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**Dentistry — Water-based cements —  
Part 1:  
Powder/liquid acid-base cements**

*Art dentaire — Ciments à base d'eau —*

*Partie 1: Ciments acido-basiques liquides/en poudre*

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ISO copyright office  
Case postale 56 • CH-1211 Geneva 20  
Tel. + 41 22 749 01 11  
Fax + 41 22 749 09 47  
E-mail [copyright@iso.org](mailto:copyright@iso.org)  
Web [www.iso.org](http://www.iso.org)

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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. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 9917-1 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 1, *Filling and restorative materials*.

This second edition cancels and replaces the first edition (ISO 9917-1:2003), of which it constitutes a minor revision.

The main purpose for modification of this part of ISO 9917 was to include a new test method for acid erosion, a new test and requirement for radio-opacity and to distinguish between the requirements for manufacturer's instructions for hand-mixed cements and those for capsulated cements.

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this part of ISO 9917, but it is recommended that, in assessing possible biological or toxicological hazards, reference should be made to ISO 7405 and ISO 10993-1.

A bibliography has been added to this document.

ISO 9917 consists of the following parts, under the general title *Dentistry — Water-based cements*:

- *Part 1: Powder/liquid acid-base cements*
- *Part 2: Light-activated cements*

# Dentistry — Water-based cements —

## Part 1: Powder/liquid acid-base cements

### 1 Scope

This part of ISO 9917 specifies requirements and test methods for powder/liquid acid-base dental cements intended for permanent cementation, lining and restoration. This part of ISO 9917 is applicable to both hand-mixed and capsulated cements for mechanical mixing. This part of ISO 9917 specifies limits for each of the properties according to whether the cement is intended for use as a luting agent, a base or liner or as a restorative material. This part of ISO 9917 is not intended to address resin-modified water-based cements.

### 2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

ISO 3665:1996, *Photography — Intra-oral dental radiographic film — Specification*

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods*

ISO 7491, *Dental materials — Determination of colour stability*

### 3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

#### 3.1

##### **mixing time**

that part of the working time required in order to obtain a satisfactory mix of the components

#### 3.2

##### **working time**

period of time, measured from the start of mixing, during which it is possible to manipulate a dental material without an adverse effect on its properties

#### 3.3

##### **net setting time**

period of time, measured from the end of mixing, until the material has set according to the criteria and conditions specified in Annex A

NOTE For the purposes of this part of ISO 9917, in view of the wide variation in mixing times of cements, the net setting time is determined from the end of mixing.

## 4 Classification

### 4.1 Chemical type

For the purposes of this part of ISO 9917, dental cements shall be classified on the basis of their chemical composition, as follows:

- a) zinc phosphate cement, see Clause B.1;
- b) zinc polycarboxylate cement, see Clause B.2;
- c) glass polyalkenoate cement, see Clause B.3.

Acid-base setting, water-based cements other than those listed above may fall within the scope of this part of ISO 9917. If the manufacturer wishes to claim conformity for such a product, the type of material for which equivalence of properties is claimed shall be specified in accordance with 4.1 and 4.2 so that the correct performance limits are applied.

### 4.2 Application

For the purposes of this part of ISO 9917, the application of water-based cements shall be classified as follows:

- a) luting;
- b) bases or lining;
- c) restoration.

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## 5 Material

### 5.1 General

The cement shall consist of a powder and liquid which, when mixed in accordance with the manufacturer's instructions, shall conform to requirements in this clause and Clause 8.

### 5.2 Components

#### 5.2.1 Liquid

For non-encapsulated cements, visually inspect the liquid. It shall be free from deposits or filaments on the inside of its container. There shall be no visible signs of gelation.

#### 5.2.2 Powder

For non-encapsulated cements, visually inspect the powder. It shall be free from extraneous material. If the powder is coloured, the pigment shall be uniformly dispersed throughout the powder.

### 5.3 Unset cement

The cement shall be mixed in accordance with Clause 6, and then visually inspected. It shall be homogeneous and of a smooth consistency.

## 6 Preparation of test specimens

### 6.1 Ambient conditions

Specimens shall be prepared at a temperature of  $(23 \pm 1)$  °C and a relative humidity of  $(50 \pm 10)$  %.

### 6.2 Method of mixing

The cement shall be prepared in accordance with the manufacturer's instructions. Sufficient cement shall be mixed to ensure that the preparation of each specimen is completed from one mix. A fresh mix shall be prepared for each specimen.

NOTE For encapsulated materials, more than one capsule simultaneously mixed, may be required for certain specimens.

