AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION
SPECIFICATION NO. 12 FOR DENTURE BASE POLYMERS

FOREWORD
(This foreword does not form a part of ANSI/ADA Specification No. 12 for Denture Base Polymers).

This revision is an adoption of ISO 1567-1999, Dentistry – Denture Base Polymers. The ADA SCDP Working Group examined the standard and found it acceptable for adoption as a revision of ANSI/ADA Specification No. 12.

Contents

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Introduction

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this specification, but it is recommended that, in assessing possible biological or toxicological hazards, reference be made to ISO 10993-1 and ISO 7405.

1 Scope

1.1 This specification 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.

1.2 Although this specification 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 specification 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) through i).

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this specification. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this specification are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid specifications.

ISO 463: —[1)], *Geometrical product specifications (GPS) — Dimensional measuring instruments: Dial gauges — Design and metrological requirements.*

ISO 1942-1:1989, *Dental vocabulary — Part 1: General and clinical terms.*

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1) To be published. (Revision of ISO 463:1988)

ISO 1942-2:1989, *Dental vocabulary — Part 2: Dental materials.*

ISO 1942-5:1989, *Dental vocabulary — Part 5: Terms associated with testing.*

ISO 3336:1993, *Dentistry — Synthetic polymer teeth.*

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods.*

ISO 7491:1985, *Dental materials — Determination of colour stability of dental polymeric materials.*

ISO 8601:1988, *Data elements and interchange formats — Information interchange — Representation of dates and times.*

3 Definitions

For the purposes of this specification the following definitions apply.

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

3.2
capsulated material
material consisting of two or more components supplied in a container which 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 include also any additions needed for optimum function

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

3.5
heat-polymerizable polymer
product requiring application of verifiable temperatures above 65 °C to complete polymerization

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

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

3.8
outer packaging
labelled container or wrapping within which other containers are packed

3.9
packing
⟨of a denture⟩ the act of filling a denture base mould with a material (using a compression, pour or injection technique) to form a denture base

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3.10
initial packing time
time after mixing, or other preparation, at which a denture base material mixture first reaches packing consistency

3.11
final packing time
the last time, after reaching the initial packing time, at which a denture base material mixture retains packing consistency

3.12
processing
procedure of preparing a solid denture base polymer plate and/or specimen by polymerization or injection moulding

3.13
thermoplastic, adj.
characteristic of a hard polymeric material that allows it to be softened by application of heat to make it mouldable, and then return to the hardened state upon cooling

3.14
translucency
capacity of a body of material to allow the passage of light, yet diffusing the light so as not to render objects lying beyond the body clearly visible

4 Classification

Denture base polymers covered by this specificationare categorized into the following Types and Classes:

Type 1 :	**Heat-polymerizable polymers**
Class 1 :	Powder and liquid
Class 2 :	Plastic cake
Type 2 :	**Autopolymerizable polymers**
Class 1 :	Powder and liquid
Class 2 :	Powder and liquid pour-type resins
Type 3 :	**Thermoplastic blank or powder**
Type 4 :	**Light-activated materials**
Type 5 :	**Microwave cured materials**

5 Requirements

5.1 Unpolymerized material

5.1.1 Liquid component

5.1.1.1 General

The liquid shall consist essentially of monomeric material compatible with the powder.

5.1.1.2 Homogeneity

The liquid shall be free of deposit or sediment that can be observed by visual inspection (8.1).

5.1.2 Solid components

The solid or semisolid components shall be free of extraneous material that can be observed by visual inspection (8.1).

5.1.3 Packing plasticity

When Type 1 Class 1, Type 1 Class 2, Type 2 Class 1, Type 2 Class 2, Type 4 and Type 5 materials are tested in accordance with 8.2, at the initial packing time recommended by the manufacturer, they shall be capable of being intruded into at least two holes in the die (see figure 1) to a depth of not less than 0,5 mm (8.2.3.1.1). Type 1 Class 1, Type 1 Class 2, Type 4 and Type 5 materials shall also meet the requirements when tested at the final packing time (8.2.3.1.2)

5.2 Polymerized material

5.2.1 Biocompatibility

See the Introduction for guidance on biocompatibility

5.2.2 Surface characteristics

When processed in the manner and against materials recommended by the manufacturer, denture base specimens prepared in accordance with 8.4.3, 8.7.2.2 and 8.8.3 should have a smooth, hard and glossy surface.

The specimens for colour stability, the specimens for residual methyl methacrylate monomer and the specimens for sorption and solubility testing shall retain their form without visible distortion after processing.

When polished in accordance with 8.5.1.3, the specimen plates shall present a smooth surface with a high gloss (8.1).

When prepared in accordance with the manufacturer's instructions, all types of denture base polymers shall produce a test specimen plate (8.5.1) with defined edges after deflasking (see figure 3).

5.2.3 Colour

A specimens strip shall show no more than a slight difference when compared with the corresponding shade of the shade guide, when tested in accordance with 8.3 and inspected in accordance with 8.1.

