



American National Standard/
American Dental Association
Standard No. 130

Dentifrices — Requirements, Test Methods and Marking

Identical adoption of ISO 11609:2010, *Dentistry — Dentifrices — Requirements, test methods and marking*

ADA American
Dental
Association®
Council on
Scientific Affairs

2013

ADA Documents
Document Sharing Hub

These materials are subject to copyright claims of ISO, ANSI, and ADA. No part of this publication may be reproduced in any form, including electronic retrieval system, without the prior permission of ADA. All requests pertaining to ANSI/ADA Standard No. 130 should be submitted to ADA.

AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION STANDARD NO. 130 FOR DENTIFRICES – REQUIREMENTS, TEST METHODS AND MARKING

The Council on Scientific Affairs of the American Dental Association has approved revised American Dental Association Standard No. 130 for Dentifrices-Requirements, Test Methods and Marking. This and other standards 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 standards, showing professional recognition of their usefulness in dentistry, and has forwarded them to the American National Standards Institute with a recommendation that the standards be approved as American National Standards. The American National Standards Institute granted approval of revised ADA Standard No. 130 as an American National Standard on August 12, 2013.

The ADA Standards Committee on Dental Products thanks the members of Working Group 7.56 and the organizations with which they were affiliated at the time the standard was developed:

Bruce Schemehorn (chairman), Therametric Technologies, Inc., Noblesville, IN;

Jack Amburgey, Procter & Gamble, Mason, OH;

Clifton Carey, ADA Foundation, Gaithersburg, MD;

Carlos Gonzales-Cabezas, University of Michigan, Ann Arbor, MI;

Anderson Takeo-Hara, Indiana University, Indianapolis, IN;

John Hefferren, University of Kansas, Lawrence, KS;

Burton Schmuck, ADA Foundation, Gaithersburg, MD; and

Kevin Yost, Ranir Global, Grand Rapids, MI.

AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION STANDARD NO. 130 FOR DENTIFRICES – REQUIREMENTS, TEST METHODS AND MARKING

FOREWORD

(This Foreword does not form a part of ANSI/ADA Standard No. 130 for Dentifrices – Requirements, Test Methods and Marking).

This first edition of ANSI/ADA Standard No. 130 is an identical adoption of ISO 11609:2010, Dentistry – Dentifrices – Requirements, test methods and marking. ADA SCDP Working Group No 7.56 on Toothpastes examined the international standard and found it acceptable as an identical adoption.

AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION STANDARD NO. 130 FOR DENTIFRICES – REQUIREMENTS, TEST METHODS AND MARKING

1 SCOPE

This standard specifies requirements for the physical and chemical properties of dentifrices and provides guidelines for suitable test methods. It also specifies requirements for the marking, labelling and packaging of dentifrices.

This standard applies to dentifrices, including toothpastes, destined to be used by the public on a daily basis with a toothbrush to promote oral hygiene.

Specific qualitative and quantitative requirements for freedom from biological and toxicological hazards are not included in this standard. These are covered in ISO 7405^[1] and ISO 10993-1^[2].

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

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

(Copies of ISO Standards for dentistry may be obtained from the American Dental Association, Department of Standards Administration, 211 E. Chicago Ave., Chicago, IL, or <http://catalog.ada.org>. Other ISO Standards may be obtained from the American National Standards Institute, 25 West 43 St., New York, NY 10036; or www.ansi.org).

Nomenclature of Cosmetic Ingredients (INCI), *in Cosmetic Ingredient Dictionary and Handbook*

(Nomenclature developed by the Personal Care Products Council (Formerly CTFA). Available at: <http://www.ctfa.org/council-bookstore>)

3 TERMS AND DEFINITIONS

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

3.1

dentifrice

any substance or combination of substances specially prepared for the public for hygiene of the accessible surfaces of teeth and surrounding tissues

3.2

toothpaste

any semi-solid dentifrice preparation presented in the form of a paste, cream or gel

NOTE The products' common constituents are abrasives, humectants, binders, surfactants, flavourings, fluorides and other agents for oral health benefits.

