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ISO/FDIS 9917-1

Dentistry — Water-based cements —

Part 1: Acid-base cements

Médecine bucco-dentaire — Ciments à base d'eau —

Partie 1: Ciments acido-basiques

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 1, *Filling and restorative materials*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 9917-1:2007), which has been technically revised.

The main changes are as follows:

— change of the title;

— inclusion of pit and fissure sealing cements in the scope;

— adoption of ISO 13116 test method for radio-opacity;

— adoption of table-type formatting of requirements of marking and information;

— addition of declaration of components;

— addition of Annex I.

A list of all parts of the ISO 9917 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document specifies the requirements and test methods for cements in which setting is achieved by an acid-base reaction.

This document does not include specific qualitative and quantitative requirements for ensuring the absence of biological hazards. It is recommended that reference be made to ISO 10993-1 and ISO 7405 when assessing possible biological or toxicological hazards.

Dentistry — Water-based cements —

Part 1: Acid-base cements

1 Scope

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

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 1942, *Dentistry — Vocabulary*

ISO 2590, *General method for the determination of arsenic — Silver diethyldithiocarbamate photometric method*[1)]

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

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

ISO 8601-1, *Date and time — Representations for information interchange — Part 1: Basic rules*

ISO 13116, *Dentistry — Test method for determining radio-opacity of materials*

ISO 15223-1, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

ISO 20417, *Medical devices — Information to be supplied by the manufacturer*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

1) Withdrawn.

3.1
mixing time
part of the manipulation time, measured from first contact between different components of a material, required to achieve a homogeneous mixture of the components when they have been stored, proportioned and mixed according to the manufacturer's instructions

[SOURCE: ISO 1942:2020, 3.3.1.36]

3.2
working time
period of time measured from the commencement of mixing the components of a material or otherwise activating the chemistry of the material and ending before the material has developed properties that prevent it from being manipulated as required to achieve its purpose in a subsequent procedure or in its intended end function

[SOURCE: ISO 1942:2020, 3.3.3.22]

3.3
net setting time
period of time from the end of mixing until the material has set according to the criteria and conditions specified in Annex A and Annex I

Note 1 to entry: For the purposes of this document, in view of the wide variation in mixing times of cements, the net setting time is determined from the end of mixing.

3.4
encapsulated cements
acid-base cements packaged as a unit dose whose packaging includes the powder and the liquid for mixing by the clinician at the time of use by some mechanical means other than hand apportioning

Note 1 to entry: The alternative to encapsulated cements is hand-mixed cement.

4 Classification

4.1 Chemical type

For the purposes of this document, acid base cements shall be classified on the basis of their chemical composition as follows:

a) zinc phosphate cements, see Clause B.1;

b) zinc polycarboxylate cements, see Clause B.2;

c) glass polyalkenoate cements, see Clause B.3.

Acid-base reaction setting, water-based cements other than those listed above can fall within the scope of this document. A manufacturer shall specify whether their product shall conform to the specifications for list items a), b) or c) and 4.2.

NOTE Materials that do not involve an acid-base reaction (e.g., "calcium silicate-based cement") are usually not covered by this document.

4.2 Application

For the purposes of this document, the applications of water-based cements shall be classified as follows:

a) luting;

b) bases or lining;

c) restoration;

d) pit and fissure sealing.

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, i.e. no formation of insoluble or solid matter.

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 (23 ± 1) °C and a relative humidity of (50 ± 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 cements, more than one capsule simultaneously mixed can 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 can be necessary to complete the tests.

7.2 Encapsulated cements

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

8 Requirements

8.1 General

Calibrate all critical apparatus in accordance with the general requirements for the competence of testing and calibration laboratories; see ISO/IEC 17025.

8.2 Net setting time (except pit and fissure sealing cements)

Net setting time shall be determined in accordance with Annex A and in accordance with the relevant requirements specified in Table 1.

8.3 Film thickness (luting cements only)

Film thickness shall be determined in accordance with Annex C and in accordance with the relevant requirements specified in Table 1.

8.4 Compressive strength

Compressive strength shall be determined in accordance with Annex D and in accordance with the relevant requirements specified in Table 1.

8.5 Acid erosion

Acid erosion shall be determined in accordance with Annex E and in accordance with the relevant requirements specified in Table 1.

8.6 Optical properties (polyalkenoate restorative cements only)

Opacity and colour shall be determined in accordance with Annex F and 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 Table 2, item 13).

b) The colour of the set cement shall match the manufacturer's shade guide. If the manufacturer does not provide a shade guide, the manufacturer shall nominate a commercially available shade guide that shall be used in assessing conformity with this requirement (see Table 2, item 12).

8.7 Acid-soluble arsenic and lead contents

8.7.1 Acid-soluble arsenic content

Acid-soluble arsenic content shall be determined in accordance with Annex G and in accordance with the relevant requirements specified in Table 1.

8.7.2 Acid-soluble lead content

Acid-soluble lead content shall be determined in accordance with Annex G and in accordance with the relevant requirements specified in Table 1.

8.8 Radio-opacity (if claimed)

When the manufacturer describes the material as being radio-opaque (see Table 2, item 14), the radio-opacity shall be determined in accordance with Annex H and shall be at least equivalent to that for the same thickness of aluminium. When the manufacturer claims a greater radio-opacity (see Table 2, item 15), the measured value shall not be less than the value claimed when determined in accordance with Annex H.

8.9 Net setting time (pit and fissure sealing cements only)

Net setting time shall be determined in accordance with Annex I and in accordance with the relevant requirements specified in Table 1.

Table 1 — Requirements for acid-base cements

Application	Chemical type	Film thickness	Net setting time		Comp-ressive strength	Acid erosion	Opacity $C_{0,70}$		Acid-soluble As content	Acid-soluble Pb content
		µm	minutes		MPa	mm			mg/kg	mg/kg
		max.	min.	max.	min.	max.	min.	max.	max.	max.
Luting	Zinc phosphate	25	2,5	8	50	0,30	—	—	2	100
	Zinc polycarboxylate	25	2,5	8	50	0,40	—	—	2	100
	Glass polyalkenoate [a]	25	1,5	8	50	0,17	—	—	—	100
Base/lining	Zinc phosphate	—	2,0	6	50	0,30	—	—	2	100
	Zinc polycarboxylate	—	2,0	6	50	0,40	—	—	2	100
	Glass polyalkenoate [a]	—	1,5	6	50	0,17	—	—	—	100
Restoration	Glass polyalkenoate [a]	—	1,5	6	100	0,17	0,35	0,90	—	100
Pit and fissure sealing	Glass polyalkenoate [a]	—	1,5	6	50	0,17	—	—	—	5

[a] Synonymous with “glass-ionomer”.

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

9.1 General

Information shall be clearly marked on the outermost packaging or containers (for multi-dose packs), as indicated in Table 2 and conform to ISO 20417.

Visually inspect to verify the requirements in Table 2.

NOTE 1 Additional information to that specified in Table 2 can be supplied at the discretion of the manufacturer or as required by regulation.

NOTE 2 Table 2 contains optional items and serves as a guide to the manufacturer as to the type of information which can be useful to clinicians.

9.2 Packaging

a) The cements shall be supplied in containers or capsules that afford adequate protection and have no adverse effect on the quality of the contents.

b) For the purposes of this document, a container or capsule shall be considered to be the immediate packaging of the cements.

c) The outermost packaging contains the material, the instructions for use and any proportioning or mixing devices that are supplied for the material.

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