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Dentistry — Denture adhesives

Médecine bucco-dentaire — Adhésifs pour prothèses dentaires

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 7, *Oral care products,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 10873:2010), which has been technically revised. The main changes compared to the previous edition are as follows:

— the powder/water ratio described in 7.5.3.1 and 7.6.3.1 has been revised;

— the method for pH value measurement has been modified in part;

— the surface roughness of the sample holder has been revised.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Denture adhesives are used for the improvement in retention stability of removable denture to soft supporting tissues temporarily. This document is intended to determine the physical and chemical properties of denture adhesives.

Specific qualitative and quantitative requirements for freedom from biological hazards are not included in this document.

Dentistry — Denture adhesives

1 Scope

This document classifies denture adhesives used by wearers of removable dentures; it also specifies requirements, test methods and instructions to be supplied for the use of such products.

This document is applicable to denture adhesives for use by the consumer and excludes the dental lining materials prescribed or applied by dental professionals. It is recommended that, in assessing possible biological hazards, reference be made to ISO 7405 and ISO 10993-1.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 3696:1987, *Water for analytical laboratory use — Specification and test methods*

ISO 7823-2, *Plastics — Poly(methyl methacrylate) sheets — Types, dimensions and characteristics — Part 2: Extruded sheets*

ISO 8601-1, *Date and time — Representations for information interchange — Part 1: Basic rules*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
denture adhesive
dental product placed on the intaglio surface of a removable denture to temporarily improve its retention to soft supporting tissues

Note 1 to entry: The intaglio surface is also known as the fitting surface.

[SOURCE: ISO 1942:2020, 3.3.1.23, modified — Note 1 to entry has been added.]

3.2
glue type
denture adhesive (3.1) in powder, cream, sheet or tape form with a water-soluble polymer as the adhesive constituent

3.3
liner type
denture adhesive (3.1) in non-aqueous form

4 Classification

4.1 General

For the purposes of this document, denture adhesives are categorized as one of the following types:

4.2 Types and classes

a) Type 1: glue type:

- Class 1: powder form;
- Class 2: cream form;
- Class 3: sheet or tape form.

b) Type 2: liner type.

5 Requirements

5.1 General

5.1.1 Biocompatibility

Particular attention should be given to assessing the effects on biocompatibility from the release of metallic ions from the denture adhesive.

5.1.2 pH value

Denture adhesives shall have a pH value within the range of 4 to 10 when tested in accordance with 7.2 or another validated method.

5.1.3 Microbiology

Testing for microbiological contamination shall be carried out according to appropriate methods such as those listed in References [3] to [15].

5.1.4 Stability

The denture adhesive shall show no signs of deterioration which may affect compliance with this document after being subjected to one of the aging procedures specified in 7.3.

5.2 Specific requirements for Type 1 adhesives

5.2.1 Washability

There shall be no residual lump when tested in accordance with 7.4.

5.2.2 Strength of the adhesion to the prosthesis

Adhesion strength shall not be less than 5 kPa when tested in accordance with 7.5 and 7.6.

5.3 Specific requirements for Type 2 adhesives

5.3.1 Adhesion strength

Adhesion strength shall not be less than 5 kPa when tested in accordance with 7.7.

5.3.2 Peeling property

There shall be no residual lump when tested in accordance with 7.8.

5.3.3 Consistency

Consistency shall not be less than 15 mm when tested in accordance with 7.9.

6 Sampling

The sample shall be taken from one lot and shall be sufficient to complete all tests specified in Clause 7.

7 Measurements and test methods

7.1 Test conditions

All test shall be conducted at a temperature of (23 ± 3) °C.

7.2 pH value measurement

7.2.1 Apparatus and material

7.2.1.1 pH meter

7.2.1.1.1 pH meter, with a glass and comparison electrode assembly with an accuracy of ±0,02.

7.2.1.1.2 pH meter, with a flat type pH compound electrode.

7.2.1.2 Container

7.2.1.2.1 Glass container, of 500 ml capacity.

7.2.1.2.2 Container, of 35 mm in diameter and 10 mm in height.

7.2.1.3 Circular filter paper, of 40 mm in radius.

7.2.2 Reagents

7.2.2.1 Propylene glycol, analytical grade.

7.2.2.2 Water, shall be of grade 3 in accordance with ISO 3696:1987.

7.2.2.3 Sodium chloride, analytical grade.

7.2.3 Procedure

7.2.3.1 Type 1 adhesives

7.2.3.1.1 Class 1

Take (1,0 ± 0,1) g of a Class 1 denture adhesive in the container (7.2.1.2.1), add 5 g of propylene glycol (7.2.2.1) to disperse it, and while stirring, add 300 ml of water (7.2.2.2) and mix them sufficiently. Insert the electrode of the pH meter (7.2.1.1.1) into the dispersion and take the pH meter reading 3 min after the insertion.

