



Revised American National Standard/
American Dental Association
Standard No. 17

Denture Base Temporary Relining Resins

ADA American
Dental
Association®
Council on
Scientific Affairs

AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 17 FOR DENTURE BASE TEMPORARY RELINING RESINS

Revised American Dental Association Specification No. 17 for Denture Base Temporary Relining Resins has been approved by the Council on Dental Materials, Instruments and Equipment of the American Dental Association. This and other specifications for dental materials, instruments and equipment are being formulated by the ADA Standards Committee on Dental Products (formerly American National Standard Committee MD 156 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 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 Revised ADA Specification No. 17 as an American National Standard was granted by the American National Standards Institute on April 29, 1983. This specification was reaffirmed by ANSI on April 23, 1999.

The Council acknowledges, with thanks, the work of the Subcommittee members who formulated the revision: Gerhard Brauer (chairman), National Bureau of Standards, Washington, D.C.; Sheldon Winkler, Temple University, Philadelphia; George Cowperthwaite, Esschem Co., Essington, PA; Emery Dougherty, Dentsply International, York, PA; Eugene Huges, J.M. Ney Co., Bloomfield, Ct; Andrew Koran, University of Michigan, Ann Arbor; Robert McConnell, University of Texas, San Antonio; Zaker Sabri, American Dental Association, Chicago, and Julian Woelfel, Columbus, OH.

The revision of Specification No. 17 was submitted and approved to update and upgrade the requirements for denture base temporary relining resins. This draft is the first revision of the specification which was approved in August 1961. Each section of this specification was evaluated by the subcommittee, and changes made make the draft completely independent of ANSI/ADA Specifications No. 12 and 13. Changes include the updating of the toxicity requirement according to ANSI/ADA Document No. 41 for Recommended Standards Practices for Biological Evaluation of Dental Materials. New sections testing thermal stability, mold characteristics and the stability of the liquid have been added. The revision modifies the sections on consistency, peak temperature, color stability, hardness, water sorption and solubility, and deletes the translucency requirement. These and other changes reflect similar trends in other specifications and should aid in the overall usefulness of Specification No. 17.

**AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 17 FOR
DENTURE BASE TEMPORARY RELINING RESINS****Foreword**

(This foreword does not form a part of ANSI/ADA Specification No. 17 for Denture Base Temporary Relining Resin).

This draft is the first revision of the specification, which was approved in August 1961.

The draft brings Specification No. 17 up-to-date and makes it completely independent of Specifications Nos. 12 and 13.

The toxicity section 2.2 and 3.3.1 have been re-written to bring this section up-to-date with the "Recommended Standard Practices for Biological Evaluation of Dental Materials - 1979". Other editorial revisions have been made to comply with the present requirements for toxicity.

Scope 1.1 and Applicable Specification have been modified editorially.

Consistency 3.2.1. The consistency requirement has been modified and is based on values observed on certification of products.

Net content 3.3.1. Has been changed to conform with the revised specification No. 13.

A thermal stability requirement 3.1.2.2, similar to the one in Specification No. 13 has been added.

Solid components 3.1.3. The section has been revised editorially.

Peak temperature 3.2.2. This section has been revised editorially.

Porosity and other defects 3.3.2. This section has be revised editorially.

Hardening time 3.3.3 in original specification has been deleted as a separate requirement and incorporated in 3.2. of the draft.

The translucency requirement (3.4.2 in original specification) has been deleted, since it was considered to be of no significance to the performance of the material.

Water sorption and water solubility requirements are now given in percent instead of mg/cm²/ The new requirements are based on approximate conversion of values obtained for presently acceptable materials.

Color stability 3.3.6. The requirement test are changed to conform to the procedure incorporated in the ANSI/ADA Specification No. 13.

Instructions for use, 3.3.8. This section has been modified.

Sampling, 4.1. This section has been modified editorially.

Test conditions 4.3.1 has been added.

Mold characteristics 4.3.2.1 has been added. This procedure is providing conditions approximating those to which the material is exposed in service.

Mixing and filling the mold 4.3.2.2. This procedure has been found to be effective in reducing the time required to produce acceptable specimens for the relining resins.

Curing the specimen 4.3.2.3. This section has been editorially revised.

Stability of liquid 4.3.2. This test has been added to the specification.

Consistency 4.3.4. This section has been modified.

Peak temperature 4.3.5. This section has been modified.

Water sorption and water solubility 4.3.6 and 4.3.7 These sections have been modified and expanded. Description for averaging the results are given.

Color stability 4.3.8. The modified test employed in Specification No. 13 is described in detail.

Hardness 4.3.9. This section has been revised.

Preparation for delivery, 5. This section 5.1. and 5.2.1 to 5.2.7 have been spelled out in detail and are independent of Specifications Nos. 12 and 13.

Additional note to the Foreword for this Reaffirmation:

In 2012, the ADA Standards Committee on Dental Products approved a change in the terminology used for standards. ADA standards will no longer utilize the term Specification; standards will now be named as ADA Standards.

With this notice, this ADA Specification is now termed an ADA Standard. Where the term "specification" is used, it should be considered as "standard." It will be re-named as an ADA Standard in its next revision.

**AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 17 FOR
DENTURE BASE TEMPORARY RELINING RESINS****1 SCOPE**

- 1.1 This specification is for pink and clear powder/liquid auto-polymerizing (self-initiating cure) type hard-setting resins used as temporary relining materials for denture bases.¹ The soft relining materials are not covered by this specification.

2 APPLICATION SPECIFICATION

- 2.1 American National Standard N210.1 (ASTM 380) Metric Practice Guide is used as a guide in selecting symbols and units of measurement, procedures for style and usage, and for procedures for conversion and rounding off in ANSI/ADA Specifications. Copies are available from American National Standards Institute, 25 W. 43rd St., New York, NY 10036..
- 2.2 The American National Standard/American Dental Association Document No. 41 for Recommended Standard Practices for Biological Evaluation of Dental Materials contains the following procedures and Acceptance criteria for Denture Base Temporary Relining Materials for Toxicity requirement in 3.3.1; 4.4.1 Cytotoxicity; 4.4.2 Hemolysis; 4.4.3 Ames' test;' 4.4.4 Styles cell transformation; 4.4.6 Oral LD; 4.4.9 Mucus membrane irritation; and 4.4.13 sensitization. Copies of this standard and ANSI/ADA Specifications are available from the American Dental Association, Dept. of Standards Administration, 211 E. Chicago Ave., Chicago, IL 60611.

3 REQUIREMENTS**3.1 Materials as received****3.1.1 Net content**

The net contents of the powder and liquid furnished in a unit package shall be no less than 99% of the contents stated on the label of each immediate container. (5.2.3)

3.1.2 Liquid**3.1.2.1 Clarity**

The liquid shall be clear and free of deposits or sediment.

3.1.2.2 Thermal stability

Liquids shall show no turbidity or deposit when tested according to the procedure described in 4.3.3.

¹ For other than temporary use it is recommended that dentures be relined or rebased employing a cast and flasking technique.