
INTERNATIONAL STANDARD



3106

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

Dental zinc oxide/eugenol filling materials

Produits d'obturation dentaire à base d'oxyde de zinc-eugénol

First edition — 1974-10-01

FOREWORD

ISO (the International Organization for Standardization) is a worldwide federation of national standards institutes (ISO Member Bodies). The work of developing International Standards is carried out through ISO Technical Committees. Every Member Body interested in a subject for which a Technical Committee has been set up 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.

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.

International Standard ISO 3106 was drawn up by Technical Committee ISO/TC 106, *Dentistry*, and circulated to the Member Bodies in May 1973.

It has been approved by the Member Bodies of the following countries :

Australia	Germany	Spain
Brazil	India	Sweden
Bulgaria	Ireland	Switzerland
Canada	Netherlands	Thailand
Czechoslovakia	New Zealand	United Kingdom
Egypt, Arab Rep. of	Romania	U.S.A.
France	South Africa, Rep. of	Yugoslavia

No Member Body expressed disapproval of the document.

Dental zinc oxide/eugenol filling materials

0 INTRODUCTION

This International Standard only covers commercially available accelerated zinc oxide/eugenol filling materials. While it is appreciated that there is a need in some countries for a specification to cover the purity of unmodified zinc oxide and eugenol intended for dental use, it is felt that, despite certain similarities, this could be much more conveniently covered by a separate specification. It is envisaged that further work with this in mind will be scheduled on a national level with possible consideration by ISO/TC 106 at a later date.

Although the zinc oxide/eugenol materials covered by this International Standard are those intended for use in dental filling procedures and not cementation, the more familiar and convenient generic term "cement" has been used in the text as this is in accord with both common usage and the definition for dental "cement" currently being considered by ISO/TC 106.

1 SCOPE

This International Standard specifies requirements for accelerated zinc oxide/eugenol filling materials supplied as two separate components and intended for use in the oral cavity.

2 FIELD OF APPLICATION

Zinc oxide/eugenol filling materials covered by this International Standard are those manufactured for use as cavity linings and bases, temporary and root-canal fillings.

3 CLASSIFICATION

Zinc oxide/eugenol filling materials covered by this International Standard shall be classified as one of the following two types, according to their setting time (see 4.2.1) :

Type 1 — Fast setting (3 to 5,5 min)

Type 2 — Normal setting (4,5 to 7 min)

4 REQUIREMENTS

4.1 Components

4.1.1 General

The components, when mixed in accordance with the manufacturer's instructions, shall set rapidly to a condition suitable for the intended dental use.

4.1.2 Liquid

The liquid shall be clear with possibly a light amber tinge, and free from suspended matter, deposit or sediment.

4.1.3 Powder

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

4.1.4 Purity of ingredients

The quality of the ingredients used in the manufacture of the cement components shall conform with the relevant national pharmacopœia standards of purity, or such national regulations as are applicable to purity of pharmaceutical products.

4.2 Physical properties (see table)

TABLE — Physical properties — Test requirements

Consistency: Disc diameter at $23 \pm 1^\circ\text{C}$	Setting time at $37 \pm 1^\circ\text{C}$		Compressive strength: Minimum after 24 h	Solubility and disintegration: after 24 h
25 ± 1 mm (see 6.2)	Type 1 3 to 5,5 min (see 6.3)	Type 2 4,5 to 7 min (see 6.3)	25 MN/m ² (see 6.4)	0.5 % by mass (see 6.5)

4.2.1 Setting time

The setting time of the cement determined in accordance with 6.3 shall conform to the following limits :

Type 1 : 3 to 5,5 min

Type 2 : 4,5 to 7 min

4.2.2 Compressive strength

The compressive strength of the cement 24 h after mixing, determined in accordance with 6.4, shall not be less than 25 MN/m².

4.2.3 Solubility and disintegration

The amount of non-volatile material removed from the test specimen, when determined in accordance with 6.5, shall not be more than 0,5 % by mass, after immersion for 23 h.

4.3 Information to be supplied by the manufacturer

Adequate instructions for guidance of the user in proportioning, mixing and manipulation shall accompany each container. The following details shall be included :

- a) the recommended temperature and humidity for mixing and condition and type of mixing surface;
- b) an appropriate component ratio at the recommended ambient conditions;
- c) the rate of incorporation of one component with the other and the maximum mixing time.

5 SAMPLING AND INSPECTION

5.1 Sampling

5.1.1 Powder

Not less than 50 g of powder from the same batch shall comprise the test sample.

5.1.2 Liquid

Not less than 25 ml of liquid from the same batch shall comprise the test sample.

5.2 Inspection

Compliance with the requirements outlined in 4.1.2, 4.1.3 and 4.3 shall be determined by visual inspection.

6 TEST METHODS

6.1 Preparation of test specimens

6.1.1 Ambient conditions

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

6.1.2 Mixing

6.1.2.1 APPARATUS

- a) **Smooth glass slab** approximately 150 mm X 75 mm X 20 mm.
- b) **Rigid spatula** with a blade having dimensions approximately 45 mm X 8 mm, made from a material not affected by the cement.

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

Before the commencement of mixing, condition the test samples and apparatus at the ambient conditions specified in 6.1.1, except where otherwise stated.

6.1.2.2 PROCEDURE FOR POWDER/LIQUID MIXING

Place on the glass slab the correct mass of powder and volume of liquid, as determined by the consistency test specified in 6.2, and divide into four portions as follows :

- a) Divide the powder approximately in two halves.
- b) Divide one half into two quarters.
- c) Divide one quarter into two eighths.

Mix the material by incorporating the half-portion of the powder into the liquid in the first 15 s, then the quarter- and eighth-portions, each at 15 s intervals, each portion being thoroughly mixed before introducing the next portion. Then spatulate the whole mass with reasonable pressure for a further 15 s, utilizing approximately one-third of the top surface of the glass slab. The total mixing time shall be 1,25 min.

Leave no powder or liquid on the slab when the mixing has been completed.

6.2 Consistency test

6.2.1 Apparatus

6.2.1.1 Load of mass $2\,480 \pm 5$ g mounted on a loading device such as that shown in figure 1, in such a manner as to allow essentially frictionless movement in a vertical direction.

6.2.1.2 Two glass plates of minimum dimensions 30 mm X 30 mm, one having a mass of 20 ± 2 g.

6.2.1.3 Graduated hypodermic-type syringe, capacity 0,50 ml, with an accuracy of $\pm 0,005$ ml.

6.2.1.4 Measuring device designed to deliver $0,50 \pm 0,05$ ml of mixed cement.