



American National Standard/
American Dental Association
Specification No. 82

Dental Reversible/ Irreversible Hydrocolloid Impression Material Systems

Identical to ISO 13716:1999



American Dental Association
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**AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION
SPECIFICATION NO. 82 FOR DENTAL REVERSIBLE/IRREVERSIBLE
HYDROCOLLOID IMPRESSION MATERIAL SYSTEMS**

American Dental Association Specification No. 82 for Dental Reversible/Irreversible Hydrocolloid Impression Material Systems has been approved by the Council on Scientific Affairs of the American Dental Association. This and other specifications for dental materials, instruments and equipment are being formulated by working groups of the Accredited Standards Committee MD156 for Dental Materials, Instruments and Equipment. The Council acts as administrative sponsor of that committee, which has representation from all interests in the United States in the standardization of materials, instruments and equipment in dentistry. The Council has adopted the specifications, showing professional recognition of their usefulness in dentistry, and has forwarded them to the American National Standards Institute with a recommendation that the specifications be approved as American National Standards. Approval of ADA Specification No. 82 as an American National Standard was granted by the American National Standards Institute on August 27, 1998. This standard becomes effective August 27, 1999.

The Council thanks the working group members and the organizations with which they were affiliated at the time the specification was developed: Kenneth D. Rudd (Chairman), University of Texas, San Antonio; David C. Appleby, Temple University, Philadelphia, PA; Ramon J. Baez (Secretary), University of Texas, San Antonio; Richard Bennett, L.D. Caulk Company, Milford, DE; Robert G. Craig, University of Michigan, Ann Arbor; Jerry Horn, 3M Unitek Corporation, Monrovia, CA; Robert M. McConnell, University of Texas, San Antonio; Anna Wieveg McSorley, Cottage Grove, OR; Daniel T. Menis, Harry J. Bosworth Company, Skokie, IL; Richard Schwartz, University of Texas, San Antonio; and Duncan Waller, Kerr Corporation, Romulus, MI.

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FOREWORD

This foreword does not constitute a part of ANSI/ADA Specification No. 82 for Dental Reversible/Irreversible Hydrocolloid Impression Material Systems.

1. GENERAL INFORMATION

Shortly after work began on the development of this Specification, the International Organization for Standardization (ISO) initiated steps towards the development of an almost identical document, ISO Standard 13176, Dentistry – Reversible-Irreversible Hydrocolloid Impression Materials Systems. Work on the development of ISO 13176 and ANSI/ADA Specification No. 82 has proceeded concurrently since that time. Final drafts for the two documents are essentially the same with respect to the requirements and tests specified.

The Accredited Standards Committee (ASC) MD 156 is an independent committee accredited by the American National Standards Institute and sponsored by the American Dental Association. The ASC MD 156 coordinates efforts toward drafting, review and approval of dental product specifications in the United States of America.

The final structure of this edition of ANSI/ADA Specification No. 82 for Dental Reversible/Irreversible Hydrocolloid Impression Material Systems was recommended by Subcommittee 2: Prosthodontic Materials, Working Group on aqueous impression materials.

Suggestions for improvement of this specification will be welcome. Send comments to:

Department of Standards Administration
American Dental Association
211 E. Chicago Ave.
Chicago, IL 60611

2. BASIC DEVELOPMENTAL REFERENCES

ISO Standard 13716 for Dental reversible/irreversible hydrocolloid impression systems.

ISO Directive Part 2, Methodology.

ISO Directive Part 3, Drafting

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1. SCOPE

This ANSI/ADA specification applies to the syringeable agar impression materials which have been formulated such that they will bond to each other when used in combination to form elastic impressions of oral tissues.

2. NORMATIVE REFERENCES

The specifications listed below contain provisions which, through reference in this text, constitute provisions of this ANSI/ADA specification. At the time of publication, the editions indicated were valid. All specifications are subject to revision, and parties to agreements based on these specifications are encouraged to investigate the possibility of applying the most recent editions.

ANSI/ADA Specification No. 11, Agar impression materials, 1997.

ANSI/ADA Specification No. 18, Alginate impression materials, 1992.

3. DEFINITIONS

For the purposes of this specification, the following definitions shall apply.

3.1 Bond (between dental reversible and irreversible impression material):

Adherence of one impression material to the other after both materials have set.

3.2 Storing (of an agar impression material):

The conditioning of the material, immediately after liquefaction, needed to reduce and maintain the temperature required for use in the succeeding step.

3.3 Tensile bond strength (of a reversible/irreversible impression material specimen):

The force per unit area required to create a rupture in the specimen when tested in the tensile mode.

NOTE 1: Relevant definitions in ANSI/ADA Specifications No. 11 and No. 18 also apply.

4. REQUIREMENTS

4.1 Biocompatibility advisory

Specific qualitative and quantitative requirements for freedom from biological hazards are not included in this ANSI/ADA specification; it is recommended that, in assessing possible biological or toxicological hazards, reference should be made to the appropriate clauses of the most recent editions of ANSI/ADA Specifications 41 and 41a, and ISO Standards 7405 and 10993-1.

4.2 Requirements associated with ANSI/ADA Specifications Nos. 11 and 18

When a manufacturer identifies any alginate material as being acceptable for use in combination with a particular agar material, each alginate so identified shall be subject to all requirements stated in this specification and in ANSI/ADA Specification No. 18. Likewise, any agar material identified for use with a particular alginate shall be subject to all applicable requirements in this specification and to those in ANSI/ADA Specification No. 11—except for the gelation temperature requirement.

4.3 Requirements specified in this specification for characteristics and physical properties**4.3.1 Tensile bond strength**

When tested in accordance with 8.1, the tensile bond strength between the agar and alginate shall not be less than 50 kPa.

4.3.2 Linear dimensional change

When tested in accordance with 8.2, the negative dimensional change of the combined impression material system specimens shall not be more than 1.0% when measured 20 minutes after commencement of mixing of the alginate component.

4.4 Requirements for the instructions and labeling

See clauses 9 and 10.

5. SAMPLING

Samples shall be procured from a single manufacturing batch as packaged for retail marketing. The manufacturer's instructions shall be included.

6. COMMON APPROACHES TO SPECIMEN PREPARATION AND TESTING**6.1 Laboratory conditions**

Unless otherwise specified in this specification, all specimen preparation and physical property tests shall be conducted under ambient laboratory conditions of $23 \pm 2^\circ\text{C}$ and $50\% \pm 10\%$ relative humidity, and unless otherwise specified in this specification, all equipment and materials used in the tests shall be brought to the ambient temperature before beginning specimen preparation and testing.

6.2 Mixing and manipulating the materials

Unless otherwise specified in this specification, the materials used for forming the test specimens shall be prepared and manipulated using the equipment and procedures recommended in the manufacturer's instructions (Clause 9).

A mix of 15 g of alginate and approximately 2 ml of agar are needed to make each bond test specimen. About 6 to 10 g of alginate and 1 carpule or stick, 1 to 2 ml, of agar are needed for each linear dimensional change specimen.

6.3 How to arrive at Pass/Fail determinations for tests in this specification

The following criteria apply to the tensile bond strength test (8.1) and to the linear dimensional change test (8.2) prescribed in this specification.

Prepare a series of five specimens initially for each of the tests. If four of the five specimens comply with the specified requirement, the material passes. If only one or two specimens comply, the material fails. If only three specimens comply, test an additional series of five specimens. If eight of the ten specimens tested in the two series comply, the material passes; otherwise the material fails.

6.4 How to express test results

Report the number of specimens tested, the number of specimens complying with the specified requirement, and whether the material passes or fails.