
Dentistry — Fluoride varnishes

Médecine bucco-dentaire — Vernis fluorés



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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).

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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*.

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.

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