



American National Standard/American Dental Association  
**Specification No. 116**

# Oral Rinses

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Identical adoption of ISO 16408:2004, *Dentistry-Oral hygiene products-Oral rinses.*

**ADA** American  
Dental  
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Scientific Affairs

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## RINSES

The Council on Scientific Affairs of the American Dental Association has approved American Dental Association Specification No. 116 for Oral Rinses. This and other specifications for dental materials, instruments and equipment are being formulated by working groups of the ADA Standards Committee on Dental Products (formerly Accredited Standards Committee MD156 for Dental Materials, Instruments and Equipment). The Committee has representation from all interests in the United States in the standardization of materials, instruments and equipment in dentistry. The Council has adopted the specifications, showing professional recognition of their usefulness in dentistry, and has forwarded them to the American National Standards Institute with a recommendation that the specifications be approved as American National Standards. The American National Standards Institute granted approval of ADA Specification No. 116 as an American National Standard on February 25, 2010.

The Council thanks the members of Working Group 7.55 and the organizations with which they were affiliated at the time the specification was developed:

Clifton Carey (chairman), ADAF, Gaithersburg, MD;

An-Shih Cheng, Cheng & Associates, Chicago, IL;

John Hefferren, University of Kansas, Lawrence, KS;

William Landrigan, Procter & Gamble Co., Mason, OH; and

Mark Putt, Indiana University-Fort Wayne, IN.

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## RINSES

### FOREWORD

(This Foreword does not form a part of ANSI/ADA Specification No. 116 for Oral Rinses).

This specification is an identical adoption of ISO 16408:2004, Dentistry – Oral hygiene products – Oral rinses. ADA SCDP Working Group No. 7.55 on Oral Rinses examined the international standard and found it acceptable for adoption as ANSI/ADA Specification No. 116.

Oral rinses are used for oral hygiene purposes intended to provide health and/or cosmetic benefits. This specification defines the chemical and physical properties of oral rinses. Common labeling aspects are also specified in order to enhance international understanding and trade.

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## RINSES

### 1 SCOPE

This specification defines 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 labeling requirements.

This specification 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 specification 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 1942:2009, *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*

(ISO standards for dentistry are available from the American Dental Association, Department of Standards, 211 E. Chicago Ave., Chicago, IL 60611 or [www.adacatalog.org](http://www.adacatalog.org). Other ISO standards are available from the American National Standards Institute, 25 W. 43rd St., New York, NY 10036 or [www.ansi.org](http://www.ansi.org)).

INCI, *International Nomenclature of Cosmetic Ingredients*

(INCI is available from MakingCosmetics.com, Inc., P.O. Box 3372, Renton, WA 98056 or <http://www.makingcosmetics.com/INCI-63.html>).

### 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