International Standard

ISO 16408

Dentistry — Oral care products — Oral rinses

Médecine bucco-dentaire — Produits de soins bucco-dentaires — Bains de bouche

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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 of 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 www.iso.org/iso/foreword.html.

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).

This third edition cancels and replaces the second edition (ISO 16408:2015), which has been technically revised. The main changes are as follows:

— Clauses 1 and 3 were updated according to the ISO/IEC Directives, Part 2;

— Clause 2 was updated to include the latest version of ISO 8601-1 and to include ISO 19448;

— Clause 3 was updated to remove the definition of "mouth spray" as it is beyond the scope of this document;

— subclause 5.1 was clarified as ISO 28888 contains a screening method for non-fluoridated oral rinses, and was also updated to include a reference for the critical pH of enamel erosion;

— subclause 5.2 was updated to note the concentration of fluoride in mg/kg, to lower the maximum fluoride per container and to reference 7.4, which was added, and ISO 19448;

— subclause 5.3 was updated to include a reference to USP <233> Elemental Impurities Procedures;

— subclause 5.5 was updated to include references to USP <61>, USP <62>, and Ph.Eur. 2.6.12, to add a note on acceptance criteria and to harmonize language with ISO 11609;

— Clause 8 g) was updated to include the date of the test, the names of samples and deviations from procedure;

— subclause 9.1 and 9.2 were updated for clarity;

— subclause 9.2 e) was updated to note that the International Nomenclature for Cosmetic Ingredients is normally used for listing ingredients on the packaging;

— subclause 9.2 g) was clarified regarding ethanol;

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— subclause 9.2 j) was updated to include “and under adult supervision”;

— Annex A was removed as 7.4 and ISO 19448 are now referenced for the determination of fluoride;

— the Bibliography was reorganized according to the order that the references are mentioned in the document.

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

Oral rinses are used for oral hygiene purposes. They are intended to provide either health or cosmetic benefits or both.

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Dentistry — Oral care products — Oral rinses

1 Scope

This document specifies physical and chemical requirements and test methods for oral rinses. It also specifies requirements on the accompanying information to be given in the manufacturer's instructions for use and on containers as well as the requirements for packaging. Common labelling aspects are specified in order to enhance international understanding and trade.

This document is not applicable to other delivery systems (e.g. mouth sprays, foams, powders). It is not intended to describe regulatory aspects, e.g. methods of prescription.

This document is not applicable to oral rinses available by prescription only.

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

ISO 28888, *Dentistry — Screening method for erosion potential of oral rinses on dental hard tissues*

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

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
oral rinse
mouthwash
mouth rinse
liquid formulation used by the public for oral care purposes

[SOURCE: ISO 1942:2020, 3.6.2.1, modified — The term "formulation" was added.]

3.2
unintended heavy metal
heavy metal elements, which are detected in the analysis but not purposely included

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