INTERNATIONAL STANDARD

ISO 6874

Third edition
2015-09-01

Dentistry — Polymer-based pit and fissure sealants

Médecine bucco-dentaire — Produits dentaires à base de polymères pour comblement des puits et fissures

Reference number
ISO 6874:2015(E)

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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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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 SC1, *Filling and restorative materials*.

This third edition cancels and replaces the second edition (ISO 6874:2005), of which it constitutes a minor revision.

Introduction

The efficacy of pit and fissure sealants for the prevention of dental caries is widely accepted. The polymer-based materials intended for this purpose and covered by this International Standard harden by a free-radical polymerisation reaction that is either initiated by mixing components or by external energy, e.g. visible light.

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this International Standard but, when assessing possible biological hazards, reference can be made to ISO 10993 (all parts) and ISO 7405.

Dentistry — Polymer-based pit and fissure sealants

1 Scope

This International Standard specifies requirements and test methods for polymer-based materials intended for sealing pits and fissures in teeth.

This International Standard covers both self-curing and external-energy-activated materials.

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

3 Classification

For the purposes of this International Standard, polymer-based pit and fissure sealants are classified, according to the method of curing, as follows:

Class 1: Materials whose setting is effected by mixing an initiator and activator ("self-curing" materials).

Class 2: Materials whose setting is effected by the application of energy from an external source, such as visible light ("external-energy-activated" materials).

4 Requirements

4.1 Biocompatibility

See the Introduction for guidance on biocompatibility, ISO 7405 and ISO 10993-1.

4.2 Physical properties

4.2.1 Working time, Class 1 sealant

The working time for Class 1 sealants, determined in accordance with 6.4, shall not be less than 40 s.

4.2.2 Setting time, Class 1 sealant

The setting time for Class 1 sealants, determined in accordance with 6.5, shall not be greater than 5 min.

4.2.3 Depth of cure, Class 2 sealant

The depth of cure for Class 2 sealants, determined in accordance with 6.6, shall be not less than 1,5 mm. If the material is supplied in more than one shade, each shade shall comply with this requirement.

5 Sampling

The test sample shall consist of a retail package, or packages, from the same batch containing sufficient material (a minimum of 20 g) to carry out the specified tests and repeat tests, if necessary.

6 Test methods

6.1 Inspection

Inspect visually to check that requirements specified in Clause 7 have been met.

6.2 Test conditions

Unless specified otherwise by the manufacturer, prepare and test all specimens at (23 ± 2) °C. Control the relative humidity to ensure that it remains greater than 30 % at all times. If the material was refrigerated for storage, allow it to attain (23 ± 2) °C before use.

For the preparation of class 2 materials, reference shall be made to the manufacturer's instructions [see 7.3 e) and g)] that state the external energy source or sources recommended for the materials to be tested. Care shall be taken to ensure that the source is in a satisfactory operating condition.

NOTE See also ISO 10650 (all parts).

6.3 Preparation of test specimens

Mix or otherwise prepare the material in accordance with the manufacturer's instructions and the test conditions specified in 6.2.

6.4 Working time, Class 1 sealant

6.4.1 Apparatus

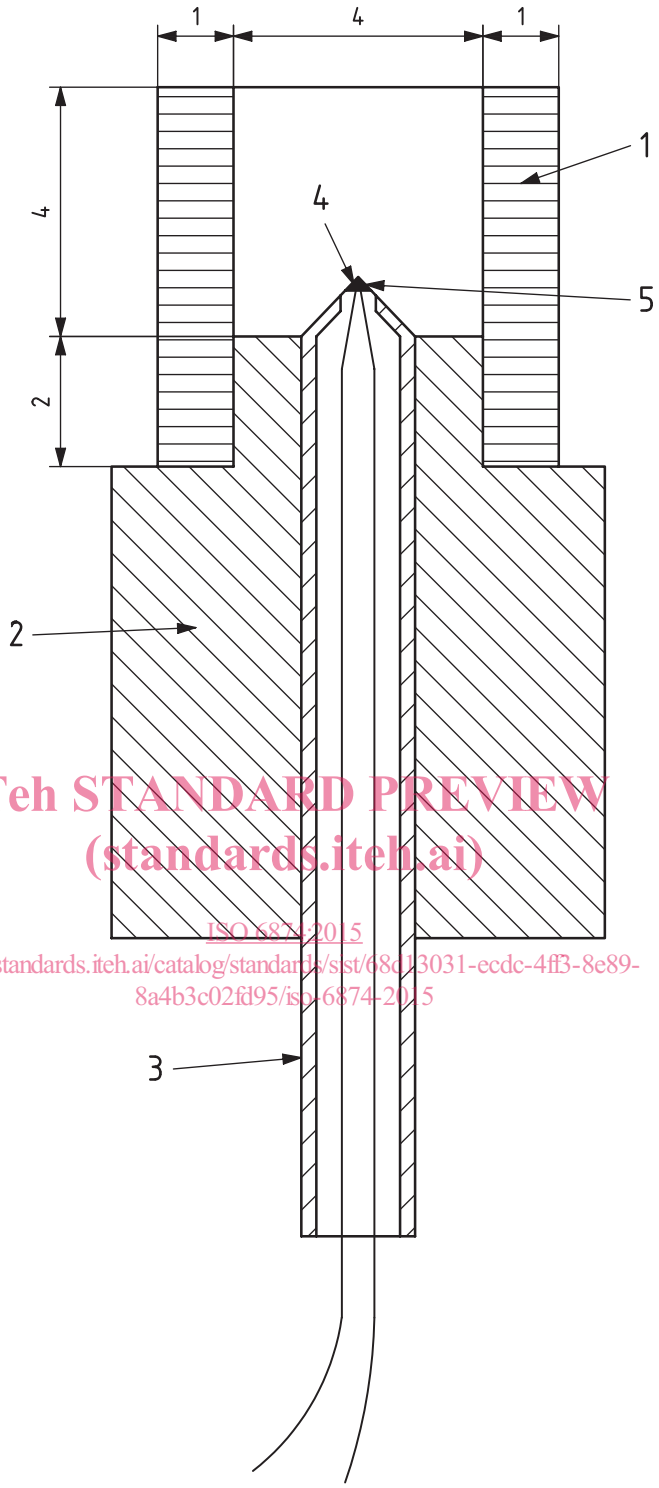
6.4.1.1 **Thermometry apparatus**, as shown in Figure 1.

The apparatus consists of a piece of polyethylene (or similar material) tubing, A, located on a block of polyamide or similar material, B, which has a hole into which is inserted a stainless steel tube, C, containing a stabilized thermocouple D.

The polyethylene tube A is 6 mm long, 4 mm in internal diameter and has a wall thickness of 1 mm. The locating part of block B is 4 mm in diameter and 2 mm high. When assembled, the two components form a specimen well 4 mm high × 4 mm in diameter. In order to facilitate removal of the specimen after testing, the thermocouple D has a conical tip that protrudes 1 mm into the base of the specimen well. The tolerances on the above-mentioned dimensions are ± 0,1 mm.

The thermocouple consists of wires (0,25 ± 0,05) mm in diameter, made of a material (e.g. copper/constantan) capable of registering rapid temperature changes in a specimen of setting material to an accuracy of 0,1 °C. The thermocouple is connected to an instrument (e.g. voltmeter or chart recorder) capable of recording the temperature to that accuracy.

NOTE A prefabricated thermocouple of similar size and performance can be substituted.



Key

1 polyethylene tubing
2 polyamide block
3 stainless steel tube
4 thermocouple
5 silver soldering

Figure 1 — Apparatus for determination of working and setting times