## 7 Sampling

### 7.1 Hand-mixed cements

A sample drawn from one batch shall provide sufficient material to complete all the prescribed tests and any necessary repeats.

NOTE Approximately 50 g of powder is necessary to complete the tests.

### 7.2 Encapsulated cements (standards.iteh.ai)

The test sample shall comprise a retail package of a sufficient number of capsules from one batch to complete all the tests and any necessary repeats.

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## 8 Requirements

### 8.1 Net setting time

When determined in accordance with Annex A, the net setting time of the cement shall conform to relevant requirements specified in Table 1.

### 8.2 Film thickness (luting cements only)

When determined in accordance with Annex C, the film thickness shall conform to relevant requirements specified in Table 1.

### 8.3 Compressive strength

When determined in accordance with Annex D, the compressive strength of the cement shall conform to the relevant requirements specified in Table 1.

### 8.4 Acid erosion

When determined in accordance with Annex E, the acid erosion of the cement shall conform to the relevant requirements specified in Table 1.

## 8.5 Optical properties (polyalkenoate restorative cements only)

When prepared, stored and tested in accordance with Annex F, cements shall meet the following requirements.

- a) The opacity of the set restorative cements shall be within the limits specified in Table 1, unless the restorative cement is designated as opaque by the manufacturer [see 9.2 f)].
- b) The colour of the set cement shall match the manufacturer's shade guide. If a shade guide is not supplied by the manufacturer, then the manufacturer shall nominate a commercially available shade guide that shall be used in assessing compliance with this requirement [see 9.3.1 c)].

## 8.6 Acid-soluble arsenic and lead contents

### 8.6.1 Acid-soluble arsenic content

When determined in accordance with Annex G, the acid-soluble arsenic content shall not exceed the relevant limits specified in Table 1.

### 8.6.2 Acid-soluble lead content

When determined in accordance with Annex G, the acid-soluble lead content shall not exceed the relevant limits specified in Table 1.

## 8.7 Radio-opacity (if claimed)

When the manufacturer describes the material as being radio-opaque [see 9.2 g)], the radio-opacity shall be at least equivalent to that for the same thickness of aluminium when determined in accordance with Annex H. When the manufacturer claims a greater radio-opacity, the measured value shall not be less than the value claimed when determined in accordance with Annex H.

## 9 Packaging, marking and information to be supplied by manufacturer

NOTE Additional information can be included at the discretion of the manufacturer or as required by other applicable rules or regulations.

### 9.1 Packaging

The materials shall be supplied in containers or capsules (for the purposes of this part of ISO 9917, the container or capsule shall be considered to be the immediate wrapping of the material) that afford adequate protection and have no adverse effect on the quality of the contents.

An outer pack may also be used to present the containers or capsules as a single unit.

### 9.2 Marking

Each outer container shall be clearly marked with the following details:

- a) the name and/or trademark of the manufacturer and the trade name, type and application of the cement;
- b) the shade of the powder according to the manufacturer's nominated shade guide;
- c) the minimum net mass, in grams, of the powder or the minimum net volume, in millilitres of the liquid as appropriate;
- d) the manufacturer's batch or lot number;



- e) on the outermost packaging, the recommended conditions of storage, and the “expiry date” for the material under those conditions of storage;
- f) on the outer packaging, whether the cement is designated opaque;
- g) on the outer packaging, whether the cement is designated as radio-opaque;
- h) on each outer container of encapsulated cements, the number of capsules in the container, and the net mass in each capsule.

### 9.3 Manufacturer's instructions

#### 9.3.1 General

Instructions shall accompany each package of the material and shall include the following:

- a) the trade name of the product;
- b) the manufacturer's name and contact details;
- c) a shade guide or, when no shade guide is provided, details of a commercially available shade guide for use with the material.

In addition, at least the information in 9.3.2 or 9.3.3, as appropriate, shall be given. For those materials not mentioned specifically in 4.1, the manufacturer shall indicate the type of material (see 4.1 and 4.2) against whose performance requirements the material shall be tested.

#### 9.3.2 Hand-mixed cements

For hand-mixed cements, the following information shall be supplied:

- a) the temperature range for preparation;
- b) the recommended powder:liquid ratio, expressed as a mass:mass ratio for the recommended temperature range, and an indication of how the user may achieve this ratio [for test purposes, the powder:liquid ratio on a mass:mass basis to a precision of 0,01 g at a temperature of  $(23 \pm 1) ^\circ\text{C}$  and a relative humidity of  $(50 \pm 10) \%$  shall be included];
- c) the type of the mixing slab and spatula and their condition;
- d) the rate of incorporation of the powder into the liquid;
- e) the mixing time (see 3.1);
- f) the working time (see 3.2);
- g) the net setting time (see 3.3);
- h) if appropriate, a statement recommending that a liner should be placed between the cement and the dentine;
- i) if appropriate, the minimum time at which finishing may be commenced and the recommended method of finishing;
- j) if appropriate, a statement indicating that the surface of the cement must be coated with a protective coating and guidance on the type of coating to be used.

