BS EN ISO 20795-1:2013

BSI Standards Publication

Dentistry – Base polymers

Part 1: Denture base polymers

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The UK participation in its preparation was entrusted to Technical Committee CH/106/2, Prosthodontic materials.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Published by BSI Standards Limited 2013

ISBN 978 0 580 79560 2

ICS 11.060.10

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 March 2013.

Amendments issued since publication

Date	Text affected

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 20795-1

March 2013

ICS 11.060.10

Supersedes EN ISO 20795-1:2008

English Version

Dentistry - Base polymers - Part 1: Denture base polymers (ISO 20795-1:2013)

Médecine bucco-dentaire - Polymères de base - Partie 1: Polymères pour base de prothèses dentaires (ISO 20795-1:2013)

Zahnheilkunde - Kunststoffe - Teil 1: Prothesenkunststoffe (ISO 20795-1:2013)

This European Standard was approved by CEN on 26 February 2013.

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Ref. No. EN ISO 20795-1:2013: E

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Foreword

This document (EN ISO 20795-1:2013) has been prepared by Technical Committee ISO/TC 106 "Dentistry" in collaboration with Technical Committee CEN/TC 55 “Dentistry” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2013, and conflicting national standards shall be withdrawn at the latest by September 2013.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

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Endorsement notice

The text of ISO 20795-1:2013 has been approved by CEN as EN ISO 20795-1:2013 without any modification.

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Document Sharing Hub

Full document details: BS EN ISO 20795-1:2013

Contents

Page

Foreword ... **iv**

Introduction ... **v**

1 Scope ... **1**

2 Normative references ... **1**

3 Terms and definitions ... **2**

4 Classification ... **3**

5 Requirements ... **3**
5.1 Unpolymerized material ... 3
5.2 Polymerized material ... 4

6 Sampling ... **6**

7 Preparation of test specimens ... **6**
7.1 Laboratory environment ... 6
7.2 Procedures ... 7
7.3 Special equipment ... 7

8 Test methods ... **7**
8.1 Inspection for compliance determination ... 7
8.2 Packing plasticity ... 7
8.3 Colour ... 9
8.4 Colour stability ... 10
8.5 Polishability, translucency, freedom from porosity, ultimate flexural strength, and flexural modulus ... 12
8.6 Fracture toughness with a modified bending test ... 17
8.7 Bonding to synthetic polymer teeth ... 21
8.8 Residual methyl methacrylate monomer ... 22
8.9 Water sorption and solubility ... 27

9 Requirements for labelling, marking, packaging, and instructions supplied by the manufacturer ... **29**
9.1 Packaging ... 29
9.2 Marking of outer packages and containers ... 30
9.3 Manufacturer's instructions ... 31

Annex A (normative) **HPLC method for determination of MMA content** ... **32**

Bibliography ... **35**

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Documents
Document Sharing Hub
Full document details: BS EN ISO 20795-1:2013

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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ISO 20795-1 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials*.

This second edition cancels and replaces the first edition (ISO 20795-1:2008), of which it constitutes a minor revision. It also incorporates the Technical Corrigendum ISO 20795-1:2008/Cor 1:2009.

ISO 20795 consists of the following parts, under the general title *Dentistry — Base polymers*:

— *Part 1: Denture base polymers*

— *Part 2: Orthodontic base polymers*

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Introduction

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this part of ISO 20795, but it is recommended that, in assessing possible biological or toxicological hazards, reference be made to ISO 10993-1 and ISO 7405.

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Dentistry — Base polymers —

Part 1:
Denture base polymers

1 Scope

1.1 This part of ISO 20795 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 ISO 20795 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 ISO 20795 is applicable 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, *Geometrical Product Specifications (GPS) — Dimensional measuring equipment — Design and metrological characteristics of mechanical dial gauges*

ISO 1942, *Dentistry — Vocabulary*

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

ISO 7491:2000, *Dental materials — Determination of colour stability*

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

ISO 22112:2005, *Dentistry — Artificial teeth for dental prostheses*

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 mouldable dough or fluid resin mixture used for forming denture bases

3.8
powder
polymeric particles to be mixed with monomeric liquid to form a mouldable 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 mould with a material (using a compression, pour, or injection technique) to form a denture base

3.11
initial packing time
time after mixing, or other preparation, when a denture base material mixture first reaches packing consistency

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3.12
final packing time
last time, after achievement of the initial packing time, at which a denture base material mixture retains packing consistency

3.13
processing
procedure of preparing a solid denture base polymer plate and/or specimen by polymerization or injection moulding

3.14
thermoplastic
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

3.15
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 part of ISO 20795 are categorized into the following types and classes:

- Type 1: Heat-polymerizable materials
  - Class 1: Powder and liquid
  - Class 2: Plastic cake
- Type 2: Autopolymerizable materials
  - Class 1: Powder and liquid
  - Class 2: Powder and liquid for 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 (see 8.1.1).

