

INTERNATIONAL STANDARD



3851

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

Capsulated dental silicate and silico-phosphate filling materials

Produits d'obturation dentaire en capsules, à base de silicates et de silicophosphates

First edition — 1977-07-01

UDC 616.314-089.27 : 615.463

Ref. No. ISO 3851-1977 (E)

Descriptors: dentistry, dental materials, materials specifications, tests, mechanical tests, chemical analysis, determination of content, arsenic.



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FOREWORD

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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 3851 was developed by Technical Committee ISO/TC 106, *Dentistry*, and was circulated to the member bodies in August 1975.

It has been approved by the member bodies of the following countries :

Australia	Iran	Sweden
Brazil	Mexico	Switzerland
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The member body of the following country expressed disapproval of the document on technical grounds :

U.S.A.

Capsulated dental silicate and silico-phosphate filling materials

0 INTRODUCTION

This International Standard has been prepared taking into account the contents of both ISO/R 1565, *Dental silicate cement*, and ISO 3824, *Dental silico-phosphate cements*. The significant difference is the specific coverage of the capsulated packaging, which has resulted in a number of basic changes in the test procedures and requirements. These changes include the specimen size, the reference point for setting time, and the use of the consistency test.

The silicate and silico-phosphate materials covered by this specification are those intended for use as dental fillings. For convenience of expression, however, and in accordance with common usage, the term "cement" has been used throughout the text.

At the present time it is capsulated silicate cements, rather than silico-phosphate, which are of more significance in terms of clinical usage, and the former have therefore been used as the main basis of the specification limits and tests. In the event of this situation changing, more emphasis could be given to the silico-phosphate group of materials.

1 SCOPE AND FIELD OF APPLICATION

This International Standard specifies requirements for dental silicate and silico-phosphate filling materials, presented as two separate preweighed components contained in a capsule and intended for mechanical mixing. The powder component is a finely ground alumina silicate glass, together with metal oxides, such as zinc oxide in the case of silico-phosphate cements, and the liquid is a solution of orthophosphoric acid and metal phosphates.

2 REFERENCE

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

3 REQUIREMENTS

3.1 Material

The cement shall consist of a powder and a liquid which, when mixed according to the manufacturer's instructions, will set to a condition suitable for its intended dental use.

3.2 Components

3.2.1 Liquid

The liquid shall form no obvious deposits or filaments on the inside of its container.

3.2.2 Powder

The powder shall be free from extraneous materials; when coloured, the pigment shall be uniformly dispersed throughout the powder.

3.3 Unset cement

3.3.1 Mixing

The cement, when mixed mechanically as directed in the manufacturer's instructions, shall be of a homogeneous, smooth consistency. In the event of the contents of a capsule being found not to comply with this requirement during mixing for the test methods described in the specification, then a further capsule shall be taken for examination. Such defective capsules shall not comprise more than 2 % of a test sample (i.e. 1 in 50).

3.3.2 Variation of cement consistency

The consistency of the mixed cement from any nine capsules, when determined in accordance with 5.3, shall not deviate more than 10 % from the mean of the ten tested.

3.4 Colour of set cement

The colour of the set cement of any shade selected at random from capsules of a test sample shall match the manufacturer's shade guide within the limits of professional acceptance. The sample shall be immersed in water for at least five days before comparison with the manufacturer's shade guide.

3.5 Physical properties

The time of setting, compressive strength, opacity¹⁾, solubility and disintegration shall be as specified in the table, when determined in accordance with the relevant test method given in clause 5.

1) The opacity requirement is not applicable to silico-phosphate cements.

3.6 Toxicity

3.6.1 General

The mixed cement, when used in accordance with the manufacturer's instructions, shall neither cause prolonged damage to oral tissues nor have any adverse systemic effect [see also 3.7 e)].

3.6.2 Arsenic content

The total arsenic content of the cement shall be as specified in the table, when tested in the manner described in clause 5.

3.7 Manufacturer's instructions

Adequate information on the following shall be included in the manufacturer's instructions :

- a) the method of bringing about physical contact between the powder and liquid;
- b) the method and timing of mechanical mixing;
- c) the setting time of the cement;
- d) the time normally available for manipulation and placement of the cement, when mixed in accordance with the manufacturer's instructions;
- e) if the cement can cause pulpal irritation, information on the use of a base/liner or other recommended protective measures;
- f) the minimum time at which finishing may be commenced.
- g) the minimum net volume of mixed cement in one capsule.

4 SAMPLING

A test sample shall comprise two retail packages of 50 or more capsules from different manufacturing batches.

A single retail package of 50 capsules is sufficient for the specified tests, but the second package is necessary in the event of repeat testing for the consistency test (5.3) being required.

5 TEST METHODS

5.1 Preparation of test specimens (General)

5.1.1 Ambient temperature

Unless stated otherwise all equipment shall be maintained and the preparation of all test specimens shall be carried out at $23 \pm 1\text{ }^{\circ}\text{C}$.

5.1.2 Mixing

Use the mechanical mixing technique outlined in the manufacturer's instructions, subject to calibration of the timing device against a stop-watch prior to each series of tests. Include any necessary correction in the subsequent timing of the capsule mixing for specimen preparation.

5.2 Inspection procedures

Visual inspection should be used in determining compliance with 3.3.1, 3.4 and clause 6.

5.3 Consistency

5.3.1 Apparatus

5.3.1.1 Loading device of the type illustrated in figure 1, or an equivalent means whereby a load of 15,0 kg mass may be applied vertically onto the cement specimen; the surfaces of the upper and lower anvils of the loading device must be parallel.

5.3.1.2 Two flat glass plates 40 mm square and approximately 3 mm thick.

5.3.1.3 Measuring device to deliver 0,075 ml of mixed cement in the form of a cylinder 6,0 mm high and 4,0 mm in diameter; a suitable device would be a glass tube and a PTFE plunger.

5.3.2 Procedure

After mixing in accordance with the manufacturer's instructions, collect and load the cement into the measuring device. Deliver 0,075 ml of the mixed cement, preferably as an upright cylinder, onto the centre of one of the glass

TABLE — Requirements for capsulated dental silicate and silico-phosphate cements

Time of setting* at 37 °C		Strength in compression	Opacity**		Solubility	Arsenic content
minutes		MN/m ²	C _{0,70}		Max.	mg/kg (ppm)
Min.	Max.	Min.	Min.	Max.		Max.
2	5	170 (1 750 kgf/cm ²)	0,35	0,55	9,0 mg phosphate calculated as P ₂ O ₅ per gram of cement	2

* It should be noted that the time of setting is determined from the completion of mixing (see 5.3).

** Silicate cements only.