
**Dentistry — Base polymers —
Part 2:
Orthodontic base polymers**

*Médecine bucco-dentaire — Polymères de base —
Partie 2: Polymères pour base orthodontique*

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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.

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

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

This second edition cancels and replaces the first edition (ISO 20795-2:2010), which has been technically revised.

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

- *Part 1: Denture base polymers*
- *Part 2: Orthodontic base polymers*

Introduction

Polymeric materials based on methacrylates have been widely used in the construction of both active and passive removable orthodontic appliances for many years. These removable appliances are mainly used in the orthodontic treatment of children. The method of preparing the polymeric part of the orthodontic appliance has several potential problems. Depending on the polymerization process and polymer/monomer mixing ratio, the polymer part of the removable orthodontic appliance may be weaker than if conventional flasking and heat systems of polymerization were used. There may be a greater risk that an appliance will have more residual substances such as monomers than a conventional heat-cured denture base polymer. In addition, a high monomer content of the polymer/monomer mix may cause increased contraction on polymerization.

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 2: Orthodontic base polymers

1 Scope

This part of ISO 20795 is applicable to orthodontic base polymers and copolymers used in the construction of both active and passive orthodontic appliances and specifies their requirements. It also specifies 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.

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 1942, *Dentistry — Vocabulary*

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

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

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

ISO 20795-1:2008, *Dentistry — Base polymers — Part 1: Denture base polymers*

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

build up technique

spray on technique

gradual addition of increments of powder and liquid on the master cast until the desired shape is attained

3.3

immediate container

container that is in direct contact with the (orthodontic) base materials

3.4

light activated polymers

products having polymerization initiated by the application of energy from an external radiation source, such as visible light

3.5

liquid

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

3.6

orthodontic base

polymer part of the (orthodontic) appliance

3.7

outer packaging

labelled container or wrapping within which other containers are packed

3.8

powder

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

3.9

processing

procedure of preparing a solid (orthodontic) base polymer plate and/or specimen by polymerization or injection

3.10

thermoplastic material

hard (orthodontic) polymeric material that can be softened by application of heat to make it mouldable, and then returned to the hardened state upon cooling

4 Classification

Orthodontic base polymers covered by this part of ISO 20795 are categorized into the following types:

- Type 1: autopolymerizable materials;
- Type 2: light-activated materials;
- Type 3: thermoplastic 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](#)).

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](#)).

5.2 Polymerized material

5.2.1 Biocompatibility

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.

5.2.2 Surface characteristics

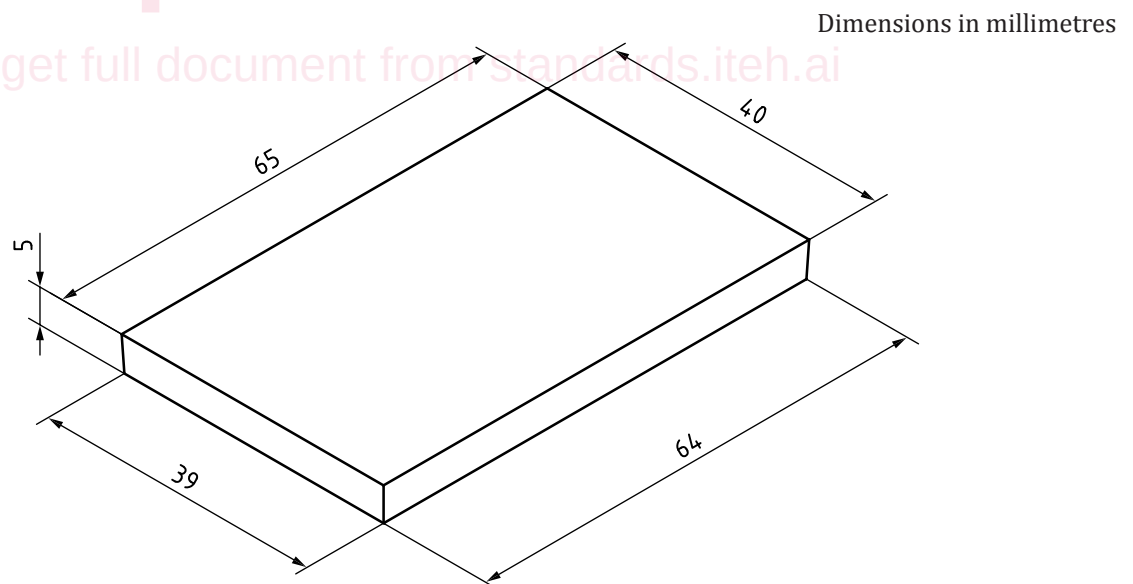
5.2.2.1 When processed in the manner recommended by the manufacturer and in contact with materials recommended by the manufacturer, orthodontic base polymer test specimens prepared in accordance with [8.5.2](#) and [8.6.3](#) shall have a smooth, hard, and glossy surface (see [8.1.1](#)).

5.2.2.2 The test specimens for residual methyl methacrylate monomer (see [8.5](#)) and the specimens for water sorption and solubility testing (see [8.7](#)) shall retain their form without visible distortion after processing (see [8.1.1](#)).

5.2.2.3 When polished in accordance with [8.3.1.4](#), 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 orthodontic base polymers shall produce a test specimen plate (see [8.3.1.4](#)) with defined edges and dimensions as given in [Figure 1](#).



NOTE Dimensional tolerance shall be ± 1 mm.

Figure 1 — Model of the specimen plate (see [8.3.1.2.1](#))

5.2.4 Colour

The colour of a test specimen strip prepared in accordance with [8.3.2.3](#) shall be as stated by the manufacturer when tested and inspected in accordance with [8.1.1](#) and [8.2](#).

Coloured orthodontic base polymers shall be evenly pigmented and/or coloured.