

ISO

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION

ISO RECOMMENDATION R 1559

ALLOY FOR DENTAL AMALGAM

1st EDITION

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BRIEF HISTORY

The ISO Recommendation R 1559, *Alloy for dental amalgam*, was drawn up by Technical Committee ISO/TC 106, *Dentistry*, the Secretariat of which is held by the British Standards Institution (BSI).

Work on this question led to the adoption of Draft ISO Recommendation No. 1559, which was circulated to all the ISO Member Bodies for enquiry in December 1968. It was approved, subject to a few modifications of an editorial nature, by the following Member Bodies :

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

The following Member Bodies opposed the approval of the Draft :

Sweden
Switzerland

This Draft ISO Recommendation was then submitted by correspondence to the ISO Council, which decided to accept it as an ISO RECOMMENDATION.

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ALLOY FOR DENTAL AMALGAM

INTRODUCTION

This ISO Recommendation is technically identical with F.D.I.* 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 ISO Recommendation in the light of technological advances supported by well-documented data.

NOTE. — Throughout this ISO Recommendation the figures for SI units are approximate conversions of the technical metric units using the conversion factors $1\text{ N} = 0.102\text{ kgf}$ and $1\text{ MN/m}^2 = 10.2\text{ kgf/cm}^2$.

1. SCOPE

This ISO Recommendation gives the 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 ISO Recommendation applies to alloy, either in 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 should conform to the following requirements :

- Silver : minimum 65 %
- Tin : maximum 29 %
- Copper : maximum 6 %
- Mercury : maximum 3 %
- Zinc : maximum 2 %

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.

* Fédération Dentaire Internationale.

3.3 Working qualities

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

3.3.1 Time of amalgamation. The amalgam should be ready for condensation, when tested in accordance with clause 6.2, not longer than 90 seconds after trituration is commenced.

3.3.2 Consistency. A smooth plastic amalgam should be formed from the alloy.

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

3.4 Flow

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

3.5 Dimensional change during hardening

A test specimen of amalgam prepared from the alloy should not show any decrease or increase in length during hardening of more than 20 μm per centimetre (0.20 %) at the end of 24 hours when tested in accordance with clause 6.4.

3.6 Instructions for use

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

3.6.1 Proportions. The ratio of alloy to mercury.

3.6.2 Trituration. The method of trituring the alloy and mercury should 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 revolutions per minute that the pestle is revolved, 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 ISO Recommendation.

3.6.3 Condensation. Details relating to condensation should 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 should 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 mullled 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 should be the subject of agreement between the parties concerned.

5. PREPARATION OF TEST SPECIMENS

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

6. TEST METHODS

6.1 Visual inspection

Visual inspection should be used in determining compliance with the requirements outlined in clauses 3.3.1, 3.3.2, 3.3.3, 3.6 and section 7.

6.2 Time of amalgamation

The mortar with an inside mound (raised centre) and an appropriate glass pestle should be surfaced by wet grinding with a silicon carbide powder of approximate particle size $25\text{ }\mu\text{m}$.* In this mortar, 0.40 g of alloy and the appropriate quantity of mercury should be triturated in accordance with the manufacturer's instructions. The amalgam should 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, should be considered as the time of amalgamation.

6.3 Flow

6.3.1 Preparation of test specimen. The test specimen of amalgam should be a cylinder 4 mm in diameter and 8 mm in length which should be 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 should be maintained at $37 \pm 1^\circ\text{C}$ except during the packing of the specimen. The specimen should be removed from the die on completion of condensation and should then be transferred to an environment of $37 \pm 1^\circ\text{C}$. Prior to testing, the ends should 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. The test specimen, prepared as detailed in clause 6.3.1, is inserted into a flow micrometer. 3 hours after amalgamation is started the specimen should be subjected to a constant axial load of 10.3 MN/m^2 (105 kgf/cm^2). This load should be maintained for 21 hours. The change in length of the specimen should then be measured and the average shortening obtained from two such specimens, expressed as a percentage of the original length of the specimen. This should be the recorded value for flow. During the test the temperature of the specimen should 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 should be prepared by condensing the amalgam into a rigid steel die having a cavity 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 should be maintained at $37 \pm 1^\circ\text{C}$ except during the packing of the specimen. The specimen should be removed from the die as soon as condensation is completed, but not later than 10 minutes from the start of mixing, and should then be transferred to an environment having a temperature of $37 \pm 1^\circ\text{C}$.

6.4.2 Procedure. The test specimen should be placed in the measuring instrument and should not be subjected to restraint during the test. The initial measurement should be made 15 minutes after the start of mixing and the final measurement at the end of 24 hours. During this test the specimen should be maintained at a temperature of $37 \pm 1^\circ\text{C}$. The average change in length of two such specimens should be the recorded value for setting change.

* Sometimes known as grade F.F.F.F.

7. PACKAGING AND MARKING

7.1 Packaging

The alloy should be supplied in accordance with commercial practice.

7.1.1 *Containers.* Containers should not be made either wholly or in part with materials which amalgamate readily.

7.1.2 *Instructions for use.* Each package should contain instructions for use, as specified in clause 3.6.

7.2 Marking

7.2.1 *Lot numbers.* Each container of material should 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) should 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 grammes* should be given in legible type on the container.

* Attention is drawn to the common usage of Troy ounces when referring to quantities of amalgam alloy.