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Dentistry — Dental amalgam

Médecine bucco-dentaire — Amalgame dentaire

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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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 1, *Filling and restorative materials*.

This third edition cancels and replaces the second edition (ISO 24234:2015), which has been technically revised.

The main changes compared to the previous edition are as follows.

— Pre-capsulated dental amalgam products have been removed from the scope of this document.

— A requirement for corrosion resistance has been added.

— In previous editions of this document, the presence of a limited number of foreign body particles in the dental amalgam alloy powder was permitted. Now, as a requirement, foreign body particles are not permitted to be present in the dental amalgam alloy powder.

— The roughness parameter used to specify the finish required on working surfaces of test-piece moulds has been changed from R_k to R_a.

— An instruction to lightly abrade the ends of the cylindrical test-pieces, if required for removing flash, has been deleted.

— The requirement for early compression strength has been altered. Measurement of the value is made at 2 h and not at 1 h.

— An additional four items of information have been added to each of the test reports.

— The edition number of the manufacturer's instructions and information, and the date of its introduction have been added as a requirement to the Manufacturer's Instructions.

— For each test method used to determine conformity to a requirement, a new subclause, "Principle", has been added in which a brief summary is present to explain the method adopted.

— For each test method used to determine conformity to a requirement, a new subclause, “Test report”, has been added.

— A new clause “7 Report" has been added which provides details of the evaluation that are to accompany a statement or claim of conformity to this document overall.

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

Continuing concern about the use of dental mercury and a move in some counties to limit its use to pre-capsulated products led to the development of ISO 20749. The scope of ISO 20749 is restricted to pre-capsulated products alone. Consequently, it is appropriate to remove pre-capsulated dental amalgam products from the scope of this document.

Dental amalgam alloy supplied as a free-flowing powder and as tablets remain in use in some countries. For their use, dental mercury is required and the supply of dental mercury sachets (also referred to as pillows) continues to be consistent with the objective to restrict the supply of dental mercury only in sealed capsules containing a mass suitable for a single restoration. All such products are within the scope of this revision.

NOTE In some jurisdictions only pre-capsulated products are allowed to be used. ISO TC 106 *Dentistry* must consider global use and not restrict the standards it produces to the position prevailing in individual states or regional blocks. For as long as product types within the scope of this document are in legal use in other nations, this standard will continue to be required.

Specific qualitative and quantitative test methods for demonstrating freedom from unacceptable biological hazard are not included in this document and it is recommended that, for the assessment of possible biological hazards, reference should be made to ISO 10993-1 and ISO 7405.

Dentistry — Dental amalgam

1 Scope

This document specifies the requirements and test methods for dental amalgam alloy powder and dental mercury that are suitable for the preparation of dental amalgam together with the requirements and test methods for that dental amalgam and the requirements for packaging and marking.

NOTE Two of the requirements apply only to dental mercury (as supplied). All of the other requirements apply to the dental amalgam alloy (as supplied) and dental amalgam.

This document is not applicable to dental amalgam alloy powder and dental mercury supplied in a pre-capsulated form.

This document is not applicable to other metallic materials in which an alloy powder reacts with an alloy that is liquid at ambient temperature to produce a solid metallic material intended for dental restoration.

This document applies to products used to make dental amalgam restorations, supplied to the user in the following forms: dental amalgam alloy as a fine free flowing powder, or as a fine powder compacted into tablets and dental mercury in dental mercury sachets (sometimes referred to as dental mercury pillows). The mass of dental mercury in these sachets is limited to the amount required to make a small to medium-sized restoration in a single tooth.

This document is not applicable to dental mercury that is supplied in a primary container in an undivided mass that exceeds the amount suitable for a small to medium-sized restoration.

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 286-2, *Geometrical product specifications (GPS) — ISO code system for tolerances on linear sizes — Part 2: Tables of standard tolerance classes and limit deviations for holes and shafts*

ISO 1942, *Dentistry — Vocabulary*

ISO 3310-1, *Test sieves — Technical requirements and testing — Part 1: Test sieves of metal wire cloth*

ISO 3864-2, *Graphical symbols — Safety colours and safety signs — Part 2: Design principles for product safety labels*

ISO 4287, *Geometrical Product Specifications (GPS) — Surface texture: Profile method — Terms, definitions and surface texture parameters*

ISO 7488, *Dentistry — Mixing machines for dental amalgam*

ISO 13897, *Dentistry — Dental amalgam reusable mixing-capsules*

ISO 15223-1:2016, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 23325, *Dentistry — Corrosion resistance of dental amalgam Globally Harmonized System of Classification and Labelling of Chemicals (GHS). United Nations, New York and Geneva, 7th Edition, 2017, eISBN 978-92-1-060457-4*

UN Recommendations on the Transport of Dangerous Goods, Model Regulations. United Nations, New York and Geneva, 19th Edition, 2015, eISBN 978-92-1-139154-1

3 Terms and definitions

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

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

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

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

3.1
dental amalgam alloy
alloy in fine particles, composed mainly of silver, tin and copper, which when mixed with *dental mercury* (3.2) produces a dental amalgam for dental restoration

[SOURCE: ISO 20749:2017, 3.1, modified — "for dental restoration" has been added at the end of the definition.]