9.3.3 Encapsulated cements

For encapsulated cements the following instructions shall be supplied:

- a) the method of bringing about physical contact between the powder and liquid;
- b) the type of mechanical mixing device and the mixing time to be employed;
- c) the net setting time (see 3.3);
- d) the working time (see 3.2);
- e) if appropriate, a statement recommending that a liner should be placed between the cement and the dentine;
- f) if appropriate, the minimum time at which finishing may be commenced and the recommended method of finishing;
- g) the minimum deliverable volume, in millilitres, of mixed cement in one capsule;
- h) if appropriate, a statement indicating that the surface of the cement must be coated with a protective coating and guidance on the type of coating to be used.

Table 1 — Requirements for dental cements

Chemical type	Application	Film thickness µm max.	Net setting time		Compressive strength MPa min.	Acid erosion mm max.	Opacity C <sub>0,70</sub>		Acid-soluble As content mg/kg max.	Acid-soluble Pb content mg/kg max.
			min.	max.			min.	max.		
Zinc phosphate	Luting	25	2,5	8	50	0,30			2	100
Zinc polycarboxylate	Luting	25	2,5	8	50	0,40			2	100
Glass polyalkenoate	Luting	25	1,5	8	50	0,17				100
Zinc phosphate	Base/lining		2	6	50	0,30			2	100
Zinc polycarboxylate	Base/lining		2	6	50	0,40			2	100
Glass polyalkenoate	Base/lining		1,5	6	50	0,17				100
Glass polyalkenoate	Restoration		1,5	6	100	0,17	0,35	0,90		100

## Annex A (normative)

### Determination of net setting time

#### A.1 Apparatus

**A.1.1 Cabinet**, capable of being maintained at a temperature of  $(37 \pm 1) ^\circ\text{C}$  and a relative humidity of at least 90 %.

**A.1.2 Indentor**, of mass  $(400 \pm 5)$  g, with a needle having a flat end of diameter  $(1,0 \pm 0,1)$  mm which is plane and perpendicular to the long axis of the needle.

**A.1.3 Metal mould**, similar to that shown in Figure A.1.

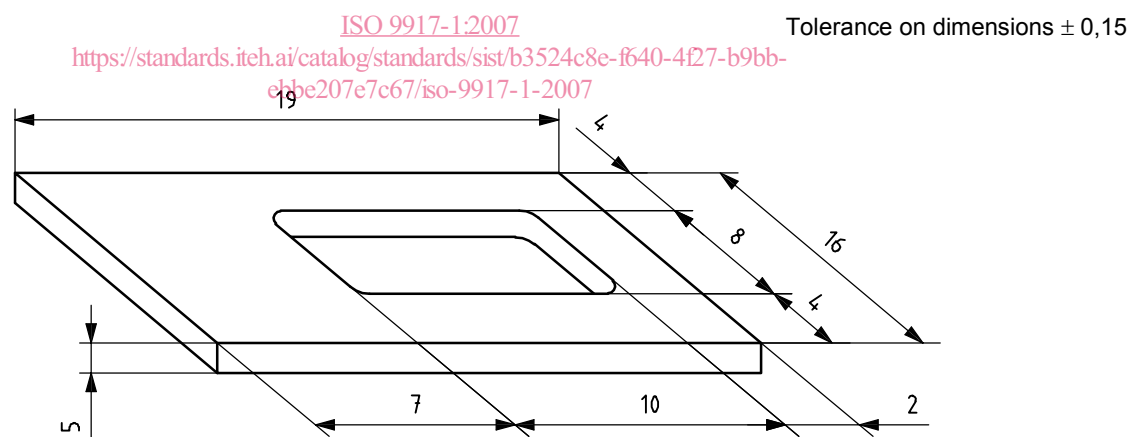
**A.1.4 Metal block**, of minimum dimensions  $8 \text{ mm} \times 75 \text{ mm} \times 100 \text{ mm}$  positioned within the cabinet and maintained at  $(37 \pm 1) ^\circ\text{C}$ .

**A.1.5 Aluminium foil**.

**A.1.6 Timer**, accurate to 1 s.

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Dimensions in millimetres



NOTE Internal corners may be square or rounded.

Figure A.1 — Mould for preparation of specimens for determination of net setting time