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Dentistry — Pre-capsulated dental amalgam

Médecine bucco-dentaire — Amalgame dentaire en capsules prédosées

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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 on 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 the following URL: www.iso.org/iso/foreword.html.

This document was prepared by ISO/TC 106, *Dentistry*, Subcommittee SC 1, *Filling and restorative materials*.

Introduction

This is the first edition of this document. Its scope is limited solely to dental amalgam alloy and dental mercury that are supplied pre-capsulated in masses that are sufficient to produce a mass of dental amalgam that is considered to be suitable for a single small or medium size restoration in a single tooth.

Dental amalgam alloy and dental mercury are the essential and only components of dental amalgam restorative material. This document 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, those for the capsules themselves and the requirements for packaging and marking.

This document has been developed in response to the UNEP Minamata Convention on Mercury. The objective of the Minamata Convention is to reduce anthropogenic mercury pollution by restricting the use of mercury, products containing mercury and materials that release mercury during use. In this convention, dental amalgam is classified as a "mercury-added product", for which parties to the agreement are to adopt two or more measures from a list of nine. One of these is "restricting the use of dental amalgam to its encapsulated form". In some countries, the term *encapsulated* has been interpreted as the *pre-capsulated* form alone. Given the increased vigilance on the use of dental amalgam products since 2013, when the Minamata Agreement was signed, this document will enable countries that do not allow the use of products other than those that are pre-capsulated to adopt an ISO standard on dental amalgam. Not all of the membership of the UN has signed the Minamata Convention and in non-signatory countries, dental amalgam products outside the scope of this document, but within the scope of ISO 24234, will continue to be marketed. Thus, both standards are required to provide full global coverage for compliance.

Although this document is based on ISO 24234, there have been significant technical changes. Also, the requirements for the capsule that were in ISO 13897 have been transferred to this document, treating a product that falls within the scope as an entity. This document differs technically from ISO 24234 in the following respects:

— The scope of this document is restricted to pre-capsulated products alone.

— A requirement for packaging and capsule to be free from contamination is present.

— The requirement concerning foreign matter in the dental amalgam alloy powder has been removed.

— A requirement for loss of mass from the capsule during mixing has been added.

— A requirement for the yield of dental amalgam from a capsule replaces the requirement for the masses of dental mercury and dental amalgam powder present before mixing.

— A requirement for the consistency in the ratio of dental mercury to dental amalgam alloy powder in capsules has been changed radically. Determination of the effect of variation in this ratio upon properties replaces weighing the dental mercury and the dental amalgam alloy powder.

— Requirements for the capsule have been introduced and revised technically.

A decision was taken not to alter requirements upon which capsulation has no bearing, these being:

— the requirements on chemical composition and purity of the dental amalgam alloy;

— the requirements for the properties of dental amalgam;

— the requirement for the appearance of dental amalgam before setting.

As with ISO 24234, the inclusion of a requirement for corrosion resistance was considered. However, it was agreed that the data available were insufficient to set a corrosion resistance requirement in this edition of this document. 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 can be made to ISO/TS 17988.

Dentistry — Pre-capsulated dental amalgam

1 Scope

This document specifies the requirements and test methods for dental amalgam products supplied to the user in capsules, pre-dosed with dental amalgam alloy and dental mercury in quantities suitable for the creation of a single dental restoration.

This document specifies the requirements and test methods for dental amalgam alloys that are suitable for the preparation of dental amalgam and the capsule, together with the requirements and test methods for that dental amalgam and the requirements for packaging and marking.

This document is not applicable to dental amalgam alloys supplied as a free-flowing powder in bulk quantities or as powder compressed into tablets, or to dental mercury supplied in sachets or bulk quantities.

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.

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

The scope of this document is restricted to dental amalgam products marketed in pre-capsulated form alone. Other products intended for use in the production of dental amalgam restorations (dental amalgam alloy as a free-flowing powder supplied in bulk masses, dental amalgam alloy powder supplied as compressed tablets and dental mercury sachets) are within the scope of ISO 24234.

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 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 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 Revised Edition, 2013, ISBN 978-92-1-117067-2

UN Recommendations on the Transport of Dangerous Goods, Model Regulations. United Nations, New York and Geneva, 18th Edition, 2013, ISBN 978-92-1-193146-6

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:

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

— ISO Online browsing platform: available at http://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

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

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* (3.2) 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
self-activating capsule
pre-capsulated product (3.3) capsule in which contact between the *dental amalgam alloy* (3.1) powder and the *dental mercury* (3.2) occurs automatically during mixing

Note 1 to entry: There is another type of design that requires a physical action by the user to rupture the separating barrier for *activation* (3.6) before placing the capsule in the mechanical mixing machine.

3.5
percentage by mass
mass fraction expressed as a percentage

Note 1 to entry: The terminology “mass fraction” is favoured when expressing a composition in which this is measured by mass. However, for *dental amalgam alloys* (3.1), the terminology “by mass” is in general use. Because it is the intention for this document to be user-friendly, the latter has been adopted. In both cases, the composition is expressed as a percentage.

3.6
activation
action that renders the capsulated *dental amalgam alloy* (3.1) powder and *dental mercury* (3.2) mixable

3.7
dental amalgam pellet
coherent mass of dental amalgam that is produced by mixing and drops from the opened and upended capsule

Note 1 to entry: A light tap of the rim of the open capsule on a hard surface may be required to dislodge the pellet and is permitted.

4 Requirements

4.1 Package and capsule contamination

The interior of the packaging container and the outer surface of the capsules shall be free of both dental mercury and dental amalgam alloy powder contamination when tested in accordance with 6.1.

4.2 Chemical composition and purity of the dental amalgam alloy

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

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

Determine the chemical composition in accordance with 6.2.

The chemical composition shall comply with Table 1.

