INTERNATIONAL STANDARD

ISO 24234

First edition
2004-10-15

Dentistry — Mercury and alloys for dental amalgam

Art dentaire — Mercure et alliages pour amalgame dentaire

Reference number
ISO 24234:2004(E)

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Published in Switzerland

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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 24234 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 1, *Filling and restorative materials*.

This International Standard cancels and replaces ISO 1559:1995, ISO 1559:1995/Cor.1:1997 and ISO 1560:1985.

A number of technical revisions have been made as improvements or as a consequence of combining the International Standards that have been replaced.

— The scope of this International Standard applies to alloys for dental amalgam and dental mercury, whether provided individually or together.

— The clause permitting a deviation in the composition of alloys for amalgam has been removed.

— Guidance on biocompatibility assessment has been introduced.

— A limit on the presence of large alloy particles has been introduced.

— The requirement for loss of mercury from predosed capsules has been removed, since it is a requirement in ISO 13897.

— The values for the requirements on creep, dimensional change and compressive strength at 1 h have been revised.

— The criterion for compliance with the compressive strength requirements has been revised.

— Provisions for packaging and marking have been revised.

— Markings required for mercury safety warnings and precautions have been revised to conform to ISO requirements and the United Nations *Globally Harmonized System of Classification and Labelling of Chemicals* (GHS). They are no longer dependent upon national or regional requirements.

— Procedures for corrosion testing have been added as normative annexes.

Introduction

Dental amalgam alloy and mercury are the essential and only components of dental amalgam restorative material. This International Standard combines the requirements and the test methods for the alloy with those for the mercury in a single standard, of which this is the first edition. Formerly, these were contained in two separate standards.

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

To enhance the safety of dentists and support staff, it would have been preferred to limit the scope solely to the use of predosed capsules of alloy and mercury. It is, however, recognised and accepted that both amalgam alloy and mercury are supplied in bulk form in some parts of the world where, for economic reasons, this is necessary for the provision of dental treatment. Therefore requirements for these products are included in this International Standard. Safety precautions relating to marking, labelling and packaging have been strengthened in this revision.

Inclusion of a requirement for corrosion resistance was considered, using the procedures for corrosion testing given in ISO/TS 17576. However it was decided that the data available were insufficient to justify a corrosion requirement in this International Standard, and as a consequence the test methods alone are given, as normative annexes. A requirement for the corrosion resistance will be set and incorporated at the earliest possible date.

Dentistry — Mercury and alloys for dental amalgam

WARNING — The use of this International Standard may involve hazardous materials, operations and equipment. This International Standard does not purport to address all of the safety problems associated with its use. It is the responsibility of the user of this International Standard to establish appropriate safety and health practices and to determine the applicability or regulatory limitations prior to use.

1 Scope

This International Standard specifies the requirements and test methods for alloys and for mercury suitable for the preparation of dental amalgam, together with the requirements and test methods for that amalgam and the requirements for packaging and marking.

It is applicable to alloys supplied in the form of either a powder in bulk, or a powder compressed to form a tablet, or a powder in predosed capsules.

It is applicable to dental mercury supplied either in bulk quantities, or in predosed sachets, or in predosed capsules.

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

This International Standard is not applicable to alloys intended for use with liquid metals that are not mercury, nor is it applicable to liquid metal alloys.

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 286-2, *ISO system of limits and fits — Part 2: Table of standard tolerance grades and limit deviations for holes and shafts*

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

ISO 3585, *Borosilicate glass 3.3 — Properties*

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

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

ISO 4793:1980, *Laboratory sintered (fritted) filters — Porosity grading, classification and designation*

ISO 6344-1:1998, *Coated abrasives — Grain size analysis — Part 1: Grain size distribution test*

ISO 7488, *Dental amalgamators*

ISO 8282, *Dental equipment — Mercury and alloy mixers and dispensers*

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*

Globally Harmonized System of Classification and Labelling of Chemicals (GHS). United Nations, New York and Geneva, 2003, ISBN 92-1-116840-6

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

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

3.2
predosed capsule
capsule, as-supplied, containing measured amounts of alloy powder and mercury for dental amalgam, separated in such a way that premature combination is prevented

NOTE The separating barrier is broken immediately prior to mixing or breaks during mixing, allowing the alloy and mercury to come into contact.

