

INTERNATIONAL
STANDARD

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**Dentistry — Oral hygiene products —
Oral rinses**

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



Reference number
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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.

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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