The manufacturer shall provide a shade guide on request.

Coloured denture base polymers shall be translucent (5.2.5 and 8.5.2) and evenly pigmented and/or, where applicable, evenly fibred.

Clear denture base polymers shall be clear and colourless.

5.2.4 Colour stability

When tested in accordance with 8.4 and inspected in accordance with 8.1, test specimens shall not show more than a slight change in colour, perceptible with difficulty.

5.2.5 Translucency

When tested in accordance with 8.5.2.3 the shadow of the illuminated opaque disc shall be visible from the opposite side of the test specimen plate.

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5.2.6 Freedom from porosity

When prepared in accordance with 8.5.3.3, specimens strips shall not show voids (8.1) that can be observed by visual inspection.

5.2.7 Flexural strength

When determined in accordance with 8.5.3.5, the flexural strength shall be not less than 65 MPa for Type 1, Type 3, Type 4 and Type 5 polymers and not less than 60 MPa for Type 2 polymers when tested in water at (37 ± 1) °C (see table 1).

5.2.8 Flexural modulus

When determined in accordance with 8.5.3.5, the flexural modulus of the processed polymer shall be at least 2 000 MPa for Type 1, Type 3, Type 4 and Type 5 polymers and at least 1 500 MPa for Type 2 polymers when tested in water at (37 ± 1) °C (see table 1).

5.2.9 Bonding to synthetic polymer teeth

Denture base polymers intended for use with synthetic polymer teeth shall meet one of the following requirements.

a) The polymer shall, when tested in accordance with 8.6, be capable of bonding to polymer teeth complying with the bonding requirements of ISO 3336.

b) If there are problems of achieving bonding, the outer packages and containers shall contain information about special treatments necessary to achieve bonding and/or indicate that further information is provided in the manufacturer's instructions [8.6.3, 9.2.1 k), 9.2.2 k), and 9.3 h)].

5.2.10 Residual methyl methacrylate monomer

When prepared and tested in accordance with 8.7, the following shall apply (see table 1).

The upper limit (maximum) for residual methyl methacrylate is 2,2 % mass fraction for denture base polymers of Type 1, Type 3, Type 4 and Type 5.

The upper limit (maximum) for residual methyl methacrylate is 4,5 % mass fraction for denture base polymers of Type 2.

If lower percentages of residual methyl methacrylate monomer are claimed by the manufacturer, the content shall not be more than 0,2 % higher than that stated by the manufacturer.

5.2.11 Sorption

When the processed polymer is tested in accordance with 8.8, the increase in volumic mass (water sorption) shall not exceed 32 µg/mm^3 for Type 1, Type 2, Type 3, Type 4 or Type 5 polymers (see table 1).

5.2.12 Solubility

When the processed polymer is tested in accordance with 8.8, the loss in volumic mass (soluble matter) shall not exceed 1,6 µg/mm^3 for Type 1, Type 3, Type 4 or Type 5 polymers, and shall not exceed 8,0 µg/mm^3 for Type 2 polymers (see table 1).

Table 1 — Summary of the limits for requirements described in 5.2.7, 5.2.8, 5.2.10, 5.2.11 and 5.2.12

Requirement	Flexural strength [MPa] min.	Flexural modulus [MPa] min.	Residual methyl methacrylate monomer Percent mass fraction max.	Sorption [µg/mm^3] max.	Solubility [µg/mm^3] max.
Type 1,3,4,5	65	2000	2,2	32	1,6
Type 2	60	1500	4,5	32	8,0

6 Sampling

The test sample shall consist of a retail package or packages, containing sufficient material to carry out the specified tests, plus an allowance for any necessary repetition of the tests. If more than one package is required, all material shall be of the same batch.

7 Preparation of test specimens

7.1 Laboratory environment

Unless otherwise specified in this specification or the manufacturer's instructions, the test specimens shall be prepared and tested at (23 ± 2) °C and (50 ± 10) % relative humidity.

7.2 Procedures

Unless otherwise specified in this specification, the materials used for making the specimens shall be prepared, manipulated and processed using the equipment and procedures recommended in the manufacturer's instructions (9.3)

A separate mix shall be made for each specimen prepared from a material requiring mixture of two or more ingredients.

7.3 Special equipment

Any special equipment specified by the manufacturer for processing a material shall be made available by the manufacturer (or the manufacturer may prepare injection-moulded specimens, and submit them to the test laboratory).

8 Test methods

8.1 Inspection for compliance determination

Observe the test samples by visual inspection to determine compliance with the requirements laid down in 5.1.1.2, 5.1.2, 5.2.2, 5.2.3, 5.2.4, 5.2.5, 5.2.6 and clause 9. [Inspect for colour (5.2.3) and colour stability (5.2.4) in accordance with ISO 7491].

8.2 Packing plasticity

8.2.1 Apparatus

8.2.1.1 Perforated brass die, having the dimensions shown in figure 1, with perforations having a diameter of (0,75 ± 0,05) mm.