INTERNATIONAL STANDARD

ISO 28399

First edition
2011-01-15

Dentistry — Products for external tooth bleaching

Médecine bucco-dentaire — Produits d'éclaircissement dentaire, à usage externe

Reference number
ISO 28399:2011(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

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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 28399 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 7, *Oral care products*.

Introduction

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

Dentistry — Products for external tooth bleaching

1 Scope

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

NOTE A tooth bleaching product can be evaluated for its biological safety using 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*

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.

3.2
professional home use
〈of a product〉 use prescribed by a professional and for use at home under the repeated supervision of the dentist

4 Classification

4.1 General

Products for external tooth bleaching can be classified for either:

a) professional application; or

b) consumer application.

NOTE Products for external tooth bleaching can be used alone or in conjunction with auxiliary means of application.

4.2 Products for professional application

These products are tooth bleaching products that are intended by the manufacturer to be applied only by dental professionals (in-office tooth bleaching products).

4.3 Products for consumer application

These products are tooth bleaching products that are intended by the manufacturer to be applied by the consumer (for professional home use or for non-professional home use).

NOTE Such external bleaching products can be prescribed by a dental professional or directly available to consumers.

5 Requirements

5.1 Concentration of active ingredients for bleaching

The concentration of active ingredients for bleaching (equivalent to hydrogen peroxide) delivered by the unexpired product according to manufacturer's instructions for use shall be within the range of +10 % and −30 % of the original concentration stated by the manufacturer for the unopened product, when tested in accordance with Annex A or other equivalent method.

5.2 Surface microhardness

The reduction in the Knoop hardness (KHN) or Vickers hardness (VHN) after the treatment shall be not more than 10 %, when tested in accordance with 6.3.

5.3 Surface erosion

Surface erosion of the teeth tested in accordance with B.6.1 shall be no more than three times the level which is caused by the positive control (B.6.2.1), when tested in accordance with Annex B or other equivalent methods.

6 Test methods

6.1 Preparation of tooth specimens

Prepare enamel and dentine specimens taken from a consistent location on extracted human or bovine teeth that have been stored in a 0,2 % solution (mass concentration) of sodium azide or other solutions of equivalent efficacy for disinfection purpose. Grind the specimen surface using a sequence starting at P400 and sequentially to a minimum of P1200 silicon carbide paper in accordance with ISO 6344-1 under a constant flow of water and then polish the surface using a slurry or paste of 0,3 µm mean particle size aluminium oxide. Ensure a minimum of 1 mm thickness of enamel or dentine tissue for the test specimen. Prevent dehydration of test specimens during the specimen preparation procedure.

6.2 Preparation and application of tooth bleaching product

The dispensing, processing and application of the tooth bleaching product used in tests shall follow manufacturer's instructions for use. The method of bleach application shall simulate the clinical procedure relative to quantity, frequency and duration of the application. Specimens shall be stored in a 37 °C artificial saliva solution similar to the one described in the ANSI/ADA Specification No. 41[6] between bleaching intervals and for 24 h after the last bleach application prior to testing.

6.3 Surface microhardness

Evaluate enamel surface hardness before and after bleaching treatment.

Determine the surface microhardness with the KHN or VHN by applying a load of 0,49 N (equivalent to a 50 g load) for 15 s. Evaluate a minimum of 10 specimens for each group, with three indentations for each specimen. Prevent dehydration of test specimens during the specimen preparation procedure.

7 Packaging, marking and information to be supplied by the manufacturer

7.1 General

Additional information may be included at the discretion of the manufacturer or as required by regulation.

7.2 Packaging

The components of the material shall be supplied in properly sealed containers which adequately protect the contents and do not adversely affect the quality of the product.

7.3 Marking and instructions for use

For each package, the following applies.

a) Information shall be clearly marked on the outermost package or containers appropriate to the product, as indicated in Table 1.

b) Instructions shall accompany each package of the product and shall include the information appropriate to the product, as indicated in Table 1.

Table 1 — Requirements for marking and instructions for use

No.	Information	Outermost package	Container	Manufacturer's instructions for use
1	Name of the product	M	M	M
2	Identification or name of the manufacturer	M	M	M
3	Address of the manufacturer or the agent responsible for sale	M	—	M
4	Recommended conditions of storage	M	—	M
5	Manufacturer's lot or batch identification	M	M	—
6	Expiry date in accordance with ISO 8601 for the materials under the storage conditions recommended by the manufacturer	M	M	—
7	Classification of the materials (Clause 4)	M	—	M
8	Clinical application of the material (Clause 4)	—	—	M
9	Number of containers	M	—	—
10	Net mass of product in each container	M	M	M
11	Chemical name of active ingredient(s)	M	—	M
12	Concentration of active ingredient(s)	M	M	M
13	Concentration equivalent to hydrogen peroxide	M	M	M
14	Instructions for use	—	—	M
15	Recommended auxiliary device(s), exposure times and any special instructions for use of the equipment (for the materials requiring an auxiliary device only)	—	—	M
16	Specific contra-indication(s) and/or warning(s), such as “irritation”, “avoid contact with eyes”, as necessary.	—	—	M
17	Statement equivalent to “It is recommended that you consult with your dental professional before using this product.”	—	—	M
Explanation of symbols: “M” indicates mandatory information. “—” indicates non-mandatory information.				

Annex A
(informative)

Test method for the measurement of hydrogen peroxide concentration

A.1 Principle

The content of hydrogen peroxide (H_2O_2) in tooth bleaching products is determined using a modified thiosulfate titration method.

A.2 Test condition

Perform the test at (23 ± 2) °C.

A.3 Procedure (modified thiosulfate titration method, USP[10])

Equivalent methods can also be used.

Use analytic grade of sulfuric acid, potassium iodide, ammonium molybdate, sodium thiosulfate, starch and hydrogen peroxide. Conduct a titration calibration curve using a series of freshly prepared H_2O_2 solutions at concentrations that include the highest possible H_2O_2 concentration in the test product. Add approximately 1,0 g (weighing precision to 0,001 g) of test product or an amount appropriate to the test, with rapid stirring, to 400 ml distilled water that contains 10 ml of sulfuric acid (25 %), 25 ml potassium iodide (10 %), and 4 drops of ammonium molybdate solution (5 %). Use starch as the indicator, and perform the titration using 0,1 N (normality) sodium thiosulfate.

Determine the H_2O_2 content using the titration calibration curve.

When using standardized titrants (e.g. USP standard grade), construction of calibration curve is not necessary. Calculate the mass concentration of H_2O_2 from the following equation:

$$C = (1{,}701\ 18 \times V/m) \times 100$$

where

C is the mass concentration of H_2O_2, expressed as a percentage;

V is the titre of 0,1 N sodium thiosulfate, in millilitres;

m is the mass of the test product dispensed, in grams.

Repeat the measurement five times ($n = 5$) and calculate the mean H_2O_2 concentration.