INTERNATIONAL STANDARD

ISO 17730

First edition
2014-11-01

Dentistry — Fluoride varnishes

Médecine bucco-dentaire — Vernis fluorés

Reference number
ISO 17730:2014(E)

© ISO 2014



COPYRIGHT PROTECTED DOCUMENT

© ISO 2014

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword ..... **iv**
Introduction ..... **v**
1 Scope **1**
2 Normative references **1**
3 Terms and Definitions **1**
4 Requirements **2**
4.1 Total fluoride content 2
5 Sampling **2**
6 Test method **2**
6.1 Test for total fluoride content 2
6.2 Test conditions 3
7 Test report **4**
8 Instructions for use **4**
9 Packaging, labelling, and marking **5**
9.1 Packaging 5
9.2 Labelling 5
Bibliography **6**

© ISO 2014 – All rights reserved

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 meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword — Supplementary information.

The committee responsible for this document is ISO/TC 106, *Dentistry,* Subcommittee SC7, *Oral care products*.

© ISO 2014 – All rights reserved

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 hazard are not included in this International Standard, 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.

© ISO 2014 – All rights reserved

Dentistry — Fluoride varnishes

1 Scope

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

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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, *Water for analytical laboratory use — Specification and test methods*

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

3 Terms and Definitions

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

3.1
consumer packaging
retail packaging
sales packaging
package, with labelling and contents as a sales unit to the user or consumer at the point of retail

Note 1 to entry: A consumer packaging can consist of a secondary packaging wrapping or container covering one or more primary packaging elements or, it can consist of a single primary packaging element containing the product.

Note 2 to entry: Adapted from ISO 21067:2007, definition 2.2.5.

3.2
fluoride varnish
dental product, in paintable liquid 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

3.3
total fluoride
mass percent of fluoride in the fluoride varnish

© ISO 2014 – All rights reserved