3.3

single-unit container

container of dentifrice marketed to individual consumers

3.4

primary container

container that is in contact with the product

4 REQUIREMENTS RELATIVE TO THE PHYSICAL AND CHEMICAL PROPERTIES OF DENTIFICES

4.1 Total fluoride

4.1.1 Total fluoride concentration

The total fluoride concentration shall not exceed a mass fraction of 0.15 % when tested in accordance with one of the procedures given in Annex C.

Other validated methods of similar sensitivity and accuracy may be used (see References [5] to [12], [28] and [29]).

4.1.2 Total fluoride in a single-unit container

The amount of total fluoride in a single-unit container shall not exceed 300 mg.

This requirement does not apply to containers of dentifrice to be dispensed under supervised conditions in community-based caries prevention programmes such as school tooth brushing programmes.

4.2 Heavy metals

The total maximum concentration shall not exceed 20 mg/kg.

Test in accordance with References [13], [14] or [15], or another validated method of similar sensitivity and accuracy.

4.3 pH

When tested in accordance with 5.1, the dentifrice shall have a pH below 10.5.

4.4 Microbiology

Testing for microbiological contamination shall be carried out according to References [17] to [22] and [31] to [38] or any other validated method of equivalent sensitivity, accuracy and specificity.

4.5 Abrasivity

The abrasivity of the dentifrice shall not exceed the following limits for dentine:

2.5 times that of the primary reference material, if using the procedure specified in Annex A; or

2 times that of the primary reference material, if using the procedures specified in Annex B.

The abrasivity of the dentifrice shall not exceed the following limits for enamel:

— 4 times that of the primary reference material, if using the procedure specified in Annex A; or

— 4 times that of the primary reference material, if using the procedures specified in Annex B.

Test in accordance with 5.2 or 5.3 or any other validated method of similar sensitivity and accuracy.

4.6 Stability

The dentifrice shall show no deterioration that may affect compliance with this standard after being subjected to one of the ageing procedures specified in 5.4 or after 30 months of storage at room temperature. If deterioration is detected, the dentifrice shall be labelled with an expiry date.

4.7 Readily fermentable carbohydrates

The dentifrice 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.

5 TEST METHODS

5.1 Determination of pH

Suspend one part by mass of the dentifrice into three parts by mass of water for analytical laboratory use complying with ISO 3696 (grade 3). Determine the pH of the suspension within 10 min, using a pH-meter and electrode assembly.

5.2 Determination of dentine abrasivity

Determine the mean relative abrasivity compared to the primary reference sample, or any other reference material calibrated to the primary reference sample for human dentine, using one of the methods specified in Annex A or B.

Other validated measurement methods on dentine of similar sensitivity and accuracy may be used; see for example References [23] and [24].

5.3 Determination of enamel abrasivity

Determine the mean relative abrasivity compared to the primary reference sample, or any other reference material calibrated to the primary reference sample for human enamel, using one of the methods specified in Annex A or B.

Other validated measurement methods on enamel of similar sensitivity and accuracy may be used; see for example References [23] and [24].

5.4 Determination of stability

For the accelerated ageing procedure, the dentifrice shall be stored in its original container at $40\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$ at $75\% \pm 5\%$ relative humidity for three months or at such conditions of time and temperature as will simulate storage at room temperature for 30 months^[25]. Following storage, test the product according to this standard.

6 MARKING AND LABELLING

With the exception of small single units (less than 10 ml), all primary containers shall be marked with the following information:

- A. the word “dentifrice” or equivalent (see Clause 3);
- B. the trade name;
- C. the name and contact information of the manufacturer or responsible distributor;
- D. the tracking code that includes an intelligible production date;
- E. a complete list of ingredients according to the Nomenclature of Cosmetic Ingredients (INCI);
- F. the concentration and type of fluoride, if present, expressed in micrograms per gram, or percent by mass, or both;
- G. the net volume, in milliliters, or net mass in grams, or both;
- H. the expiry date, expressed according to ISO 8601, if the period of stability (shelf-life) is less than 30 months;
- I. a safety notice regarding the use, by children below six years of age, of dentifrices containing concentrations of fluoride of 1 000 µg/g or more.

7 PACKAGING

The product shall be packaged in such a way that under normal conditions of handling and transport, the container or dispensing system, or both, shall not contaminate or permit contamination of the dentifrice inside, so as to affect its compliance with this standard, after being subjected to the ageing procedure described in 5.4.