SLOVENSKI STANDARD
SIST EN 23107:2000

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Dental zinc oxide/eugenol cements and zinc oxide non-eugenol cements (ISO 3107:1988)

Dental zinc oxide/eugenol cements and zinc oxide non-eugenol cements (ISO 3107:1988)

Zahnärztliche Zinkoxid-Eugenol- und Zinkoxid-Noneugenol-Zemente (ISO 3107:1988)

Ciments dentaires a base d'oxyde de zinc-eugénol et ciments dentaires a base d'oxyde de zinc sans eugénol (ISO 3107:1988)

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English version

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This European Standard was approved by CEN on 1991-11-04 and is identical to the ISO standard as referred to.
CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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FOREWORD

This European Standard has been taken over by CEN/TC 55, "Dental products" from the work of ISO/TC 106 "Dentistry" of the International Organization for Standardization (ISO).

CEN/TC 55 decided to submit this final draft to the CEN Members for voting by Unique Acceptance Procedure (UAP). The standard was approved.

National standards identical to this European Standard shall be published at the latest by 92-05-06 and conflicting national standards shall be withdrawn at the latest 92-05-06.

In accordance with the Common CEN/CENELEC Rules the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland , France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

ENDORSEMENT NOTICE

The content of this European Standard is identical with the International Standard ISO 3107 "Dental zinc oxide/eugenol cements and zinc oxide non-eugenol cements" published in 1988.

INTERNATIONAL STANDARD

ISO 3107

Second edition
1988-11-01

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION
ORGANISATION INTERNATIONALE DE NORMALISATION
МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ

Dental zinc oxide/eugenol cements and zinc oxide non-eugenol cements

Ciments dentaires à base d'oxyde de zinc-eugénol et ciments dentaires à base d'oxyde de zinc sans eugénol

Reference number
ISO 3107 : 1988 (E)

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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 3107 was prepared by Technical Committee ISO/TC 106, *Dentistry*.

This second edition cancels and replaces the first editions of ISO 3106 : 1974 and ISO 3107 : 1974.

Users should note that all International Standards undergo revision from time to time and that any reference made herein to any other International Standard implies its latest edition, unless otherwise stated.

Printed in Switzerland

Dental zinc oxide/eugenol cements and zinc oxide non-eugenol cements

0 Introduction

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this International Standard, but it is recommended that in assessing possible biological or toxicological hazards, reference should be made to ISO/TR 7405.

1 Scope

This International Standard specifies requirements and test methods for zinc oxide/eugenol or zinc oxide/non-eugenol cements supplied as two separate components which may be either powder/liquid or paste/paste and which are suitable for use in the oral cavity. These non-aqueous cements may contain eugenol or an aromatic oil, compounds capable of reacting with zinc oxide such as accelerators, and gums, resins and inert inorganic fillers.

2 Field of application

This International Standard covers commercially manufactured zinc oxide/eugenol and modified zinc oxide/eugenol cements suitable for use in restorative dentistry for temporary cementation, for permanent cementation, such as temporary restorations and bases, and as cavity liners. This International Standard also covers non-eugenol cements containing zinc oxide and aromatic oils suitable for temporary cementation.

3 References

ISO 2590, *General method for the determination of arsenic — Silver diethyldithiocarbamate photometric method.*

ISO/TR 7405, *Biological evaluation of dental materials.*

4 Classification

For the purposes of this International Standard, zinc oxide/eugenol cements are classified, according to their intended use in restorative dentistry, into the following types.

Type I: For temporary cementation — setting and non-setting

Class 1: Powder and liquid

Class 2A: Setting paste and paste containing eugenol

Class 2B: Setting paste and paste not containing eugenol

Class 3: Non-setting paste and paste

Type II: For permanent cementation

Class 1: Powder and liquid

Type III: For temporary restorations and bases

Class 1: Powder and liquid

Class 2: Paste and paste

Type IV: For cavity liners

Class 1: Powder and liquid

Class 2: Setting paste and paste

Zinc oxide/non-eugenol cements covered by this International Standard are indicated as such.

5 Requirements

5.1 Material

The components of the material, when mixed in accordance with the manufacturer's instructions, shall produce a material with characteristics suitable for its intended use within a given time.

5.2 Components

5.2.1 Liquid

The liquid shall be clear, colourless or have only a slight amber tinge, and shall be free from suspended matter or deposits.

5.2.2 Powder

The powder shall be free of extraneous materials. When coloured, the pigment shall be uniformly dispersed throughout the powder.

5.2.3 Pastes

The unit package of pastes shall consist of two collapsible tubes or other containers, one containing the zinc oxide paste with or without modifiers, and the other containing eugenol or non-eugenol paste with or without modifiers. These pastes shall be homogeneous and free from extraneous matter.

5.3 Performance requirements

When tested in accordance with the appropriate test methods specified in clause 7, cements shall comply with the performance requirements specified in the table.

5.4 Biocompatibility

See clause 0 for use of ISO/TR 7405.

The total arsenic content of the cement shall not exceed the limit specified in the table, when tested in accordance with 7.6.

5.5 Manufacturer's instructions

Instructions for guidance of the user in proportioning, mixing and manipulation shall accompany each unit package. The following details shall be included:

a) the recommended temperature and humidity for mixing, and condition and type of mixing surface;

b) the component ratio recommended for each specific application;

c) the rate of incorporation of the components;

d) the time of mixing;

e) the working time after the end of mixing;

f) the setting time, where appropriate.

6 Sampling and inspection

6.1 Procurement

The method of procurement shall be the subject of an agreement between the manufacturer and test authority, and shall be recorded.

