
Dentistry — Oral care products — Oral rinses

*Médecine bucco-dentaire — Produits de soins bucco-dentaire —
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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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 meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](#)

The committee responsible for this document is ISO/TC 106, *Dentistry*, Subcommittee SC 7, *Oral care products*.

This second edition cancels and replaces the first edition (ISO 16408:2004), which has been technically revised with the following changes:

- “heavy metals” has been replaced by the term *unintended heavy metals*, which has been defined in [3.3](#);
- reference to ISO 28888 and corresponding requirement in [5.1](#) were added;
- ambient storage conditions of real time test for determination of stability against ageing ([7.4.1](#)) was changed (23 ± 2) °C at (60 ± 15) % relative humidity;
- the bibliography was updated by including latest ISO/TC 217 standards.

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.

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Dentistry — Oral care 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 the 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 documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 28888, *Dentistry — Screening method for erosion potential of oral rinses on dental hard tissues*

INCI, *International Nomenclature for 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

[SOURCE: ISO 1942, 2009, 2.209]

3.2

mouthspray

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

[SOURCE: ISO 1942, 2009, 2.185]

3.3

unintended heavy metals

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

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 screening test as specified in ISO 28888.

Test the pH value in accordance with [7.1](#) and [7.3](#).

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

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.

Test fluoride-containing oral rinses in accordance with [Annex A](#).

As an alternative one of the procedures given in [ISO 11609, Annex C](#), [\[3\]](#) or other validated method of similar sensitivity and accuracy, may be use, for example References [\[13\]](#) or [\[14\]](#).

5.3 Unintended heavy metals

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

Test in accordance with a validated method, for example References [\[15\]](#), [\[16\]](#), [\[17\]](#) or [\[22\]](#).

If this is not suitable other method of similar sensitivity and accuracy shall be used.

NOTE There may be other potentially dangerous elements, especially arsenic, which are not covered by this International Standard as currently no analytical test methods and no effect levels are consented.

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.

5.5 Microbial contamination

The microbial contamination of oral rinses shall not exceed 100 colony-forming units (CFU) per gram. Oral rinses shall be free of pathogens.

Testing for microbial contamination shall be carried out according to a validated method, for example References [6], [7], [8], [9], [10], [11] or [12].

5.6 Stability against ageing

Oral rinses shall show no signs of deterioration, such as agglomeration or change in clarity, after being subjected to the determination of stability to ageing procedure specified in 7.4.

5.7 Container and/or dispensing system

The container and/or dispensing system shall neither contaminate nor permit contamination of the oral rinse inside such that it will affect its compliance with the requirements of Clause 5 after being subjected to the determination of stability to ageing described in 7.4.

5.8 Readily fermentable carbohydrates

Oral rinses 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.

6 Sampling

The oral rinses used for testing shall be representative of actual/manufactured oral rinse and shall not be altered in any way.

Eight containers of oral rinses from the same manufacturing tracking code (e.g. batch code, lot number) shall be tested before the determination of stability to ageing (see 7.4).

7 Test methods

7.1 General

All tests shall be performed before and after the stability to ageing test (7.4).

7.2 Visual inspection

Before and after agitation, examine the oral rinse under a bright light with normal visual acuity without magnification.

7.3 Determination of pH value

Test the pH value of the oral rinse in its intended concentration for use.

Determine the pH value of the solution using a calibrated pH-meter with an accuracy of $\pm 0,1$ mV.

7.4 Determination of stability against ageing

7.4.1 Test

One of the following two tests shall be performed.

a) Accelerated test

Store the oral rinse at (40 ± 2) °C for 3 months at (75 ± 5) % relative humidity or under such conditions of time and temperature as will simulate storage at room temperature for 30 months.