

INTERNATIONAL STANDARD



1559

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

Alloy for dental amalgam

Alliage pour amalgame dentaire

First edition — 1978-11-15

STANDARDSISO.COM : Click to view the full PDF of ISO 1559:1978

UDC 616.314 : 615.462

Ref. No. ISO 1559-1978 (E)

Descriptors : dental materials, silver alloys, mercury amalgams, zinc-containing alloys, materials specifications.

Price based on 3 pages

FOREWORD

ISO (the International Organization for Standardization) is a worldwide federation of national standards institutes (ISO member bodies). The work of developing International Standards is carried out through ISO technical committees. Every member body interested in a subject for which a technical committee has been set up 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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council.

International Standard ISO 1559 was developed by Technical Committee ISO/TC 106, *Dentistry*.

It was submitted directly to the ISO Council, in accordance with clause 6.13.1 of the Directives for the technical work of ISO. It cancels and replaces ISO Recommendation R 1559-1970, which had been approved by the member bodies of the following countries :

Australia	France	Peru
Belgium	Greece	Poland
Brazil	India	South Africa, Rep. of
Canada	Israel	Spain
Czechoslovakia	Korea, Rep. of	United Kingdom
Denmark	Netherlands	U.S.A.
Egypt, Arab Rep. of	New Zealand	Yugoslavia

The member bodies of the following countries had expressed disapproval of the document on technical grounds :

Sweden
Switzerland

Alloy for dental amalgam

0 INTRODUCTION

This International Standard is technically identical with FDI¹⁾ Specification No. 1, the only difference being in the wording and layout, to bring the text into standard ISO form. Further studies are being undertaken to provide, if necessary, for a future revision of this International Standard in the light of technological advances supported by well-documented data.

NOTE — Throughout this International Standard the figures for SI units are approximate conversions of the technical metric units using the conversion factors 1 N = 0,102 kgf and 1 MPa = 1 MN/m² = 10,2 kgf/cm².

1 SCOPE

This International Standard specifies requirements for alloy, composed essentially of silver and tin, used in the preparation of dental amalgam, together with the test methods to be employed to determine compliance with these requirements.

2 FIELD OF APPLICATION

This International Standard applies to alloy, in either powder or tablet form, of a high-silver type, with or without zinc and/or mercury.

3 REQUIREMENTS

3.1 Chemical composition

The chemical composition of the alloy shall conform to the following requirements :

- Silver : 65 % min.
- Tin : 29 % max.
- Copper : 6 % max.
- Mercury : 3 % max.
- Zinc : 2 % max.

3.2 Deviations in chemical composition

Other elements may be present in the alloy provided that the manufacturer discloses the composition and that adequate evidence of clinical and biological investigations is presented to show that the alloy is safe to use in the mouth.

3.3 Working qualities

Amalgam prepared from this alloy in accordance with the manufacturer's instructions shall have the following working qualities.

3.3.1 Time of amalgamation

The amalgam shall be ready for condensation, when tested in accordance with 6.2, not longer than 90 s after trituration is commenced.

3.3.2 Consistency

A smooth plastic amalgam shall be formed from the alloy.

3.3.3 Carving

The amalgam shall be susceptible to carving immediately after condensation, and shall remain so for at least 15 min after amalgamation. If after 15 min the amalgam can be carved easily and shows evidence of not hardening promptly, it shall be rejected.

3.4 Flow

Specimens of amalgam prepared from the alloy and tested in accordance with 6.3 shall show not more than 4 % flow in a period of 21 h.

3.5 Dimensional change during hardening

A test specimen of amalgam prepared from the alloy and tested in accordance with 6.4 shall show

- a) no decrease in length at the end of 24 h hardening;
- b) no increase in length exceeding 2 µm per millimetre (0,20 %) at the end of 24 h hardening.

1) Fédération dentaire internationale.

3.6 Instructions for use

Adequate and accurate instructions for the manipulation of the contents shall accompany each package. These instructions shall contain at least the following details.

3.6.1 Proportions

The ratio of alloy to mercury.

3.6.2 Trituration

The method of triturating the alloy and mercury shall be specified for hand trituration by stating the size, shape, design and the material of which the mortar and pestle are constructed, the load exerted on the pestle, the approximate frequency of rotation of the pestle, and the time required for a mix of approximately 0,4 g of alloy with the recommended amount of mercury.

Other methods of trituration may be specified by the manufacturer provided that the instructions are in sufficient detail to obtain test data reproducible under the test procedures specified in this International Standard.

3.6.3 Condensation

Details relating to condensation shall include when and how the excess mercury should be expressed from the prepared amalgam and the method for packing both small and large restorations.

