



SLOVENSKI STANDARD
oSIST prEN ISO 9917-1:2024
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Zobozdravstvo - Cementi na osnovi vode - 1. del: Cementi, ki se vežejo na osnovi kislinsko-bazne reakcije mešanice prahu in tekočine (ISO/DIS 9917-1:2024)

Dentistry - Water-based cements - Part 1: Powder/liquid acid-base cements (ISO/DIS 9917-1:2024)

Zahnheilkunde - Wasserhärtende Zemente - Teil 1: Zemente, die beim Vermischen von Pulver und Flüssigkeit über eine Säure-Base-Reaktion abbinden (ISO/DIS 9917-1:2024)

Médecine bucco-dentaire - Ciments à base d'eau - Partie 1: Ciments acido-basiques (ISO/DIS 9917-1:2024)

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Part 1: Powder/liquid acid-base cements

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Contents

	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Classification	2
4.1 Chemical type.....	2
4.2 Application.....	2
5 Material	2
5.1 General.....	2
5.2 Components.....	3
5.2.1 Liquid.....	3
5.2.2 Powder.....	3
5.3 Unset cement.....	3
6 Preparation of test specimens	3
6.1 Ambient conditions.....	3
6.2 Method of mixing.....	3
7 Sampling	3
7.1 Hand-mixed cements.....	3
7.2 Encapsulated cements.....	3
8 Requirements	3
8.1 Net setting time (except pit and fissure sealing cements).....	3
8.2 Film thickness (luting cements only).....	4
8.3 Compressive strength.....	4
8.4 Acid erosion.....	4
8.5 Optical properties (polyalkenoate restorative cements only).....	4
8.6 Acid-soluble arsenic and lead contents.....	4
8.6.1 Acid-soluble arsenic content.....	4
8.6.2 Acid-soluble lead content.....	4
8.7 Radio-opacity (if claimed).....	4
8.8 Net setting time (pit and fissure sealing cements only).....	4
9 Packaging, marking and information to be supplied by manufacturer	5
9.1 General.....	5
9.2 Packaging.....	5
9.3 Declaration of components.....	7
Annex A (normative) Determination of net setting time (except for pit and fissure sealing cements)	8
Annex B (informative) Chemical composition and applications of dental cements	10
Annex C (normative) Determination of film thickness (luting cements only)	11
Annex D (normative) Determination of compressive strength	14
Annex E (normative) Determination of acid erosion	17
Annex F (normative) Determination of optical properties (polyalkenoate restorative cements only)	20
Annex G (normative) Determination of acid-soluble arsenic and lead contents	23
Annex H (normative) Determination of radio-opacity (if claimed)	24
Annex I (normative) Determination of net setting time (pit and fissure sealing cements only)	26

ISO/DIS 9917-1:2023(en)

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.

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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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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 as the measuring procedure of the test method for radio-opacity;
- adoption of table-type formatting of requirements of marking and information;
- addition of declaration of components.

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.

ISO/DIS 9917-1:2023(en)**Introduction**

This document has been prepared to present the requirements and test methods for cements in which setting is achieved by an acid-base reaction.

No specific qualitative and quantitative requirements for ensuring the absence of biological hazard are included in this document, but it is recommended that reference be made to ISO 10993-1 and ISO 7405 when assessing possible biological or toxicological hazards.

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Dentistry — Water-based cements —

Part 1: Powder/liquid 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, as a restorative material or as a pits and fissure (excluding application for an extended 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*

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*

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

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/>

3.1

mixing time

part of the manipulation time, measured from first contact between different components of a material, required to achieve a homogenous 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]

ISO/DIS 9917-1:2023(en)

3.2

working time

period of time measured from the commencement of mixing components of a material or otherwise activating the chemistry of the material and ending before the material has developed properties that prevents 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, measured from the end of mixing, until the material has set according to the criteria and conditions specified in [Annex A](#)

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.

4 Classification

4.1 Chemical type

For the purposes of this document, dental 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 setting, water-based cements other than those listed above may fall within the scope of this document. 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 document, the application 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](#).

ISO/DIS 9917-1:2023(en)

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 ± 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, 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

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.

8 Requirements

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

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