3.3
amalgam alloy tablet
quantity of dental amalgam alloy powder that has been compressed to form a single entity for the purpose of providing a predosed quantity of the alloy.

NOTE During mixing, the tablet is intended to break apart, forming a fine powder.

3.4
tailing
phenomenon which occurs when mercury that contains impurities moves over a clean surface, tending to leave behind a portion of the liquid, forming an elongated tail as if it were sticking to that surface

3.5
primary container
container or package that is in direct contact with the material

3.6
dental mercury sachet
measured quantity of dental mercury supplied in a sachet that is suitable for a reusable mixing capsule

NOTE The sachet is broken immediately prior to mixing, or breaks during mixing, allowing the mercury to come into contact with the alloy

4 Requirements

4.1 General

4.1.1 If the alloy is supplied as a powder in bulk, the product shall comply with

— requirements 4.2, 4.3, 4.4, 4.8, 4.9, and

— packaging requirement 7.1, and

— marking requirements 7.2.1 a) to f), h) to j) and 7.3.

4.1.2 If the alloy is supplied as tablets, the product shall comply with

— requirements 4.2, 4.3, 4.4, 4.7, 4.8, 4.9, and

— packaging requirement 7.1, and

— marking requirements 7.2.1 a) to f), h) to j) and 7.3.

4.1.3 If the alloy and the dental mercury are supplied together in predosed capsules, the product shall comply with

— all requirements.

4.1.4 If the dental mercury is supplied as mercury in bulk, the product shall comply with

— requirements 4.3, 4.5, 4.6, and

— packaging requirement 7.1 and

— marking requirements 7.2.1 a) to d), f) and g), 7.2.2 and 7.3.2.

4.1.5 If the dental mercury is supplied in dental mercury sachets, the product shall comply with

— requirements 4.3, 4.5, 4.6 and 4.7, and

— packaging requirement 7.1, and

— marking requirements 7.2.1 a) to d), f) and g), 7.2.2 and 7.3.2.

4.2 Chemical composition of the 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 in concentrations greater than 0,5 % (mass fraction) shall be given by name, with values rounded to the nearest percentage (mass fraction). 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 concentration of other elements shall not exceed 0,1 % (mass fraction).

Table 1 — Requirements for chemical composition of the alloy

Element	Mass fraction %
silver	⩾ 40
tin	⩽ 32
copper	⩽ 30
indium	⩽ 5
palladium	⩽ 1
platinum	⩽ 1
zinc	⩽ 2
mercury	⩽ 3

4.3 Biocompatibility

See the Introduction for guidance on biocompatibility.

4.4 Foreign material and large particles in the alloy powder

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.

4.5 Contamination of the mercury by oil, water and foreign material

When the procedure in 6.3.1 and 6.3.2 is followed, the dental mercury shall be visibly free from contamination by oil, water or foreign material and shall have a bright mirror-like surface that does not form a scum in air within the specified period.

If the dental mercury is supplied in bulk form and does not have a bright mirror-like surface, then the procedures in 6.3.3 and 6.3.4 shall be carried out. After this procedure has been completed, the dental mercury shall have a bright, mirror-like surface that does not form a scum in air within the specified period.

4.6 Purity of mercury — Free pouring

When tested according to the procedure in 6.4, the mercury shall pour freely and completely without tailing.

Small droplets not coalesced with the bulk after shaking shall not be construed as evidence of non-compliance with this subclause.

4.7 Variability of preproportioned masses

4.7.1 For products supplied as predosed capsules

The coefficients of variation of the masses of the dental alloy and the dental mercury in the capsules shall not exceed 1,5 %, when tested in accordance with 6.5.1.

