INTERNATIONAL STANDARD

ISO 24234

Second edition
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Dentistry — Dental amalgam

Médecine bucco-dentaire — Amalgame dentaire

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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).

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

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 106, *Dentistry*, Subcommittee SC 1, *Filling and Restorative Materials*.

This second edition cancels and replaces the first edition (ISO 24234:2004), which has been technically revised. It also incorporates the amendment ISO 24234:2004/Amd, 1. The following changes have been made.

— The title of this International Standard has been changed to reflect the content and requirements more accurately.

— The supply of dental mercury in units of greater mass (bulk dental mercury) is no longer within the scope of this International Standard. Through this restriction on the supply of dental mercury for a product to comply with this International Standard (introduced by ISO/TC 106 SC1), a general concern about the environmental impact from the sale of mercury in bulk volumes (for all applications) is addressed.

— As a consequence of the removal of dental mercury supplied in bulk quantities from the scope of this International Standard, requirements for freedom from contamination (by water, oil and foreign bodies) and free pouring of dental mercury are no longer present in this International Standard.

— The values for the requirements on the dimensional change during hardening and the compressive strength at 1 h and 24 h have been revised. "Permitted dimensional change during hardening" is changed from (- 0,10 to +0,20) % to (−0,10 to +0,15) %. Furthermore, the "Minimum compressive strength at 1h" is increased from 80 to 100 MPa, and the "Minimum compressive strength at 24 h" is increased from 300 to 350 MPa.

— Provisions for packaging and marking have been revised.

— Markings required for mercury safety warnings and precautions have been revised.

— Normative annexes on procedures for corrosion testing have been removed from this International Standard and are now contained in a new International Technical Specification, ISO/TS 17988: *Dentistry — Corrosion test methods for dental amalgam.*

Introduction

Dental amalgam alloy and dental mercury are the essential and only components of dental amalgam restorative material. This International Standard specifies the requirements and the test methods for dental amalgam alloy that is suitable for the preparation of dental amalgam, together with those for the set dental amalgam and the requirements for packaging and marking (including those for dental mercury), of which this International Standard is the second edition.

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

To enhance the safety of dentists and support staff, and minimize the consequence that might result from the accidental damage to containers during shipping, the scope is limited solely to dental mercury that is supplied pre-capsulated or in pre-dosed sachets. Both are limited to a mass sufficient for one mix.

Safety precautions relating to marking, labelling, and packaging have been strengthened in this revision.

Restricting the scope to dental amalgam alloys with copper contents above 12 % by mass (i.e. “high copper” dental amalgam alloy) was considered, because it is reported that restorations made with such alloys, as a group, have a better long term survival rate than those made with traditional alloys (i.e. “low copper” dental amalgam alloy). This was rejected since there are a few products with a low copper content that produce restorations that are as durable as those produced using some of the high copper products. (Factors other than the percentage of copper are important.) Also, it was felt that excluding products from compliance should not be done by a change to the composition requirement; it should be on the basis of a revision to the requirements for the properties that determine performance.

Inclusion of a requirement for corrosion resistance was considered. However, it was agreed that the data available were insufficient to set a corrosion requirement in this edition of this International Standard. A requirement for the corrosion resistance will be set and incorporated at the earliest possible date. It is recommended that, in assessing corrosion resistance of a dental amalgam product (relative to other dental amalgam products) reference should be made to ISO/TS 17988.

In the first edition of this International Standard (and before that in ISO 1559) a compression strength test was used to determine the resistance to fracture of dental amalgam. Such a test, with a compressive strength requirement, continues to be used in this edition. However, the Working Group recognizes that dental amalgam, is in effect, a brittle material and it is evaluating a suitable test procedure that produces tensile forces to initiate fracture in a way that replicates the clinical process. At this time, the work has not reached the point at which this test (with a requirement) can be included in this revision of the International Standard. When evaluation is completed, consideration will be given to adding a requirement for fracture resistance that utilizes this test. This will be in the form of a Technical Amendment.

Requirements and test methods for the capsules used for pre-capsulated products are contained in ISO 13897.

Dentistry — Dental amalgam

1 Scope

This International Standard specifies the requirements and test methods for dental amalgam alloys 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 (including those for dental mercury).