7.2.3.1.2 Class 2

7.2.3.1.2.1 Procedure using pH meter with a flat type compound electrode.

Take (1,0 ± 0,1) g of a Class 2 denture adhesive in the container (7.2.1.2.2) and spread evenly: then pour 5,0 ml of 0,9 g/dl sodium chloride (7.2.2.3) solution onto the sample. Cover the container (7.2.1.2.2), then keep it for 10 min. Insert the flat type pH compound electrode of the pH meter (7.2.1.1.2) into the 0,9 g/dl sodium chloride (7.2.2.3) solution and monitor the pH until a steady pH is determined.

NOTE This procedure is suitable for Class 2 denture adhesives which do not have internal diffusion capacity against aqueous solutions.

7.2.3.1.2.2 Alternative procedure using pH meter with a glass and reference electrode.

Take (1,0 ± 0,1) g of a Class 2 denture adhesive in the container (7.2.1.2.1), add 5 g of propylene glycol (7.2.2.1) to disperse it, and while stirring, add 300 ml of water (7.2.2.2) and mix them sufficiently. Insert the electrode of the pH meter (7.2.1.1.1) into the dispersion and take the pH meter reading 3 min after the insertion.

NOTE This procedure is suitable for various type of Class 2 denture adhesives.

7.2.3.1.3 Class 3

Take (1,0 ± 0,1) g of a Class 3 denture adhesive in the container (7.2.1.2.1), add 300 ml of water and mix them sufficiently. Insert the electrode of the pH meter and take the pH meter reading 3 min after the insertion.

7.2.3.2 Type 2 adhesives

Take (1,0 ± 0,1) g of denture adhesive, and spread evenly over a radius of approximately 40 mm on a piece of filter paper (7.2.1.3). Place the filter paper in the container (7.2.1.2.1) and add 300 ml of water to it. After immersing in water for 1 h, insert the electrode of the pH meter into water and take the pH meter reading 3 min after the insertion.

7.3 Determination of stability — Aging procedure

Store the denture adhesives in their original containers at (40 ± 2) °C at (75 ± 5) % relative humidity for 3 months or at such conditions of time and temperature as will simulate storage at room temperature for 30 months[16].

7.4 Test of washability (for Type 1 adhesives)

7.4.1 Apparatus and materials

7.4.1.1 Water bath, capable of being maintained at a temperature of (37 ± 2) °C.

7.4.1.2 Poly(methyl methacrylate) (PMMA) plate, approximately 50 mm × 50 mm, shall be in accordance with ISO 7823-2.

7.4.2 Reagent

Water, in accordance with 7.2.2.2.

7.4.3 Procedure

Apply the denture adhesive on the PMMA plate (7.4.1.2) evenly following the manufacturer's instructions for use and immerse the plate in water for 1 h in the water bath (7.4.1.1) maintained at (37 ± 2) °C.

Wash the PMMA plate following the manufacturer's instructions for use and inspect the PMMA plate surface with the naked eye, without magnification. Repeat the tests to obtain five test results.

7.5 Adhesion strength test I (for Type 1 adhesives)

7.5.1 General

Conduct the following adhesion strength test within 3 min after removal from the water bath.

7.5.2 Apparatus

7.5.2.1 Adhesion test instrument, having a sample stand, of capacity up to 10 N (for both frame and load cell), with a cross-head speed up to 5 mm/min. See Figure 1.

7.5.2.2 Sample holder I, having a hole with a diameter of (22 ± 1) mm, depth of (0,5 ± 0,1) mm and a surface roughness of 2,0 µm and below, made of poly(methyl methacrylate) complying with ISO 7823-2. See Figure 2 a).

After testing the denture adhesive left on the sample holder surface is recommended to be removed using detergent solution.

7.5.2.3 Sample holder II, having a raised circular part with a diameter of (22 ± 1) mm, a height of (5,0 ± 0,1) mm and a surface roughness of 2,0 µm and below, made of poly(methyl methacrylate) complying with ISO 7823-2. See Figure 2 b).

After testing the denture adhesive left on the sample holder surface is recommended to be removed using detergent solution.

7.5.2.4 Pressure sensitive shaft, having a circular base with a diameter of (20,0 ± 0,5) mm, made of poly(methyl methacrylate) complying with ISO 7823-2. See Figure 3.