
International Standard



7489

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Dental glass polyalkenoate cements

Ciments dentaires au polyalkénoate de verre

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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.

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 7489 was prepared by Technical Committee ISO/TC 106, *Dentistry*.

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.

Dental glass polyalkenoate cements

0 Introduction

0.1 In preparing this International Standard particular consideration was given to the specimen size used for the compressive strength test, specified as a 12 mm high cylinder of 6 mm diameter. This may present problems in preparing specimens of capsulated materials or of certain fast-setting materials, although manufacturers would be able to test the component materials prior to encapsulation. The specimen size specified in ISO 3851 for capsulated silicate and silicophosphate cements is a 6 mm high cylinder of 4 mm diameter. However, in view of the increased scatter of test results using the 6 mm × 4 mm specimen as compared to the 12 mm × 6 mm specimen, and the considerable amount of research work required to set realistic limits for a 6 mm × 4 mm specimen size, it was decided that this International Standard should utilize the 12 mm × 6 mm specimen. It is possible that the use of capsulated materials will increase and a programme of work will be undertaken on the 6 mm × 4 mm specimen to provide data for a future revision incorporating the 6 mm × 4 mm specimen, either for capsulated materials only, or for both hand-mixed and capsulated materials. The same comments apply to specimens for water-leachable material. When suitable test methods have been developed and verified this International Standard will be revised.

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

1 Scope and field of application

This International Standard specifies requirements for dental glass polyalkenoate¹⁾ cements produced by the reaction between a powder of acid-soluble, aluminosilicate glass and an aqueous solution of a poly(alkenoic acid).

Polyalkenoate¹⁾ cements prepared by the addition of water to a mixture of dry acid and aluminosilicate glass are also covered by this International Standard.

The glass polyalkenoate cements covered by this International Standard may be used as luting agents, restorative materials, or as pit and fissure fillers or sealers.

2 References

ISO 2014, *Writing of calendar dates in all-numeric form*.

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

ISO 3851, *Capsulated dental silicate and silico-phosphate filling materials*.

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

3 Classification

The cements covered by this International Standard are classified, according to their intended use, as follows:

Type 1: Luting agent

Type 2: Restorative material

Materials used to fill or seal pits and fissures may be of either type 1 or type 2.

4 Requirements

4.1 Components

4.1.1 Liquid

The liquid shall be clear and free from visible deposits or filaments on the inside of its container. There shall be no visible signs of gelling.

4.1.2 Powder

The powder shall be free from extraneous material and, if coloured, the pigment shall be uniformly dispersed throughout the powder, when examined visually.

4.2 Unset cement

The cement, prepared and mixed in accordance with 6.1.3, shall be of uniform, smooth texture and shall not evolve gases.

4.3 Colour of set cement

For those cements with a shade guide supplied by the manufacturer the following additional test shall be carried out. After

1) The term "glass polyalkenoate" is now preferred to "glass ionomer" which is deprecated.

immersion in distilled water at 37 ± 1 °C for 7 days, the colour of the set cement, viewed when under water and in natural daylight, shall match the manufacturer's shade guide.

4.4 Physical requirements

The film thickness, setting time, working time, compressive strength, water-leachable content, opacity, acid-soluble arsenic content, and lead content shall be as specified in the table, when tested in accordance with the appropriate test methods specified in clause 6.

4.5 Biocompatibility

See 0.2 for guidance on biocompatibility.

4.6 Manufacturer's instructions

Instructions for the preparation, mixing and manipulation shall accompany each container of liquid and shall include the following:

- a) the recommended temperature range for preparation; condition and type of both the slab and spatula, or the type of mixing machine;
- b) the optimum powder/liquid ratios over the recommended temperature range [see also 4.6 g)] — this requirement however shall not apply to capsulated materials for which it is inappropriate;
- c) the method of mixing and the time of mixing and, in the case of hand-mixed materials, the rate of incorporation of the powder;
- d) the manipulation time after completion of mixing;
- e) a statement recommending that, when clinical conditions warrant, a liner should be placed between the cement and dentine;
- f) for materials where the polyacid is present in aqueous solution, a recommendation that the liquid should be kept in a moisture-tight container to avoid contamination or loss of moisture;

g) the precise powder/liquid ratio on a mass basis to an accuracy of 0,1, at a temperature of 23 ± 1 °C and a relative humidity of (50 ± 5) %, to be used when it is desired to carry out tests on the material;

h) a technique for protecting the cement against early contamination by water.

5 Sampling

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

6 Test methods

6.1 Preparation of test specimens

6.1.1 Conditioning

Prepare the test specimens at a temperature of 23 ± 1 °C and a relative humidity of (50 ± 5) %.

6.1.2 Apparatus

6.1.2.1 Polished glass mixing slab, approximately 150 mm long $\times$ 75 mm wide $\times$ 20 mm thick.

6.1.2.2 Spatula, made of a material which will not react with, or be abraded by, the components.

NOTE — Apparatus used for mixing and testing should be kept clean, dry and free from hardened particles of cement.

6.1.3 Method of mixing

Completely mix the powder and liquid to a uniform, smooth texture in accordance with the manufacture's instructions (see 4.6).

Table — Physical and chemical properties

Type	Film thickness	Setting time	Working time	Compressive strength	Water-leachable content	Opacity		Acid-soluble arsenic content	Lead content
	μm	min	min	MPa	% (m/m)	$C_{0,70}$ value		mg/kg (ppm)	mg/kg (ppm)
	max.	max.	min.	min.	max.	min.	max.	max.	max.
1	25	7,5	2,0	65	1,0	—	—	2,0	50
2	—	5	1,75	125	0,7	0,35	0,90	2,0	50