It is applicable to dental amalgam alloys supplied in the form of a free-flowing powder in bulk, or a powder compressed to form a tablet, or a powder in a capsule (i.e. pre-capsulated).

With respect to dental mercury, the scope is limited solely to dental mercury which is supplied pre-capsulated or in pre-dosed sachets. Both are limited to a mass sufficient for one mix. The mass of dental mercury in one capsule or sachet shall be sufficient to produce a homogeneous plastic mix, appropriate for a small or medium sized restoration in a single tooth. This International Standard is not applicable to mercury supplied in masses greater than this in a single primary container (i.e. dental mercury in bulk). Dental mercury supplied in bulk volumes will not conform to this International Standard.

This International Standard does not exclude the supply of dental amalgam alloy or dental mercury separately.

This International Standard is not applicable to 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.

NOTE Dental mercury is at least 99,99 % pure, and as such, it is a metallic element of high commercial purity, and not an alloy

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 6344-1, *Coated abrasives — Grain size analysis — Part 1: Grain size distribution test*

ISO 7488, *Dental amalgamators*

ISO 13565-2, *Geometrical Product Specifications (GPS) — Surface texture: Profile method; Surfaces having stratified functional properties — Part 2: Height characterization using the linear material ratio curve*

ISO 13897, *Dentistry — Amalgam capsules*

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

Globally Harmonized System of Classification and Labelling of Chemicals (GHS). United Nations, New York and Geneva, 5th Edition, 2010, ISBN 92-1-116840-6

UN *Recommendations on the Transport of Dangerous Goods, Model Regulations*. United Nations, New York and Geneva, 18th Edition 2013. ISBN 978-9211931466

3 Terms and definitions

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

3.1
dental amalgam alloy
alloy in fine particles, composed mainly of silver, tin, and copper, which, when mixed with dental mercury, produces a dental amalgam

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

Note 1 to entry: Dental mercury complying with the scope of this International Standard is supplied either pre-capsulated (3.3) or in a pre-dosed sachet (3.5), with a mass that is considered suitable for a single small or medium size restoration in a single tooth.

3.3
pre-capsulated product
product supplied in a sealed capsule that contains measured amounts of dental amalgam alloy powder and dental mercury 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 sized 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 to allow their contact. The capsule remains sealed until mixing has been completed.

3.4
dental amalgam alloy tablet
dental amalgam alloy powder that has been compressed 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, produces a mass of dental amalgam that is considered to be suitable for a single small or medium sized restoration in a single tooth

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

3.5
dental mercury sachet
measured quantity of dental mercury 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, produces a mass of dental amalgam that is considered to be suitable for a single small or medium sized 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.

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 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	≤I
zinc	≤2
mercury	≤3

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

This requirement applies to all products with the exception of products in which dental mercury sachets alone are supplied.

When tested in accordance with 6.2, no more than five particles of foreign material shall be found on the sieve.

The mass of alloy particles that remain on the sieve shall not exceed 0,1 % (mass fraction) of the sample used for this test.

4.3 Accuracy and variability of pre-proportioned masses

4.3.1 For dental mercury sachet products

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 6.3.1.

The coefficient of variation of the mass of the dental mercury in the sachets shall not exceed 1,5 %, when tested in accordance with 6.3.1.

4.3.2 For pre-capsulated products

The arithmetic means of the masses of both dental amalgam alloy and dental mercury in the capsule shall be within ±2,0 % of the manufacturer's stated masses, when tested in accordance with 6.3.2.

The coefficients of variation of the masses of the dental amalgam alloy and the dental mercury in the capsules shall not exceed 1,5 %, when tested in accordance with 6.3.2.

4.3.3 For dental amalgam alloy tablet products

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 6.3.3.

The coefficient of variation of the mass of the dental amalgam alloy tablets shall not exceed 1,5 %, when tested in accordance with 6.3.3.

4.4 Properties of the dental amalgam

This requirement applies to all products in which dental amalgam alloy is supplied.

Table 2 — Properties of the dental amalgam

Maximum creep	Permitted dimensional change during hardening	Minimum compressive strength at 1 h	Minimum compressive strength at 24 h
%	%	MPa	MPa
2,0	−0,10 to +0,15	100	350

4.4.1 Creep

When tested in accordance with 6.5, either three out of three, or four out of five test-pieces shall meet the requirement in Table 2.

