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Dentistry — External tooth bleaching products

Médecine bucco-dentaire — Produits d'éclaircissement dentaire par voie externe

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 7, *Oral care products*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 28399:2020), which has been editorially revised. The changes compared to the previous edition are as follows:

— “TEM” has been removed from “TEM grid” throughout this third edition;

— B.10.2.6 EXAMPLE has been rewritten;

— “B.9 A)” has been replaced with “B.9”;

— “See Figure B.9 B” has been removed;

— “In Figure B.9 C, the value is 51,916 3 (i.e. 51,9 µm)” has been removed and Figure B.9, k), “number of ” has been replaced with “width in”;

— In C.3.3.3, “delta E*ab” has been added in the space between two commas.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

External tooth bleaching products 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.

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this document. It is recommended, that reference should be made to ISO 10993-1 and ISO 7405 when assessing possible biological or toxicological hazards.

Dentistry — External tooth bleaching products

1 Scope

This document 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 manufacturer's instructions for use.

This document is not applicable to tooth bleaching products:

— specified in ISO 11609;

— 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 document does not specify biological safety aspects of tooth bleaching products.

NOTE Maximum concentration of a bleaching agent for professional or non-professional use is subject to each country's regulatory body.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 1042, *Laboratory glassware — One-mark volumetric flasks*

ISO 1942, *Dentistry — Vocabulary*

ISO 3696, *Water for analytical laboratory use — Specification and test methods*

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

ISO 7405, *Dentistry — Evaluation of biocompatibility of medical devices used in dentistry*

ISO 8601-1, *Date and time — Representations for information interchange — Part 1: Basic rules*

ISO 8601-2, *Date and time — Representations for information interchange — Part 2: Extensions*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO/CIE 11664-1, *Colorimetry — Part 1: CIE standard colorimetric observers*

ISO 11664-2, *Colorimetry — Part 2: CIE standard illuminants*

ANSI/ADA Specification No 41: *Recommended Standard Practices for Biological Evaluation of Dental Materials*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
bleaching
<natural teeth> removal of intrinsic or acquired discolorations of natural teeth, or changing their colour towards a lighter or whiter shade using chemicals, sometimes in combination with the application of auxiliary means

Note 1 to entry: Changing the colour of natural teeth towards a lighter or whiter shade is not limited to a discoloration.

Note 2 to entry: Auxiliary means for bleaching other than the application of external energy are also conceivable.

Note 3 to entry: [SOURCE: ISO 1942:2009, 2.28, modified — Note 1 to entry and Note 2 to entry have been added.]

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

3.3
erosion
<tooth surface> progressive loss of calcified tissue by chemical processes that do not involve bacterial action

Note 1 to entry: [SOURCE: ISO 1942:2009, 2.292, modified — terms have been modified and a domain has been added.]

4 Classification

4.1 General

External tooth bleaching products can be classified for either:

a) professional application; or

b) consumer application.

NOTE External tooth bleaching products 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. Annex A or other equivalent method can be used for testing.

5.2 Surface microhardness

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

5.3 Surface erosion

Surface erosion of the teeth tested shall be less than the level which is caused by the standard reference solution. The method described in Annex B or other equivalent methods can be used.

6 Measurements and 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 neutralized solution that disinfects but does not alter the physical properties. Grind the specimen surface under a constant flow of water in accordance with ISO 3696 starting at P400 and sequentially to a minimum of P1200 silicon carbide paper in accordance with ISO 6344-1. 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 preparation procedure.

6.2 Preparation and application of tooth bleaching product

The dispensing, processing and application of the tooth bleaching product used in tests (see Annex C) shall follow the manufacturer's instructions for use. The method of bleach application shall simulate the clinical procedure in quantity, frequency and duration of the application. Between bleaching intervals, and for 24 h after the last bleach application prior to testing, specimens shall be stored at 37 °C in an artificial saliva solution similar to that described in the ANSI/ADA Specification No. 41.[4]

6.3 Surface microhardness

Evaluate enamel surface microhardness before and after bleaching treatment.

Determine KHN or VHN surface microhardness 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 ISO 22727.

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 product quality.

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 number	M	M	—
6	Expiry date given in accordance with ISO 8601-1 or ISO 8601-2	M	M	—
7	Classification of the external tooth bleaching products (Clause 4)	M	—	M
8	Clinical application of the external tooth bleaching products (Clause 4)	—	—	M
9	Number of containers	M	—	—
10	Net mass of product in each container	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
18	Date of issue or latest revision, if applicable	—	—	M

Key

M: mandatory information

—: non-mandatory information

For single use containers, instructions may be labelled on the secondary packaging. The minimum information on single use containers required are: manufacturer name, trade name, lot number, and expiry date.

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[5])

Equivalent methods can also be used.

Use analytic grade 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 a calibration curve is not necessary. Calculate the mass concentration of H_2O_2 using Formula (A.1):

$$C = (1{,}701\ 18 \times V/m) \times Y/0{,}1 \times 100 \qquad \text{(A.1)}$$

where

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

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

m is the mass of the test product dispensed, expressed in milligrams;

Y is the accurate concentration of sodium thiosulfate, expressed in mol/litre.

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

NOTE Formation of iodine can be indicative of the presence of sodium hypochlorite, which is relevant when the method is used for testing an unknown active ingredient.