The arithmetic means of the masses of both alloy and mercury shall be within ± 2,0 % (mass fraction) of the manufacturer's stated masses, when tested in accordance with 6.5.1.

4.7.2 For products supplied as tablets

The coefficient of variation of the mass of the dental alloy tablets shall not exceed 1,5 %, when tested in accordance with 6.5.2.

The arithmetic mean of the mass of the alloy tablet shall be within ± 2,0 % (mass fraction) of the manufacturer's stated mass, when tested in accordance with 6.5.2.

4.7.3 For products supplied as dental mercury sachets

The coefficient of variation of the mass of the dental mercury in the sachet shall not exceed 1,5 %, when tested in accordance with 6.5.3.

The arithmetic mean of the mass of the dental mercury in the sachet shall be within ± 2,0 % (mass fraction) of the manufacturer's stated mass, when tested in accordance with 6.5.3.

4.8 Properties of the amalgam

4.8.1 General

When tested in accordance with 6.7 to 6.9, the material shall comply with the requirements given in Table 2.

Table 2 — Properties of amalgam

Maximum creep %	Permitted dimensional change during hardening %	Minimum compressive strength at 1 h MPa	Minimum compressive strength at 24 h MPa
2,0	–0,10 to +0,20	80	300

4.8.2 Creep

When tested in accordance with 6.7, either three out of three, or four out of five specimens shall meet the requirement in Table 2.

4.8.3 Dimensional changes during hardening

When tested in accordance with 6.8, at least four out of five specimens shall meet the requirement in Table 2.

4.8.4 Compressive strength at 1 h

When tested in accordance with 6.9, at least four out of five specimens, or eight out of ten specimens shall meet the requirement in Table 2.

4.8.5 Compressive strength at 24 h

When tested in accordance with 6.9, at least four out of five specimens, or eight out of ten specimens shall meet the requirement in Table 2.

4.9 Appearance of the mixed amalgam before setting

When the alloy and mercury are mixed according to the manufacturer's instructions and tested in accordance with 6.10, it shall form a coherent plastic mass, with a shiny surface.

5 Sampling

At least 50 g of alloy of the same lot in packages produced for retail shall be procured.

At least 50 g of mercury of the same lot in packages produced for retail shall be procured.

6 Test methods

6.1 Chemical composition of the alloy

Use a recognized, instrumented analytical procedure that has adequate sensitivity to determine the composition of the alloy for the elements declared by the manufacturer in compliance with 4.2. Inductively coupled plasma spectroscopy (ICP) is a suitable example.

For other elements that are detected at levels greater than 0,01 % (mass fraction), but are not alloying elements, sum their masses and report the sum as the “mass fraction of other elements”.

6.2 Foreign material and large particles in the alloy powder

For alloy supplied as a powder in bulk, weigh a (10,0 ± 0,1) g sample to an accuracy of ± 0,001 g and record (m_s).

For alloy supplied in predosed capsules, select and open a sufficient number of capsules to obtain a (10,0 ± 0,1) g sample of alloy. Weigh this sample to an accuracy of 0,001 g and record (m_s).

For 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 using a mechanical amalgamator that complies with ISO 7488, set at the machine setting and at one-half the time recommended by the alloy manufacturer for mixing the 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 point. Repeat this using a sufficient number of tablets to obtain (10,0 ± 0,1) g of powder. Weigh this sample to an accuracy of 0,001 g and record (m_s).

Place the powder sample on a sieve of mesh size 150 µm and diameter 76 mm. The sieve shall conform 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 × 10 for any remaining foreign material and alloy particles. Record the number of foreign material particles.

Remove any foreign material and then transfer the remaining alloy particles to a balance. Weigh to an accuracy of 0,001 g and record (m_r). Calculate the percentage (mass fraction) of alloy that occurs in particles that have a size greater than 150 µm, as follows:

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

where

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

m_s is the mass of the powder sample;

w is the percentage (mass fraction) of alloy particles greater than 150 µm in diameter.