6.2 Sampling

A sample drawn from one batch shall provide sufficient powder and liquid or the appropriate pastes to complete all the specified tests.

6.3 Inspection

Compliance with the requirements specified in 5.2.1, 5.2.2, 5.2.3, 5.5 and clause 8 shall be determined by visual inspection.

7 Test methods

7.1 Preparation of test specimens

7.1.1 Ambient conditions

Carry out all mixing of the cement for the preparation of test specimens at a temperature of 23 °C ± 1 °C and a relative humidity of 50 % ± 2 %.

Table — Performance requirements

Type and class	Setting time at 37 °C, min		Compressive strength at 24 h, MPa		Disintegration after 24 h, % (*m*/*m*)	Film thickness, µm	Acid-soluble arsenic content, mg/kg (ppm)
	min.	max.	min.	max.	max.	max.	max.
Type I-class 1	4	10		35	2,5	25	2
Type I-class 2A	4	10		35	2,5	25	2
Type I-class 2B	4	10		35	2,5	25	2
Type I-class 3	Penetration at 1 h		NA*	NA*	NA*	25	2
Type II-class 1	4	10	35		1,5	25	2
Type III-class 1	3	10	25		1,5	NA*	2
Type III-class 2	3	10	25		1,5	NA*	2
Type IV-class 1	4	10	5		1,5	NA*	2
Type IV-class 2	4	10	5		1,5	NA*	2

* NA = not applicable

7.1.2 Apparatus for mixing

7.1.2.1 Smooth glass slab, approximately 150 mm × 75 mm × 20 mm. If a mixing pad is supplied by the manufacturer, it may be used.

7.1.2.2 Rigid spatula, inert to the cement.

All apparatus used for mixing and testing shall be kept clean, dry and free from particles of hardened cement.

7.1.3 Conditioning

Before the start of mixing, condition the test samples and apparatus at the ambient conditions specified in 7.1.1, for at least 1 h, except where otherwise stated by the manufacturer.

7.1.4 Procedure for mixing

Place the components on the mixing surface in the ratio specified by the manufacturer.

If the material is supplied as a paste/paste system, use a component ratio in grams per gram or in measured lengths, in accordance with the manufacturer's instructions, producing a minimum of 0,75 ml of mixed material.

Completely mix the components in accordance with the manufacturer's instructions.

7.2 Determination of setting time

7.2.1 Apparatus

7.2.1.1 Oven or **cabinet,** capable of being maintained at a temperature of 37 °C ± 1 °C and a relative humidity from 95 % to 100 %.

7.2.1.2 Indentor needle, of mass 400 g ± 2 g and having a flat end of diameter 1,0 mm ± 0,1 mm. The needle tip shall be cylindrical for a distance of approximately 5,0 mm. The needle end shall be plane and at right angles to the axis of the rod. This indentor needle shall be used for testing type I-class 1, type II-class 1, type III-class 1 and type IV-class 1.

A similar indentor needle of mass 100 g ± 0,5 g and having a flat end of diameter 2,0 mm ± 0,1 mm shall be used for type I-classes 2A and 2B, and type IV-class 2.

7.2.1.3 Mould, made of non-corrodible metal, consisting of a rectangular plate with a circular hole conforming to the dimensions given in figure 1.

7.2.1.4 Metal block, of minimum dimensions 8 mm × 20 mm × 10 mm, either as part of 7.2.1.1 or 7.2.1.2 or as a separate item.

7.2.1.5 Flat glass plate, approximately 1 mm thick (for example, a microscope slide).

7.2.2 Procedure

Condition the metal block (7.2.1.4) and indentor needle (7.2.1.2) in the oven (7.2.1.1) at 37 °C ± 1 °C.

Place the metal mould (7.2.1.3), conditioned at 23 °C ± 1 °C, on the flat glass plate (7.2.1.5) and fill to a level surface with the cement mixed in accordance with the manufacturer's instructions.

After 120 s ± 10 s for type III-class 1, or 180 s ± 10 s for type I-classes 1, 2A and 2B, type II-class 1 and type IV-classes 1 and 2 from the start of mixing, transfer the specimen to the oven for testing.

As soon as possible after placing the specimens in the oven, carefully lower the indentor needle vertically onto the surface of the cement. Make indentations at 15 s intervals until the time of setting has been reached. Maintain the needle in a clean condition between indentations.

Record the setting time as the period of time which elapses from the start of mixing to the time when the needle fails to penetrate completely the 2 mm depth of cement. This penetration can be confirmed by holding the specimen up to the light and examining visually. Repeat this test once.

NOTE — Type I-class 3 is non-setting. To verify this property, use the 100 g ± 0,5 g indentor needle and test every 15 min for 1 h. Complete penetration shall be obtained for each trial.

7.2.3 Expression of results

Calculate the average of two determinations and record the result to the nearest 15 s.

7.3 Determination of compressive strength

7.3.1 Apparatus

7.3.1.1 Oven or **cabinet,** as specified in 7.2.1.1.

7.3.1.2 Five split moulds and **plates,** such as shown in figure 2, 6 mm high and with an internal diameter of 4 mm, made of stainless steel or other material which is not attacked or corroded by the cement.

7.3.1.3 Five individual screw clamps, such as those shown in figure 3.

7.3.1.4 Compressive strength-testing apparatus, having a cross-head speed of 1,00 mm/min ± 0,25 mm/min.

7.3.2 Preparation of test specimens

Prepare at least five specimens.

Condition the moulds (7.3.1.2), screw clamps (7.3.1.3) and top and bottom plates (7.3.1.2) at 23 °C ± 1 °C.