Extensions*

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 terminology databases for use in standardization at the following addresses:

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

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

3.1
dentifrice
substance or combination of substances specially prepared for 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.

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3.2
toothpaste
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 %. For an example method, see Annex C.

Other validated methods of similar sensitivity and accuracy may be used (see References [22] to [31]).

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, e.g. school toothbrushing programmes.

4.2 Heavy metals (elemental impurities)

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

See ISO 21392 for antimony, arsenic, cadmium, lead or mercury and for other elemental impurities. The methods described in References [32] and [33], or another validated method of similar sensitivity and accuracy, may be used.

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. For some methods, see ISO 16212, ISO 18416, ISO 21148, ISO 21149, ISO 21150, ISO 22717, ISO 22718 and ISO 29621 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 (see the procedure specified in Annex A or Annex B).

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

— 4,0 times that of the primary reference material (see the procedure specified in Annex A or Annex B).

NOTE Abrasivity values below the limits specified in this document 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. When an alternative abrasivity reference to the primary reference material (calcium pyrophosphate) is used, traceability to the primary reference material shall be maintained by the testing laboratory. When any alternative abrasivity reference is used, the results shall be reported with respect to the original primary reference material (calcium pyrophosphate).

4.6 Stability

The dentifrice shall show no deterioration that can affect conformity with this document or can 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. Conformity 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

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5.1 Determination of pH

Suspend one part by mass of the dentifrice into three parts by mass of water for analytical laboratory use in accordance 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. One of the methods specified in Annex A or Annex B may be used. Other validated measurement methods on dentine of similar sensitivity and accuracy may be used. Conforming principles can be found in ISO 5725-1, ISO 5725-2, ISO 5725-3, ISO 5725-4, ISO 5725-5, and ISO 5725-6. For other references, see, for example, References [34] and [35].

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. One of the methods specified in Annex A or Annex B or another validated measurement method on enamel of similar sensitivity and accuracy may be used. Principles can be found in ISO 5725-1, ISO 5725-2, ISO 5725-3, ISO 5725-4, ISO 5725-5, and ISO 5725-6. For other references, see, for example, References [34] and [35].

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, see Reference [36]. Following storage, test the product according to this document.

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