
**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).

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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 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- “heavy metals” has been replaced by the term *unintended heavy metals*, which has been defined in [3.3](#);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.

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