3.2
dental mercury
mercury supplied for use in the preparation of dental amalgam

[SOURCE: ISO 20749:2017, 3.2]

3.3
pre-capsulated product
product supplied in a sealed capsule that contains measured amounts of *dental amalgam alloy* (3.1) powder and *dental mercury* (3.2) with masses that are appropriate for the production of a mass of dental amalgam that is considered to be suitable for a single small or medium size restoration in a single tooth

Note 1 to entry: The dental amalgam alloy powder and dental mercury are separated by a barrier that is broken immediately prior to mixing, allowing their contact. The capsule remains sealed until mixing has been completed.

[SOURCE: ISO 20749:2017, 3.3]

3.4
dental amalgam alloy tablet
quantity of *dental amalgam alloy* (3.1) powder that has been compacted to form a single entity for the purpose of providing a pre-dosed quantity of the alloy that, when mixed with an appropriate mass of *dental mercury* (3.2), produces a mass of dental amalgam that is considered to be suitable for a single small or medium size restoration in a single tooth

Note 1 to entry: During mixing the tablet is intended to break apart, forming a fine powder.

[SOURCE: ISO/TS 20746:2016, 3.4]

3.5
dental mercury sachet
dental mercury pillow
measured quantity of *dental mercury* (3.2) supplied in a sachet (for use in a reusable mixing capsule) in a mass that, when mixed with an appropriate mass of *dental amalgam alloy* (3.1) powder, produces a mass of dental amalgam that is considered to be suitable for a single small or medium size restoration in a single tooth

Note 1 to entry: The sachet is intended to rupture during mixing to allow the dental mercury to come into contact with the dental amalgam alloy powder.

[SOURCE: ISO/TS 20746:2016, 3.5, modified — "dental amalgam alloy" has been replaced with "dental amalgam allow powder" in the definition and the term "dental mercury pillow" has been added.]

3.6
mixing machine for dental amalgam
DEPRECATED: amalgamator
electrically powered mixing machine that operates using an oscillating action for mixing *dental amalgam alloy* (3.1) and *dental mercury* (3.2) (in a capsule) to produce a dental amalgam

[SOURCE: ISO/TS 17988: 2020, 3.12]

4 Requirements

4.1 Chemical composition and purity of the dental amalgam alloy

The manufacturer shall declare every element that is present in a concentration greater than, or equal to 0,1 % (mass fraction). All alloying elements present in concentrations greater than 0,5 % (mass fraction) shall be given by name with mass fraction values rounded to the nearest whole percentage point. Alloying elements that are present in concentrations between 0,1 and 0,5 % (mass fraction) shall be named without a percentage value.

Test in accordance with 6.1.

The chemical composition shall comply with Table 1.

The total mass fraction for other elements present in concentrations greater than 0,01 % (mass fraction) but below 0,1 % (mass fraction) that are not declared as alloying elements, shall not exceed 0,1 % (mass fraction).

Table 1 — Requirements for chemical composition of the dental amalgam alloy

Element	% (mass fraction)
silver	≥ 40
tin	≤ 32
copper	≤ 30
indium	≤ 5
palladium	≤ 1
platinum	≤ 1
zinc	≤ 2
mercury	≤ 3

4.2 Purity of the dental mercury

Elements other than dental mercury shall not be present in a concentration greater than 0,01 % (mass fraction) in total. Test in accordance with 6.2.

4.3 Foreign material and large particles in the dental amalgam alloy powder

When conformity to this requirement is determined in accordance with 6.3, the proportion of the dental amalgam alloy powder that occurs as particles that have a size greater than 150 µm shall not exceed 0,1 % (mass fraction).

When tested in accordance with 6.3, no particles of foreign matter shall be found on the sieve.

4.4 Accuracy and variability of pre-proportioned masses

4.4.1 For dental mercury sachets

The arithmetic mean of the mass of the dental mercury in the sachet shall be within ±2,0 % of the manufacturer's stated mass, when tested in accordance with 6.4.

The coefficient of variation of the mass of the dental mercury in the sachets shall not exceed 1,5 %, when tested in accordance with 6.4.

4.4.2 For dental amalgam alloy tablets

The arithmetic mean of the mass of the dental amalgam alloy tablet shall be within ±2,0 % of the manufacturer's stated mass, when tested in accordance with 6.4.

The coefficient of variation of the mass of the dental amalgam alloy tablets shall not exceed 1,5 %, when tested in accordance with 6.4.

4.5 Properties of the dental amalgam

4.5.1 General

Table 2 — Properties of the dental amalgam

Maximum creep %	Permitted dimensional change during hardening %	Minimum compressive fracture stress at 2 h MPa	Minimum compressive fracture stress at 24 h MPa
2,0	−0,10 to +0,15	100	350

4.5.2 Creep

When conformity to this requirement is determined in accordance with 6.5, the results for either three out of three, or four out of five test-pieces shall meet the requirement in Table 2.

4.5.3 Dimensional changes during hardening

When conformity to this requirement is determined in accordance with 6.5, the results for at least four out of five test-pieces shall meet the requirement in Table 2.

4.5.4 Compressive fracture stress at 2 h

When conformity to this requirement is determined in accordance with 6.5, the results for at least four out of five test-pieces or eight out of 10 test-pieces shall meet the requirement in Table 2.

4.5.5 Compressive fracture stress at 24 h

When conformity to this requirement is determined in accordance with 6.5, the results for at least four out of five test-pieces or eight out of 10 test-pieces shall meet the requirement in Table 2.

4.6 Appearance of the mixed dental amalgam before setting

When conformity to this requirement is determined in accordance with 6.6, the dental amalgam alloy and dental mercury being mixed according to the manufacturer's instructions, the dental amalgam shall form a coherent plastic mass with a shiny surface before packing and remain a coherent body after packing is completed.