International Standard

ISO 17730

Dentistry — Fluoride varnishes

Médecine bucco-dentaire — Vernis fluorés

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Foreword

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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).

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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 17730:2020), which has been technically revised.

The main changes are as follows:

— Abbreviated terms and jargon have been removed and edited for clarity.

— A.2.3: The minimum size range of the plastic rod was changed from 30 mm^2 to 60 mm^2 to be more precise at 28,3 mm^2 to 60 mm^2.

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.

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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 for several hours.

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

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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. This also specifies packaging and labelling requirements, including the instructions for use. This document covers fluoride varnishes to be applied by dental health care workers.

This document does not apply to fast acting topical fluoride products such as fluoride oral rinses.

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 https://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)

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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. For an example method, see 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 the 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**, described in Reference [8]

6.2.1 Chemicals and solutions

6.2.1.1 **Total ionic strength adjustment buffer (TISAB) solution**, see Reference [9] or alternative.

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 Interfering ions of, for example, calcium, aluminium, iron, magnesium, sulphate and phosphate salts, can affect the result unpredictably; see Reference [9]. 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.

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