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## Dentistry — Fluoride varnishes

*Médecine bucco-dentaire — Vernis fluorés*

ICS: 97.170

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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](http://www.iso.org/directives)).

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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](http://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 17730:2014), which has been technically revised.

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

- Additional section 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.

## 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.

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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. 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 1942, *Dentistry — Vocabulary*

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

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

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**

mass percent of fluoride in the fluoride varnish

### 3.3

#### **fluoride release potential**

detectable soluble fluoride released from the fluoride varnish 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 [6.1](#) or other validated methods for total fluoride content.

### 4.2 Fluoride release potential

The fluoride release potential is equal to or higher than 0,02 mg/l 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 reference [8] to [13] may be used.

NOTE 1 the detection limit for fluoride ion selective electrode is taken as 0,02mg/l.

NOTE 2 quantitative measurement using method in [Annex A](#) is not established to provide links to clinical findings.

## 5 Sampling

Use packages 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 “as received” samples.

## 6 Test methods

### 6.1 Test conditions

Perform tests at  $23 \pm 2^\circ\text{C}$ .

### 6.2 Test for total fluoride

#### 6.2.1 Chemicals and solutions

**6.2.1.1 Total ionic strength adjustment buffer (TISAB) solution**, described in ASTM D1179-10: 2010[6] 18.1 or alternative.

NOTE 1 TISAB II: Sodium chloride 5,8 % (w/v), acetic acid 5,7 % (w/v), CDTA 0,4 % (w/v) adjust to pH 5 to pH 5,5 with sodium hydroxide (5 mol/l).

NOTE 2 Examples are TISAB II® (Orion Research). An acceptable product (TISAB II®) is 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.

NOTE 3 It is known that interfering ions of, for example, calcium, aluminium, iron, magnesium, sulphate and phosphate salts can affect the result unpredictably. 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.

**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 8351, 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 vial (or beaker or small container)**, 25 ml or more capacity.

**6.2.2.8 pH/mV electrometer (pH meter)**, with a sensitivity of  $\pm 0,1$  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 vial 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 container.
- c) Determine and record the mass of the amount of varnish [Varnish<sub>mass</sub>] added to 0,000 1 g.
- d) If the varnish sample contains fluorosilane, add 1,0 ml of 1 mol/l KOH to the varnish in the container and mix for 5 min. If the varnish sample does not contain fluorosilane then skip this step.
- e) Add magnetic stir bar.
- f) Add  $(4 \pm 0,5)$  ml of chloroform into the container and stir.
- g) Add  $(10,0 \pm 0,1)$  ml of TISAB buffer to the chloroform + sample.