
INTERNATIONAL STANDARD



1565

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Dental silicate cement (hand-mixed)

Ciments dentaires aux silicates (mélange manuel)

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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 1565 was developed by Technical Committee ISO/TC 106, *Dentistry*, and was circulated to the member bodies in October 1976.

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

Australia	India	Sweden
Austria	Ireland	Switzerland
Canada	Mexico	Thailand
Czechoslovakia	Netherlands	United Kingdom
Egypt, Arab Rep. of	New Zealand	U.S.A.
France	Norway	
Germany	South Africa, Rep. of	

No member body expressed disapproval of the document.

This International Standard cancels and replaces ISO Recommendation R 1565-1970, of which it constitutes a technical revision.

Dental silicate cement (hand-mixed)

0 INTRODUCTION

This International Standard was first published by ISO in 1970 as an ISO Recommendation based on FDI Specification No. 7. In common with the other ISO Recommendations in this initial series on dental materials, ISO/R 1559 to ISO/R 1567, it was then the subject of a programme of revision to bring its contents up to date on the basis of technical data from both ISO/TC 106 and the Fédération Dentaire Internationale. The latter organization undertook the secretariat responsibilities of the working groups which prepared this International Standard.

Of the various changes introduced in this revision, most stem from the use of a much smaller test specimen than previously. The reason for using the small test specimen is to align the test methods for hand-mixed materials as closely as possible with those for capsulated materials. In general, this has merely necessitated some adjustments in technique to accommodate the smaller test specimen, but in some instances, the water-leachable material test in particular, more basic changes in the test method have been made.

1 SCOPE AND FIELD OF APPLICATION

This International Standard specifies requirements for manually mixed dental silicate cements based on the hardening reaction between a glass powder, the principal constituent of which is an aluminosilicate, and aqueous solutions of phosphoric acid which may contain metal ions.

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 liquid which, when mixed according to the manufacturer's instructions, will set rapidly to a condition suitable for its intended use.

3.2 Components

3.2.1 Liquid

The liquid shall be free from obvious deposits or filaments on the inside of its container.

3.2.2 Powder

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

3.3 Unset cement

The cement, when mixed as directed in 5.1, shall be of uniform smooth consistency, completely mixed, and shall not evolve gases.

3.4 Set cement

After immersion in water for 5 days, the colour of any shade of the set cement, when viewed under water by natural daylight, shall match the manufacturer's shade guide within the limits of professional acceptance.

3.5 Performance requirements

The cement shall comply with the requirements specified in the table when tested according to the methods prescribed in clause 5.

3.6 Arsenic

The total arsenic content shall not exceed the limit specified in the table, when tested in the manner prescribed in clause 5.

3.7 Toxicity

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.

TABLE – Performance requirements (at standard testing consistency)

Net setting time* at 37 °C minutes		Strength in compression (24 h) MPa	Opacity $C_{0,70}$		Water-leachable material (24 h) mg P ₂ O ₅ /g	Arsenic content mg/kg (ppm)
min.	max.	min.	min.	max.	max.	max.
2	5	170	0,35	0,55	9,0	2

* The setting time is determined from the **completion** of mixing.

3.8 Manufacturer's instructions

Instructions for bringing about physical contact of the powder and the liquid, and for the mixing of these materials to form the cement, shall be supplied by the manufacturer. The following details shall be included :

- the temperature, condition and type of the slab and spatula;
- the recommended powder/liquid ratio;
- the rate of incorporation of the powder;
- the time of mixing;
- the setting time;
- the maximum satisfactory working time after the end of mixing;
- a statement that, when clinical conditions warrant, a liner should be placed between the cement and the dentine.

4 SAMPLING AND SAMPLES

4.1 Procurement

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

4.2 Samples

A sample drawn from one batch shall provide sufficient powder and liquid to complete all the prescribed tests.

5 TEST METHODS

5.1 Preparation of test specimens

5.1.1 Ambient conditions

Unless stated otherwise, the preparation of all specimens shall be carried out at 23 ± 1 °C and at a relative humidity of 50 ± 5 %.

5.1.2 Components

All tests shall be carried out on specimens prepared from samples of the powder and liquid complying with 3.2.1 and 3.2.2.

5.1.3 Apparatus for mixing

5.1.3.1 Glass slab, approximately 150 mm long × 75 mm wide × 20 mm thick.

5.1.3.2 Spatula, inert to the cement.

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

5.1.4 Method of mixing

Place known amounts of powder and liquid on the glass slab, divide the powder into approximately two halves and then divide one half into two quarters.

Commence mixing the components by incorporating the half portion of the powder into the liquid in the first 15 s. Follow this by incorporating the quarter portions each at intervals of approximately 15 s, making sure that each portion is thoroughly mixed before introducing the next portion. Spatulate the whole mass with reasonable pressure for a further 15 s using a small area of the slab.

The total mixing time shall be 1 min. No particles of powder and no unused liquid shall remain on the slab when the mix is completed. The final mix shall appear to be homogeneous.

5.2 Inspection requirements

Visual inspection shall be used in determining compliance with 3.2.1, 3.2.2, 3.3, 3.4 and clause 6.

5.3 Determination of powder/liquid ratio for standard testing consistency

5.3.1 Apparatus

5.3.1.1 Loading device of the type illustrated in figure 1, or an equivalent means whereby a force of 147 N (15 kgf) may be applied vertically on to the cement.