SLOVENSKI STANDARD
SIST EN ISO 16408:2004

01-november-2004

Zobozdravstvo – Izdelki za ustno higieno – Sredstva za izpiranje ust (ISO 16408:2004)

Dentistry - Oral hygiene products - Oral rinses (ISO 16408:2004)

Zahnheilkunde - Mundhygieneprodukte - Mundspüllösungen und Mundwässer (ISO 16408:2004)

Art dentaire - Produits d'hygiene buccale - Bains de bouche (ISO 16408:2004)

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ICS:

11.060.01	Zobozdravstvo na splošno	Dentistry in general
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SIST EN ISO 16408:2004 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 16408

April 2004

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English version

Dentistry - Oral hygiene products - Oral rinses (ISO 16408:2004)

Art dentaire - Produits d'hygiène buccale - Bains de bouche (ISO 16408:2004)

Zahnheilkunde - Mundhygieneprodukte - Mundspüllösungen und Mundwässer (ISO 16408:2004)

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This document (EN ISO 16408:2004) 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of an identical text or by endorsement, at the latest by October 2004, and conflicting national standards shall be withdrawn at the latest by October 2004.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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The text of ISO 16408:2004 has been approved by CEN as EN ISO 16408:2004 without any modifications.

INTERNATIONAL STANDARD

ISO 16408

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Dentistry — Oral hygiene products — Oral rinses

Art dentaire — Produits d'hygiène buccale — Bains de bouche

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Foreword

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International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 16408 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 7, *Oral hygiene products*.

Introduction

Oral rinses are used for oral hygiene purposes intended to provide health and/or cosmetic benefits.

This International Standard specifies the chemical and physical properties of oral rinses. Common labelling aspects are also specified in order to enhance international understanding and trade.

Dentistry — Oral hygiene products — Oral rinses

1 Scope

This International Standard specifies physical and chemical requirements and test methods for oral rinses. It also specifies the accompanying information such as manufacturer's instructions for use, marking and/or labelling requirements.

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

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

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 3696:1987, *Water for analytical laboratory use — Specification and test methods*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

INCI, *International Nomenclature of Cosmetic Ingredients*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and the following apply.

3.1
oral rinse
mouthrinse
mouthwash
liquid formulation used by the public for oral care purposes

3.2
mouthspray
liquid formulation in spray form for oral care purposes, not requiring dilution with water

4 Classification

Oral rinses shall be classified according to their application by the user as follows:

— **Type 1:** ready-for-use solutions;

— **Type 2:** concentrated solutions for use after dilution with water;

— **Type 3:** solutions for use after mixing.

5 Requirements

5.1 pH value

Oral rinses shall have a pH value between 3,0 and 10,5. If the pH value of an oral rinse is below 5,5, it shall pass a demineralization test or erosion test, or shall demonstrate safety by other appropriate methods.

Test the pH value in accordance with 7.1 and 7.3

NOTE 1 At the time of development of this International Standard, there was no evidence that oral rinses with pH values between 5,5 and 10,5 promoted enamel erosion.

NOTE 2 At the time of development of this International Standard, several scientific test methods were available. It is intended to include one internationally- accepted test method in the next revision of this International Standard.

5.2 Total fluoride concentration and maximum amount of fluoride

The total fluoride concentration of one container of oral rinse of Type 1 shall not exceed a mass fraction of 0,15 %.

The maximum amount of ionic fluoride per single container shall not exceed 125 mg.

Fluoride-containing oral rinses shall be tested in accordance with Annex A or one of the procedures given in ISO 11609:1995, Annex B [3], or other validated method of similar sensitivity and accuracy, for example reference [4], [11] or [12].

5.3 Heavy metals

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

Test in accordance with a validated method, for example reference [5], [9] or [13], or other method of similar sensitivity and accuracy.

5.4 Compatibility with oral tissues

Oral rinses shall not cause irritation or damage to the oral hard and/or soft tissue, when used in accordance with the manufacturer's recommendation for frequency and duration of use and experience with known side effects.

Specific qualitative and quantitative requirements for freedom from biological hazards are not included in this International Standard, but it is recommended that reference be made to ISO 7405 and ISO 10993-1 when assessing possible biological or toxicological hazards.