ANSI/ADA Standard No. 139
Approved: June 6, 2012

American National Standard/
American Dental Association

Standard No. 139

Dental Base Polymers

Modified adoption of ISO 20795-1:2008, *Dentistry — Base polymers - Part 1: Denture base polymers;* ISO 20795-1:2008, *Technical Corrigendum (2009)*; and ISO 20795-2:2010, *Dentistry – Base polymers - Part 2: Orthodontic base polymers*

ADA American Dental Association®
Council on Scientific Affairs

2012

AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION STANDARD NO. 139 FOR DENTAL BASE POLYMERS

The Council on Scientific Affairs of the American Dental Association has approved American Dental Association Standard No. 139 for Dental Base Polymers. 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 Institute with a recommendation that the standards be approved as American National Standards. The American National Standards Institute granted approval of ADA Standard No.139 as an American National Standard on June 6, 2012.

The ADA Standards Committee on Dental Products thanks the members of Working Group 2.15 on Denture Base Resin and Resilient Liners and the organizations with which they were affiliated at the time the standard was developed:

Sheng Lin-Gibson (chairman), NIST, Gaithersburg, MD;

Lawrence Gettleman, University of Louisville School of Dentistry, KY;

Clyde Ingersoll, CEI Enterprises, Ltd., Tonawanda, NY;

John Jones, University of Texas Health Science Center, San Antonio, TX;

Robert Kelly, University of Connecticut Health Sciences Center, Farmington, CT;

Michael Ryan, Food and Drug Administration, Silver Spring, MD; and

Wayne Wozniak, American Dental Association, Chicago, IL.

AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION STANDARD NO. 139 FOR DENTAL BASE POLYMERS

FOREWORD

(This Foreword does not form a part of the ANSI/ADA Standard No. 139 for Dental Base Polymers).

This standard is an adoption of ISO 20795-1:2008, Dentistry – Base polymers – Part 1: Denture base polymers; and ISO 20795-2:2010, Dentistry – Base polymers – Part 2: Orthodontic base polymers. ADA SCDP Working Group 2.15 on Denture Base Resin and Resilient Liners examined the international standards and found them acceptable as a modified adoption for ANSI/ADA Standard No. 139.

ANSI/ADA Standard No. 139 incorporates ISO 20795-1:2008, Technical Corrigendum 1. The corrections contained therein are the only modifications made to ISO 20795-1:2008 and ISO 20795-2:2010 beyond combining them to form ANSI/ADA Standard No. 139. This standard is presented in two parts: 1). Denture-base polymers; and 2). Orthodontic-base polymers.

ANSI/ADA Standard No. 139 replaces ANSI/ADA Standard No. 12-2002, Denture Base Polymers.

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.

AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION STANDARD NO. 139 FOR DENTAL BASE POLYMERS

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PART 1:

DENTURE BASE POLYMERS

1 SCOPE

1.1 This part of ANSI/ADA Standard No. 139 classifies denture base polymers and copolymers and specifies their requirements. It also specifies the test methods to be used in determining compliance with these requirements. It further specifies requirements with respect to packaging and marking the products and to the instructions to be supplied for use of these materials. Furthermore it applies to denture base polymers for which the manufacturer claims that the material has improved impact resistance. It also specifies the respective requirement and the test method to be used.

1.2 Although this part of ANSI/ADA Standard No. 139 does not require manufacturers to declare details of the composition, attention is drawn to the fact that some national or international authorities require such details to be provided.

1.3 This part of ANSI/ADA Standard No. 139 applies to denture base polymers such as those listed below:

a) poly(acrylic acid esters);

b) poly(substituted acrylic acid esters);

c) poly(vinyl esters);

d) polystyrene;

e) rubber modified poly(methacrylic acid esters);

f) polycarbonates;

g) polysulfones;

h) poly(dimethacrylic acid esters);

i) polyacetals (polyoxymethylene);

j) copolymers or mixtures of the polymers listed in a) to i).

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 463:2006, *Geometrical Product Standards (GPS) — Dimensional measuring equipment — Design and metrological characteristics of mechanical dial gauges*

ISO 1942, *Dentistry — Vocabulary*

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

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

ANSI/ADA Standard No. 15 — *Artifical teeth for dental prostheses*

ANSI/ADA Standard No. 80 — *Determination of color stability*

(ANSI/ADA standards and 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. Other 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 terms and definitions given in ISO 1942 and the following apply.

3.1
autopolymerizable materials
products having polymerization initiated by chemical means and not requiring application of temperatures above 65 °C to complete the polymerization

3.2
capsulated material
material consisting of two or more components supplied in a container that keeps them separated until the time they are mixed together and dispensed for use directly from the container

3.3
denture
artificial substitute for missing natural teeth and adjacent tissues, to also include any additions needed for optimum function

3.4
denture base
that part of a denture which rests on soft tissue foundations and to which artificial teeth are added

3.5
heat-polymerizable materials
products requiring application of temperatures above 65 °C to complete polymerization

3.6
immediate container
container that is in direct contact with the denture base materials

3.7
liquid
monomeric liquid to be mixed with polymeric particles to form a moldable dough or fluid resin mixture used for forming denture bases

3.8
powder
polymeric particles to be mixed with monomeric liquid to form a moldable dough or fluid resin mixture used for forming denture bases

3.9
outer packaging
labelled container or wrapping within which other containers are packed

3.10
packing
〈of a denture〉 act of filling a denture base mold with a material (using a compression, pour or injection technique) to form a denture base