SLOVENSKI STANDARD
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Zobozdravstvo - Proizvodi za zunanje beljenje zob (ISO/DIS 28399:2019)

Dentistry - Products for external tooth bleaching (ISO/DIS 28399:2019)

Zahnheilkunde - Externe Zahnbleichmittel (ISO/DIS 28399:2019)

Médecine bucco-dentaire - Produits d'éclaircissement dentaire, à usage externe (ISO/DIS 28399:2019)

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Dentistry — Products for external tooth bleaching

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

This second edition cancels and replaces the first edition (ISO 28399:2011), which has been technically revised.

The main changes compared to the previous edition are as follows:

— a light microscopy method is recommended as an example for the measurement of erosion of enamel and dentine caused by products for external tooth bleaching.

— a visual assessment with shade guide has been revised.

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

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

This document 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 document 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[2] and ISO 7405[3].

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 1942:2009, *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 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

ISO 11609:2017, *Dentistry — Dentifrices — Requirements, test methods and marking*

ISO 11664-1:2007, *Colorimetry — Part 1: CIE standard colorimetric observers*

ISO 11664-2:2007, *Colorimetry — Part 2: CIE standard illuminants*

ISO/TR 28642:2016, *Dentistry — Guidance on colour measurement*

CIE s 014-6/E: 2013, *Colorimetry — Part 6: CIEDE2000 Colour-Difference Formula*

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 using chemicals, sometimes in combination with the application of auxiliary means

[SOURCE: ISO 1942:2009, 2.28, modified]

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

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

[SOURCE: ISO 1942:2009, 2.292, **tooth erosion**]

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) enamel surface microhardness before and after bleaching treatment shall not exceed 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 equal or less than the level which is caused by the positive control (B.4.2), 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 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 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 artificial saliva solution similar to that described in the ANSI/ADA Specification No. 41[8].

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 regulation[4].

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.