INTERNATIONAL STANDARD

ISO 17730

Second edition
2020-09

Dentistry — Fluoride varnishes

Médecine bucco-dentaire — Vernis fluorés

Reference number
ISO 17730:2020(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

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 on 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 the following URL: 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 second edition cancels and replaces the first edition (ISO 17730:2014), which has been technically revised.

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

— Additional subclause to indicate three samples are tested for total fluoride. Two aliquots are analysed for each sample.

— A requirement of minimum soluble fluoride release potential and a relevant test method have been added.

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

Fluoride varnishes are used in dentistry primarily for caries prevention and reduction of dentine hypersensitivity. Fluoride varnishes are applied in the oral cavity directly on the outer surfaces of teeth and fillings, and are intended to remain at least for several hours.

Specific qualitative and quantitative test methods for demonstrating freedom from unacceptable biological hazards are not included in this document, but it is recommended that, for the assessment of possible biological or toxicological hazards, reference should be made to ISO 10993-1 and ISO 7405.

Dentistry — Fluoride varnishes

1 Scope

This document specifies requirements and test methods for total digestible fluoride content and a minimum soluble fluoride release potential in dental varnishes containing fluoride, intended for use in the oral cavity directly on the outer surfaces of teeth and fillings. It also specifies packaging and labelling requirements, including the instructions for use. This document covers fluoride varnishes to be applied by dental health care workers.

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 648:2008, *Laboratory glassware — Single-volume pipettes*

ISO 835:2007, *Laboratory glassware — Graduated pipettes*

ISO 1942, *Dentistry — Vocabulary*

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods*

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 19448, *Dentistry — Analysis of fluoride concentration in aqueous solutions by use of fluoride ion-selective electrode*

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
fluoride varnish
dental product, in paintable liquid/paste form containing fluoride compound for topical application to the outer surfaces of teeth and fillings, intended primarily to prevent tooth caries or reduce dentine hypersensitivity

3.2
total fluoride content
mass percent of fluoride in the *fluoride varnish* (3.1)

3.3
fluoride release potential
detectable soluble fluoride released from the *fluoride varnish* (3.1) into an aqueous medium

3.4
outermost packaging
packaging used to combine material and additional items, including instructions for use and any proportioning or mixing devices that are supplied with the material

4 Requirements

4.1 Total fluoride content

The total fluoride content shall not deviate by more than 20 % from the stated amount on the package when tested in accordance with 6.2 or other validated methods for total fluoride content.

4.2 Fluoride release potential

The fluoride release potential shall be equal to or higher than 14,2 ng F/mm^2 as determined by the test method in Annex A. Other validated measurement methods on fluoride release potential with similar sensitivity and accuracy to Annex A, conforming to practices and principles found in References [1] to [6] may be used.

NOTE Quantitative measurement using method in Annex A is not established to provide links to clinical findings.

5 Sampling

Use packaged material(s) of fluoride varnishes prepared for retail sale from the same batch containing enough material to carry out the specified tests, plus an allowance for repeat tests, if necessary. Perform tests on the materials as received.

6 Measurement and test methods

6.1 Test conditions

Perform tests at 23°C ± 2 °C.

6.2 Test for total fluoride content

6.2.1 Chemicals and solutions

6.2.1.1 Total ionic strength adjustment buffer (TISAB) solution, described in ASTM D1179-16: 2016; see Reference [8] or alternative.

NOTE 1 TISAB[1)]: Dissolve sodium chloride 5,8 g, acetic acid 5,7 g, CDTA 0,4 g in 90 ml of deionized water. Adjust to pH 5,5 with sodium hydroxide (5 mol/l) and make up to a total of 100 ml solution with deionized water.

NOTE 2 It is known that interfering ions of, for example, calcium, aluminium, iron, magnesium, sulphate and phosphate salts can affect the result unpredictably; see References [9] and [10]. The use of TISAB III® or TISAB IV® buffer can be considered.

6.2.1.2 50 % Diluted TISAB solution, dilute TISAB with deionized water 1:1 by volume.

1) Examples are TISAB II® (Orion Research). Acceptable products are TISAB II®, TISAB III®, and TISAB IV® available from Thermo Fisher Scientific, Waltham, MA 02451 USA. This information is given only for the convenience of users of this document and does not constitute an endorsement by ISO of this product.

6.2.1.3 Fluoride standard solution, commercially available or prepared with sodium fluoride at 0,10 mol/l.

6.2.1.4 Chloroform, reagent grade.

6.2.1.5 Deionized water, in accordance with ISO 3696:1987, grade 2.

6.2.1.6 Potassium hydroxide at 1 mol/l.

6.2.2 Apparatus

6.2.2.1 Chloroform resistant vials and caps, 25 ml or more capacity.

6.2.2.2 Balance, accurate to 0,000 1 g.

6.2.2.3 Magnetic stir bar.

6.2.2.4 Magnetic stir plate.

6.2.2.5 Pipette, of nominal capacity 1,0 ml to smallest scale division 0,01 ml, 10,0 ml to 0,02 ml, and 20,0 ml to 0,03 ml, in accordance with ISO 835:2007, Class A.

6.2.2.6 Fluoride ion-selective electrode (F-ISE), with reference electrode, or combination F-ISE/reference electrode pair.

6.2.2.7 Plastic small container (e.g. vial or beaker), 25 ml or more capacity capable of allowing stirring with a stir bar operated by a stirrer.

6.2.2.8 pH/mV electrometer (pH meter), with a sensitivity of ±0,1 mV.

6.2.3 Procedure

6.2.3.1 Preparation of standard solutions

Prepare standard solutions in accordance with ISO 19448.

Make successive dilutions of the fluoride standard solution to obtain a set of working standard solutions that are 10^{-2}, 10^{-3}, 10^{-4}, 10^{-5} mol/l NaF.

6.2.3.2 Preparation of calibration curve

Prepare calibration curve in accordance with ISO 19448.

6.2.3.3 Sample preparation

a) Place open chloroform resistant small container that can be capped, such as a scintillation vial, on balance and tare to zero.

b) Dispense 0,05 g to 0,15 g of varnish product onto the bottom of the small container.

c) Determine and record the mass of the amount of varnish [m_{varnish}] accurate to 0,000 1 g.

d) If manufacturer's instruction for use indicates that the varnish contains fluorosilane, add 1,0 ml of 1 mol/l KOH to the varnish in the small container. Cap and vigorously swirl the small container for 5 min to mix the sample with the KOH. If the varnish does not contain fluorosilane then skip this step.