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5.1.2 Solid components

The solid or semi-solid components shall be free of extraneous material that can be observed by visual inspection (see 8.1.1).

5.1.3 Packing plasticity

When Type 1 Class 1 and Type 2 Class 1 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 (8.2.2.1) to a depth of not less than 0,5 mm (see 8.2.4.2). Type 1 Class 1, Type 1 Class 2, and Type 5 materials shall meet the requirements when tested at the final packing time (see 8.2.4.3).

5.2 Polymerized material

5.2.1 Biocompatibility

Specific qualitative requirements for freedom from biological hazard are not included in this part of ISO 20795, but it is recommended that, in assessing possible biological or toxicological hazards, reference be made to ISO 10993-1 and ISO 7405.

5.2.2 Surface characteristics

5.2.2.1 When processed in the manner recommended by the manufacturer and in contact with materials recommended by the manufacturer, denture base specimens prepared in accordance with 8.4.3, 8.8.2.2, and 8.9.3 shall have a smooth, hard, and glossy surface (see 8.1.1).

5.2.2.2 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 (see 8.1.1).

5.2.2.3 When polished in accordance with 8.5.1.4, the specimen plates shall present a smooth surface with a high gloss (see 8.1.1).

5.2.3 Shape capability

When prepared in accordance with the manufacturer's instructions, all types of denture base polymers shall produce a test specimen plate with defined edges after deflasking (see 8.5.1.4).

5.2.4 Colour

The colour of a specimen strip shall be as stated by the manufacturer when tested in accordance with 8.3 and inspected in accordance with 8.1.1.

The manufacturer shall provide a shade guide on request.

Coloured denture base polymers shall be translucent (see 5.2.6 and 8.5.2) and pigment and fibres shall be evenly distributed.

Clear (transparent) denture base polymers shall be clear and colourless.

5.2.5 Colour stability

When tested in accordance with 8.4 and inspected in accordance with 8.1.1, test specimens shall not show more than a slight change in colour.

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5.2.6 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.

5.2.7 Freedom from porosity

When prepared in accordance with 8.5.3.3, a specimen's strips shall not show voids that can be observed by visual inspection (see 8.1.1).

5.2.8 Ultimate flexural strength

When determined in accordance with 8.5.3.5, the ultimate 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 (see Table 1).

5.2.9 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 (see Table 1).

5.2.10 Maximum stress intensity factor for materials with improved impact resistance

Where a manufacturer claims a material with improved impact resistance, the maximum stress intensity factor shall be at least 1,9 MPa $m^{1/2}$ when tested in accordance with 8.6 (see Table 2).

5.2.11 Total fracture work

Where a manufacturer claims a material with improved impact resistance, the total fracture work shall be at least 900 J/m^2 when tested in accordance with 8.6 (see Table 2).

5.2.12 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 8.7, be capable of bonding to polymer teeth, complying with the bonding requirements of ISO 22112.

b) If there are problems of achieving bonding, the manufacturer's instructions shall contain information about special treatments necessary to achieve bonding [see 9.3 k)].

5.2.13 Residual methyl methacrylate monomer

When prepared and tested in accordance with 8.8, 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 [see 9.3 m)], the content shall not be more than 0,2 % mass fraction higher than that stated by the manufacturer.

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5.2.14 Sorption

When the processed polymer is tested in accordance with 8.9, the increase in mass per volume (water sorption) shall not exceed 32 µg/mm³ (see Table 1).

5.2.15 Solubility

When the processed polymer is tested in accordance with 8.9, the loss in mass (soluble matter) per volume shall not exceed 1,6 µg/mm³ for Type 1, Type 3, Type 4, and Type 5 polymers and shall not exceed 8,0 µg/mm³ for Type 2 polymers (see Table 1).

Table 1 — Summary of requirements described in 5.2.8, 5.2.9, 5.2.13, 5.2.14, and 5.2.15

Requirements	Flexural properties		Residual methyl methacrylate monomer	Sorption	Solubility
	Ultimate flexural strength	Flexural modulus			
	σ	E		w_{sp}	w_{sl}
	MPa	MPa	Percent mass fraction	µg/mm³	µg/mm³
	min.	min.	max.	max.	max.
Types 1, 3, 4, 5	65	2 000	2,2	32	1,6
Type 2	60	1 500	4,5	32	8,0

Table 2 — Additional requirements for materials with improved impact resistance described in 5.2.10 and 5.2.11

Requirements	Fracture toughness	
	Maximum stress intensity factor	Total fracture work
	K_{max}	W_f
	MPa m$^{1/2}$ min.	J/m² min.
Materials with improved impact resistance	1,9	900

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

Prepare and test specimens at (23 ± 2) °C and (50 ± 10) % relative humidity, unless otherwise specified in this part of ISO 20795 or in the manufacturer's instructions.

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