4.4.2 Dimensional changes during hardening

When tested in accordance with 6.6, at least four out of five test-pieces shall meet the requirement in Table 2.

4.4.3 Compressive strength at 1 h

When tested in accordance with 6.7, at least four out of five test-pieces, or eight out of ten test-pieces shall meet the requirement in Table 2.

4.4.4 Compressive strength at 24 h

When tested in accordance with 6.7, at least four out of five test-pieces, or eight out of ten test-pieces shall meet the requirement in Table 2.

4.5 Appearance of the mixed dental amalgam before setting

This requirement applies to all products in which dental amalgam alloy is supplied.

When the dental amalgam alloy and dental mercury are mixed according to the manufacturer's instructions and tested in accordance with 6.8, the dental amalgam shall form a coherent plastic mass with a shiny surface before packing and remain a coherent plastic mass after packing.

5 Sampling

Procure containers of capsules (pre-capsulated products), or dental mercury sachets, or dental amalgam alloy powder, or dental amalgam alloy tablets of the same lot in packages that have been produced for retail.

For products supplied as free-flowing dental amalgam alloy powder or dental amalgam alloy tablets, at least 50 g of dental amalgam alloy is required.

For pre-capsulated products, the number of capsules required depends on the masses of dental amalgam alloy and dental mercury in each.

For dental mercury supplied in sachets, 25 sachets are required.

6 Test methods

6.1 Chemical composition and purity of the dental amalgam alloy

Use a recognized, instrumented analytical procedure that has adequate sensitivity to determine the composition of the dental amalgam alloy for the elements declared by the manufacturer in compliance with 4.1.

For other elements that are detected at mass fractions greater than 0,01 %, but are not alloying elements (declared as such by the manufacturer in compliance with 4.1), sum their mass fractions and report the sum as the mass fraction of other elements.

NOTE Inductively-coupled plasma (ICP) spectroscopy is an example of a suitable analytical procedure.

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

For dental amalgam alloy supplied as a free-flowing powder in bulk, weigh a (10,0 ± 0,1) g sample to an accuracy of ±1 mg and record (m_s).

For dental amalgam alloy supplied as tablets, place a tablet in a reusable capsule that complies with ISO 13897. Break the tablet in the capsule to its constituent powder particles by using an amalgamator (that complies with ISO 7488) at the machine setting and at one-half the time recommended by the dental amalgam alloy manufacturer for mixing the dental amalgam alloy and dental mercury in accordance with 7.3.1. If the manufacturer's recommendations include any other action to break-up the tablet (e.g. use of a pestle), incorporate this at the appropriate time. Repeat this using a sufficient number of tablets to obtain (10,0 ± 0,1) g of powder. Weigh this sample to an accuracy of ±1 mg and record (m_s).

For pre-capsulated products, select and open a sufficient number of capsules to obtain a (10,0 ± 0,1) g sample of dental amalgam alloy powder. Weigh this sample to an accuracy of ±1 mg and record (m_s).

Place the powder sample on a sieve of mesh size 150 μm that conforms to ISO 3310-1. Hold the sieve assembly (consisting of collecting pan, sieve, and cover) in one hand and tap it gently against the other hand at a rate of approximately twice a second for 120 s. Inspect the sieve at a magnification of x10 for any foreign material and remaining dental amalgam alloy particles. Record the number of foreign material particles.

Remove any foreign material and then transfer the dental amalgam alloy particles remaining on the sieve to a balance. Weigh to an accuracy of ±1 mg and record (m_r). Calculate the mass fraction of the dental amalgam alloy that occurs in particles that have a size greater than 150 μm, as follows:

$$w = \frac{m_r}{m_s} \times 100 \quad (\%) \tag{1}$$

where

m_r is the mass of amalgam alloy particles remaining on the sieve;

m_s is the mass of the powder sample;

w is the mass fraction of the dental amalgam alloy particles greater than 150 μm in size, expressed as a percentage.

6.3 Determination of the accuracy and variability of pre-proportioned masses

6.3.1 Dental mercury sachet products

Select 25 sachets at random.