
Dentistry — Mercury and alloys for dental amalgam

AMENDMENT 1: Requirements for marking and manufacturer's instructions concerning mercury

Art dentaire — Mercure et alliages pour amalgame dentaire

AMENDEMENT 1: Exigences quant au marquage et aux instructions du fabricant, concernant le mercure





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Published in Switzerland

Foreword

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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.

Amendment 1 to ISO 24234:2004 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 1, *Filling and restorative materials*.

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Dentistry — Mercury and alloys for dental amalgam

AMENDMENT 1: Requirements for marking and manufacturer's instructions concerning mercury

Title page and page 1

Replace the French title with the following:

Médecine bucco-dentaire — Mercure et alliages pour amalgame dentaire

Page iv, Foreword

Replace the ninth item in the list of technical revisions with the following:

Markings required for mercury safety warnings and precautions have been revised to conform to ISO requirements. They are no longer dependent upon national or regional requirements.

Page v, Introduction

Delete the following from the first sentence in the fourth paragraph:

using the procedures for corrosion testing given in ISO/TS 17576

Page 1, Normative references

Add the following normative reference to the list, after ISO 286-2, *ISO system of limits and fits — Part 2: Table of standard tolerance grades and limit deviations for holes and shafts*:

ISO 1942, *Dentistry — Vocabulary*

Page 2, Normative references

Add the following normative reference to the list, after ISO 13897, *Dentistry — Amalgam capsules*:

ISO 15223-1:2007, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

Delete the following normative reference:

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

Page 2, Terms and definitions

Replace the first paragraph with the following:

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

Add the following defined term and renumber the existing 3.6 as 3.7:

3.6
dental mercury
mercury supplied for use in the preparation of dental amalgam

Page 16, 7.2.1

Replace the first sentence with the following:

The following information shall be included on the packaging or accompanying literature:

Page 17, 7.2.1

Add the following new item of information as the penultimate item in the list and rename the existing item k) as l):

k) a recommendation to store at a temperature of no higher than 28 °C, if the product contains mercury;

Add the following note after the list:

NOTE This list contains the minimum for items of information that are to be supplied. Further items of information and warning pictograms may be added, if necessary.

Replace the whole of this subclause with the following:

7.2.2 Safety precautions — Packs that contain dental mercury

7.2.2.1 Outer pack

Mark with the label given in Figure 6. The general warning sign and informative text shall comply with the requirements of ISO 3864-2 and the meaning of the symbol (number 5.4) in ISO 15223-1:2007, presented as follows:

- The general warning sign, an exclamation mark within a warning triangle, shall be printed in black on a yellow triangular background.
- Text information “CAUTION This product contains mercury” shall be printed in black.
- The outline of the box containing this warning shall be printed in black.



Figure 6 — Precautionary label

NOTE This marking is intended for the safety of the user. For shipment, the containers of multiple packs should be marked in accordance with the *Globally Harmonized System of Classification and Labelling of Chemicals (GHS)* (United Nations). Symbols, signal words and hazard statements shall be applied that are appropriate for mercury (UN substance number 2809).

7.2.2.2 Primary container for mercury supplied in bulk form

Each primary container for dental mercury supplied in bulk form shall carry the precautionary labelling given in Figure 6 on the outside surface of the primary container, in addition to labelling on the outer pack.

Replace the whole of this subclause with the following:

7.3.2 Precautionary notes

The manufacturer's printed instructions shall contain the following precautionary notes:

a) Effect of mercury on metals

"Mercury corrodes and embrittles particular metals and their alloys. Avoid unnecessary contact between mercury and those metals."

b) Spillages

"Mercury presents a health hazard if handled incorrectly. Mercury is toxic by vapour inhalation and the effect is cumulative. Spillages of mercury should be removed immediately, including from places which are difficult to access. Use a plastic syringe to draw it up. Smaller quantities can be covered by sulfur powder and removed. Individual small droplets can be picked up by tin foil (Sn) and removed. Avoid inhalation of the vapour. During and after clean-up thoroughly ventilate the area where the spill has occurred."

c) Moisture contamination

"If moisture is introduced into the amalgam before it has set, properties such as strength and corrosion resistance can be affected adversely. If the alloy contains zinc, such contamination can result in an excessive expansion (delayed expansion). Use a dry field, whenever possible."

d) Waste disposal

"Waste material and all primary containers that have held mercury shall be disposed of following appropriate management practice."

Delete the following reference:

- [3] ISO/TS 17576, *Dentistry — Corrosion tests for amalgam*

Add the following reference:

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