



American National Standard/
American Dental Association
Standard No. 136

Products for External Tooth Bleaching

Identical adoption of *ISO 28399:2011, Dentistry — Products for external tooth bleaching*

ADA American
Dental
Association®
Council on
Scientific Affairs

2015

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NO. 136 FOR PRODUCTS FOR EXTERNAL TOOTH BLEACHING

The Council on Scientific Affairs of the American Dental Association has approved revised American Dental Association Standard No. 136 for Products for External Tooth Bleaching. This and other standards for dental materials, instruments and equipment are being formulated by working groups of the ADA Standards Committee on Dental Products. 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. 136 as an American National Standard on January 29, 2015.

The ADA Standards Committee on Dental Products thanks the members of Working Group 7.60 and the organizations with which they were affiliated at the time the specification was developed:

Yiming Li (chairman), Loma Linda University, Loma Linda, CA; Jack Amburgey, Procter & Gamble, Mason, OH; Carla Beneduce, University of Buffalo, Buffalo, NY; Scott Benjamin, Benjamin Dental Group, Hancock, NY; Angela Blackwell, Blackwell Device Consulting, Catawba, NC; Clifton Carey, University of Colorado, Aurora, CO; Claudia Cotca, Washington Institute of Dentistry & Toxicology, Washington, DC; Scott Erickson, 3M ESPE, St. Paul, MN; P.L. Fan, Individual Representative, Santa Fe, NM; Arthur J. Ferrara, Ferrara & Company, Princeton, NJ; Robert J. Gambogi, Johnson & Johnson Consumer Products, Skillman, NJ; Stephen E. Gruninger, American Dental Association, Chicago, IL; Anderson Hara, Indiana University, Indianapolis, IN; John J. Hefferren, University of Kansas, Lawrence, KS; Robert J. Kelly, University of Connecticut, Farmington, CT; So Ran Kwon, University of Iowa, Iowa City, IA; Milton Marshall, Marshall & Associates, Houston, TX; Bruce A. Matis, Indiana University, Indianapolis, IN; William McHale, Premier Dental Products Company, Plymouth Meeting, PA; Spiro Megremis, American Dental Association, Chicago, IL; Michael Meharry, Midwestern University Dental Institute, Glendale, AZ; Sheldon Newman, University of Colorado, Centennial, CO; Rade Paravina, University of Texas Dental Branch at Houston, Houston, TX; Michael Prencipe, Colgate-Palmolive Company, Piscataway, NJ; Steve Rudolph, Septodont Confi-Dental Division, Louisville, CO; Bruce Schemehorn, Therametric Technologies, Inc., Noblesville, IN; Burton Schmuck, Washington State University Foundation, Pullman, WA; Eva Schneiderman, Procter & Gamble, Mason, OH; Clifford Whall, American Dental Association, Chicago, IL; Wayne Wozniak, Individual Representative, St. Joe, FL; Kevin Yost, Ranir Global, Grand Rapids, MI; Jeff A. Zawada, A-dec, Inc., Newberg, OR; and Wu Zhang, Loma Linda University, Loma Linda, CA.

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PRODUCTS FOR EXTERNAL TOOTH BLEACHING

FOREWORD

(This Foreword does not form a part of ANSI/ADA Standard No. 136 for Products for External Tooth Bleaching).

This standard is an identical adoption of ISO 28399:2011, Dentistry— Products for External Tooth Bleaching. ADA SCDP Working Group 7.60 on Whitening Agents examined the international standard and found it acceptable as an identical adoption for ANSI/ADA Standard No. 136.

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PRODUCTS FOR EXTERNAL TOOTH BLEACHING

INTRODUCTION

Products for external tooth bleaching are used in dentistry for changing the color of natural teeth towards a lighter or whiter shade. They are applied in the oral cavity directly on the outer surfaces of teeth. This Standard includes requirements and test methods for products intended for external bleaching of natural teeth by chemical means.

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PRODUCTS FOR EXTERNAL TOOTH BLEACHING

1 Scope

This Standard specifies requirements and test methods for external tooth bleaching products. These products are intended for use in the oral cavity, either by professional application (in-office tooth bleaching products) or consumer application (professional or non-professional home use of tooth bleaching products), or both. It also specifies requirements for their packaging, labelling and instructions for use.

This Standard is not applicable to tooth bleaching products:

- specified in ISO 11609;
- those intended to change colour perception of natural teeth by mechanical methods (e.g. stain removal) or using restorative approaches, such as veneers or crowns;
- auxiliary or supplementary materials (e.g. tray materials) and instruments or devices (e.g. lights) that are used in conjunction with the bleaching products.

This Standard does not specify biological safety aspects of tooth bleaching products.

NOTE A tooth bleaching product can be evaluated for its biological safety using ADA Standard No. 41, ISO 10993-1 and ISO 7405.

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 6344-1, *Coated abrasives — Grain size analysis — Part 1: Grain size distribution test*

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. Other ISO standards are available from the American National Standards Institute, 25 W. 43rd St., New York, NY 10036 or www.ansi.org).

3 Terms and definitions

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

3.1 bleaching

(natural teeth) removal of intrinsic or acquired discolorations of natural teeth through the use of chemicals, sometimes in combination with the application of auxiliary means

NOTE Adapted from ISO 1942:2009, 2.28.