Revised ANSI/ADA Standard No. 96 Approved by ANSI: November 2012



Revised American National Standard/ American Dental Association Standard No. 96

Dental Water-based Cements

Modified adoption of ISO 9917-1:2007, Dentistry — *Water-based cements - Part 1: Powder/liquid acid-base cements* and ISO 9917-2:2010, *Dentistry – Water-based cements - Part 2: Resin-modified cements.*

ADA American Dental Association® Council on Scientific Affairs

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The Council on Scientific Affairs of the American Dental Association has approved revised American Dental Association Standard No. 96 for Dental Water-Based Cements. This and other standards for dental materials, instruments and equipment are being formulated by working groups of the ADA Standards Committee on Dental Products (formerly Accredited Standards Committee MD156 for Dental Materials, Instruments and Equipment). The Committee has representation from all interests in the United States in the standardization of materials, instruments and equipment in dentistry. The Council has adopted the standards, showing professional recognition of their usefulness in dentistry, and has forwarded them to the American National Standards. The American National Standards Institute granted approved as American National Standards. The American National Standards Institute granted approval of revised ADA Standard No. 96 as an American National Standard on November 26, 2012.

The ADA Standards Committee on Dental Products thanks the members of Working Group 1.4 and the organizations with which they were affiliated at the time the standard was developed:

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FOREWORD

(This Foreword does not form a part of revised ANSI/ADA Standard No. 96 for Dental Water-based Cements).

This revised standard is an adoption of ISO 9917-1:2007, Dentistry — Water-based cements - Part 1: Powder/liquid acidbase cements and ISO 9917-2:2010, Dentistry – Water-based cements - Part 2: Resin-modified cements. ADA SCDP Working Group No. 1.4 on Dental Water-based Cements examined the international standards and found them acceptable as a modified adoption for revised ANSI/ADA Standard No. 96. This standard cancels and replaces ANSI/ADA Standard No. 96 – 2005, which was a modified adoption of ISO 9917:1991, Dental water-based cements.

The modifications made to ISO 9917-1:2007 and ISO 9917-2:2010 consist of combining them to form revised ANSI/ADA Standard No. 96 and the revision of certain terms and definitions to bring them into conformance with ISO 1942:2009, *Dentistry-Vocabulary* and ISO 8601, *Data elements and interchange formats-information interchange-representation of dates and times.* Revised were:

- the definition of "working time";
- the replacement of term "immediate wrapping" with "primary packaging";
- the replacement of the term "outermost packaging" and "outer container" with "secondary container" in Part 1 and "outer pack" with "secondary container" in Part 2; and
- the replacement of the term "expiry date" with "use by date."

The statement "The net mass in each container/capsule" in the Manufacturer's Instruction Leaflet was changed from mandatory to optional. This information is already required on the Secondary Container of capsules, which was deemed sufficient.

This standard is presented in two parts: 1). Powder/liquid acid-base cements; and 2). Resin-modified cements.

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this standard. In assessing possible biological or toxicological hazards, reference should be made to ANSI/ADA Standard No. 41, ISO 7405 and ISO 10993-1.

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PART 1:

POWDER/LIQUID ACID-BASE CEMENTS

1 Scope

Part 1 of ADA Standard No. 96 specifies requirements and test methods for powder/liquid acid-base dental cements intended for permanent cementation, lining and restoration. Part 1 is applicable to both hand-mixed and capsulated cements for mechanical mixing. Part 1 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. Part 1 of this standard is not intended to address resin-modified water-based cements, which are addressed in Part 2.

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 — Standard

ISO 3696:1987, Water for analytical laboratory use - Standard and test methods

ISO 7491, Dental materials - Determination of color stability

(ISO standards for dentistry are available from the American Dental Association, Department of Standards, 211 E. Chicago Ave., Chicago, IL 60611 or http://catalog.ada.org. ISO standards are available from the American National Standards Institute, 25 W. 43rd St., New York, NY 10036 or www.ansi.org).

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 commencement of mixing components or otherwise activating the chemistry of the material and ending before the material has developed properties that will prevent it from being manipulated as required to achieve its purpose in a subsequent procedure or in its intended function [derived from ISO 1942:2009, Dentistry-Vocabulary]

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 ADA Standard No. 96, in view of the wide variation in mixing times of cements, the net setting time is determined from the end of mixing.