3.6.4 Precautions

If the alloy contains zinc in sufficient quantity to cause gaseous dissociation of water, then the following precaution shall be printed in type larger than that in the body of the instructions :

"This alloy contains zinc and the amalgam made therefrom will show excessive corrosion and expansion if moisture is introduced during mixing and packing of the amalgam. Therefore the amalgam should not be milled in or touched with the bare hands, condensed in a wet cavity, nor contaminated with moisture in any other way."

4 SAMPLING

The method of procurement and the amount of alloy needed for testing shall be the subject of agreement between the parties concerned.

5 PREPARATION OF TEST SPECIMENS

The preparation of all test specimens, and all tests, shall be conducted at a temperature of $23 \pm 2^\circ\text{C}$ unless otherwise specified. The manufacturer's instructions shall be followed.

6 TEST METHODS

6.1 Visual inspection

Visual inspection shall be used in determining compliance with the requirements outlined in sub-clauses 3.3.1, 3.3.2, 3.3.3, 3.6 and clause 7.

6.2 Time of amalgamation

The mortar with an inside mound (raised centre) and an appropriate glass pestle shall be surfaced by wet grinding with a silicon carbide powder of approximate particle size $25\ \mu\text{m}^{1)}$. In this mortar, 0,40 g of alloy and the appropriate quantity of mercury shall be triturated in accordance with the manufacturer's instructions. The amalgam shall be considered suitable for packing when it clings to the sides of the mortar and presents a smooth continuous mass. The time between the beginning of the trituration and the time that the amalgam presents the foregoing appearance shall be considered as the time of amalgamation.

6.3 Flow

6.3.1 Preparation of test specimen

The test specimen of amalgam shall be a cylinder 4 mm in diameter and 8 mm in length, prepared by condensing the amalgam into a rigid cylindrical steel die having a cavity 4 mm in diameter and approximately 11 mm long using, as far as possible, the technique given in the sheet of instructions accompanying the alloy. The die shall be maintained at $37 \pm 1^\circ\text{C}$ except during the packing of the specimen. The specimen shall be removed from the die on completion of condensation and shall then be transferred to an environment of $37 \pm 1^\circ\text{C}$. Prior to testing, the ends shall be surfaced plane and at right angles to the long axis so that the length of the specimen is 8 mm.

6.3.2 Procedure

Insert the test specimen, prepared as described in 6.3.1, into a flow micrometer. Three hours after amalgamation is started, subject the specimen to a constant axial load of 10,3 MPa. This load shall be maintained for 21 h. Then measure the change in length of the specimen and obtain the average shortening from two such specimens, expressed as a percentage of the original length of the specimen. This shall be the recorded value for flow. During the test, the temperature of the specimen shall be maintained at $37 \pm 1^\circ\text{C}$.

6.4 Dimensional change during hardening

6.4.1 Preparation of test specimen

The test specimen of amalgam shall be prepared by condensing the amalgam into a rigid steel die having a cavity

1) Sometimes known as grade FFFF.

approximately 5 mm in diameter and 10 mm in length using, as far as possible, the technique given in the sheet of instructions accompanying the alloy. The die shall be maintained at $37 \pm 1^\circ\text{C}$ except during the packing of the specimen. The specimen shall be removed from the die as soon as condensation is completed, but not later than 10 min from the start of mixing, and shall then be transferred to an environment having a temperature of $37 \pm 1^\circ\text{C}$.

6.4.2 Procedure

Place the test specimen in the measuring instrument and do not subject it to restraint during the test. Make the initial measurement 15 min after the start of mixing, and the final measurement at the end of 24 h. During this test, the specimen shall be maintained at a temperature of $37 \pm 1^\circ\text{C}$. The average change in length of two such specimens shall be the recorded value for setting change.

7 PACKAGING AND MARKING

7.1 Packaging

The alloy shall be supplied in accordance with commercial practice.

7.1.1 Containers

Containers shall not be made either wholly or in part with materials which amalgamate readily.

7.1.2 Instructions for use

Each package shall contain instructions for use, as specified in 3.6.

7.2 Marking

7.2.1 Lot numbers

Each container of material shall be marked with a serial number or a combination of letters and numbers, which refer to the manufacturer's records for that particular lot or batch.

7.2.2 Date of manufacture

The date of manufacture (year and month) shall be given on the container either as a separate item or as part of a lot number.

7.2.3 Net mass

The minimum net mass in grams¹⁾ shall be given in legible type on the container.

1) Attention is drawn to the common usage of troy ounces when referring to quantities of amalgam alloy.

STANDARDSISO.COM : Click to view the full PDF of ISO 1559:1978