The total for elements that are not declared by the manufacturer as alloying elements shall not exceed 0,1 % (by mass).

4.3 Large particles in the dental amalgam alloy powder

When compliance with 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 % (by mass).

4.4 Loss of mass from the capsule during mixing

When compliance with this requirement is determined in accordance with 6.4, the average loss in mass of dental mercury and dental amalgam alloy powder from 15 capsules (during mixing in accordance with the manufacturer's instructions) shall not exceed 0,5 mg.

Also, the loss from any one capsule shall not exceed 1 mg.

4.5 The yield of amalgam from the capsule

When compliance with this requirement is determined in accordance with 6.5, the average mass of the pellet of dental amalgam obtained from a capsule (for a sample of 15 capsules) shall not be less than 95,0 % of the sum of the manufacturer's stated masses for dental mercury and dental amalgam alloy in the capsule.

Also, no capsule shall yield a pellet of dental amalgam that is less than 90,0 % of the sum of the manufacturer's stated masses for dental mercury and dental amalgam alloy in the capsule.

There may be some small free pieces of dental amalgam as well as the pellet. These are available for use and are regarded as part of the yield, i.e. their mass should be added to that of the pellet.

4.6 Consistency of the dental amalgam from capsule to capsule

When compliance with this requirement is determined in accordance with 6.6, the mean value of the hardness for dental amalgam produced from the content of any one capsule shall not be less than 85 % of the overall mean value of the hardness of the dental amalgam obtained for a specified number of capsules.

NOTE The mean value for the hardness of a test-piece is calculated from all measurements made on that test-piece. The overall mean value for hardness is calculated from all measurements on all test-pieces.

4.7 Properties of the dental amalgam

Table 2 — Properties of the dental 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 +0,15	100	350

4.7.1 Creep

When compliance with this requirement is determined in accordance with 6.7, the results for either three out of three or four out of five test-pieces shall meet the requirement in Table 2.

4.7.2 Dimensional changes during hardening

When compliance with this requirement is determined in accordance with 6.7, the results for at least four out of five test-pieces shall meet the requirement in Table 2.

4.7.3 Compressive strength at 1 h

When compliance with this requirement is determined in accordance with 6.7, 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.

4.7.4 Compressive strength at 24 h

When compliance with this requirement is determined in accordance with 6.7, 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.

4.8 Appearance of the mixed dental amalgam before setting

When compliance with this requirement is determined in accordance with 6.8, when the dental amalgam alloy and dental mercury are 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 plastic mass after packing.

4.9 Length tolerance for the capsule

When compliance with this requirement is determined in accordance with 6.9, the overall length of the activated capsule shall be within ±1 mm of the length specified by the manufacturer. All 10 capsules in the sample tested shall meet the requirement.

5 Sampling

Procure containers of capsules of the same lot in packages that have been produced for retail.

NOTE The number of capsules required depends on the masses of dental amalgam alloy and dental mercury in each.

6 Test methods

6.1 Package and capsule contamination

6.1.1 Principle

Any loss of either component from a capsule during transit is a concern. Such a loss can be detected by visual examination using low power magnification.

6.1.2 Test sample

Test all containers holding the capsules from the sample procured for testing, as well as 25 capsules selected at random from the same sample.

6.1.3 Apparatus

Stereomicroscope, ×10 magnification.

6.1.4 Procedure

Using the stereomicroscope, inspect the interior surfaces of all the containers holding capsules and the external surfaces of the 25 capsules. Examine these for traces of dental amalgam alloy powder and visible beads of dental mercury.

6.1.5 Expression of the results

Record the observations.

6.1.6 Report

6.1.6.1 General

If contamination is seen on the surface of a container, report this and the number of containers that is contaminated.

If it is the capsule surface that is contaminated, report this and the number of capsules that is contaminated.

6.1.6.2 Compliance

Report whether the product does or does not comply with the requirement for package and capsule contamination, in accordance with 4.1.

6.2 Chemical composition and purity of the dental amalgam alloy

6.2.1 Principle

Chemical analysis of the dental amalgam alloy using an instrumented technique for metallic materials.

6.2.2 Test sample

Extract dental amalgam alloy powder from a capsule selected at random. This sample should not be contaminated with the dental mercury during extraction from the capsule.

6.2.3 Apparatus

Recognized, instrumented analytical procedure, with a sensitivity adequate to determine the composition of the dental amalgam alloy for the elements declared by the manufacturer in compliance with 4.2.

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

6.2.4 Procedure

Determine the composition of the dental amalgam alloy for the elements declared by the manufacturer in compliance with 4.2.

6.2.5 Expression of results

Record all elements detected in concentrations greater than 0,01 % (by mass) and their proportions as percentages by mass.

For other elements that are detected in concentrations greater than 0,01 % (by mass) and below 0,1 % (by mass), but are not alloying elements (declared as such by the manufacturer in compliance with 4.2), sum these values and record the sum as the percentage (by mass) of other elements.

6.2.6 Report

6.2.6.1 General

Report the analytical method used. Report any irregularities in the test procedure used.

Report the percentages (by mass) for those elements that are alloying elements according to Table 1 and reported as such by the manufacturer. If any other element is declared by the manufacturer as an alloying element, report this and its percentage (by mass).

Report the sum of the percentages (by mass) of undeclared elements present in concentrations greater than 0,01 % (by mass).

Report each undeclared element that was found in a concentration greater than 0,1 % (by mass) by name and the percentage (by mass).

6.2.6.2 Compliance

Report whether the product does or does not comply with the requirement for composition and purity in accordance with 4.2

6.3 Large particles in the dental amalgam alloy powder

6.3.1 Principle

The large particles (defined as >150 µm in size) separated from the sample (a known mass of dental amalgam powder) are weighted.