

ISO

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION

ISO RECOMMENDATION R 1564

AGAR IMPRESSION MATERIAL

1st EDITION

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BRIEF HISTORY

The ISO Recommendation R 1564, *Agar impression material*, 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. 1564, 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	India	Spain
Belgium	Israel	Sweden
Brazil	Korea, Rep. of	U.A.R.
Canada	Netherlands	United Kingdom
Czechoslovakia	New Zealand	U.S.A.
Denmark	Peru	Yugoslavia
France	Poland	
Greece	South Africa, Rep. of	

The following Member Body opposed the approval of the Draft :

Switzerland

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

AGAR IMPRESSION MATERIAL

INTRODUCTION

This ISO Recommendation is technically identical with F.D.I.* Specification No. 8, 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 agar impression material, together with the test methods to be employed to determine compliance with these requirements.

2. FIELD OF APPLICATION

This ISO Recommendation is applicable to dental impression material in gel form containing a reversible agar hydrocolloid as the gel-forming ingredient.

3. REQUIREMENTS

3.1 General requirements

The material should be uniform and free from foreign matter. When used in accordance with the manufacturer's instructions accompanying the package (see clause 3.3), the material should form a smooth plastic mass suitable for taking impressions in the mouth.

3.2 Special requirements

3.2.1 *Odour and flavour.* The material when used in accordance with the manufacturer's instructions should not have an unpleasant odour or flavour.

3.2.2 *Freedom from toxicity.* The material should not contain poisonous ingredients in sufficient concentration to be harmful to human beings when used as directed in the manufacturer's instructions or in the event of accidental ingestion of 10 ml (see clause 7.3).

3.2.3 *Irritation.* The material used in accordance with the manufacturer's instructions should not normally cause visible evidence of irritation of the normal oral mucosa, when softened by boiling in water (100 °C), tempered at 40 to 50 °C and used for making impressions.

* Fédération Dentaire Internationale.

- 3.2.4 *Extrusion.* The material when prepared according to the manufacturer's instructions should be capable of extrusion through a hollow needle or tube having an inside diameter not exceeding 0.6 mm.
- 3.2.5 *Compatibility with gypsum.* The impression material should impart a smooth surface to, and separate cleanly from, a gypsum cast made from unmodified alpha calcium sulphate hemihydrate. The cast poured against the agar impression in accordance with clause 6.2.2.5 should, for the full width of the specimen, reproduce the line 0.075 mm wide, on the test block illustrated in Figure 1.
- 3.2.6 *Consistency.* The material should remain sufficiently plastic, when heated in boiling water for 8 minutes in a metal mixing syringe or 10 minutes in the original container, and tempered according to the manufacturer's instructions, to permit its easy removal from the syringe or container, and its adaptation to the impression tray.
- 3.2.7 *Temperature at gel formation.* The temperature at which the plastic mass sets to a gel on cooling should be not less than 37 °C nor more than 45 °C.
- 3.2.8 *Uniformity.* After boiling and tempering and during setting of the material, the ingredients should not segregate. The material prepared should be homogeneous, have a smooth surface and be free of lumps or granules.
- 3.2.9 *Permanent deformation.* The permanent deformation of the set material should be not more than 1.5 % after a 10 % strain is applied for 30 seconds, when tested in accordance with clause 6.2.5.
- 3.2.10 *Compressive strength.* The compressive strength should be not less than 0.2 MN/m² (2.5 kgf/cm²) when tested in accordance with clause 6.2.6.
- 3.2.11 *Strain in compression.* The strain should be not less than 4.0 % nor more than 15.0 % between a stress of 0.01 MN/m² (0.1 kgf/cm²) and a stress of 0.098 MN/m² (1.0 kgf/cm²) when tested in accordance with clause 6.2.7.

3.3 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 :

- 3.3.1 *Tray, syringe and needle.* The type of tray, syringe and needle recommended for use with the material.
- 3.3.2 *Softening and tempering conditions.* The time and temperature requirements for softening and tempering the material in the original container and in the syringe.
- 3.3.3 *Oral temperature.* The temperature at which the material should be inserted in the mouth.
- 3.3.4 *Cooling.* The technique recommended for chilling the impression in the mouth.
- 3.3.5 *Treatment.* The treatment of the impression during the interval between its withdrawal from the mouth and the preparation of the gypsum cast.
- 3.3.6 *Fungicide.* A statement that the material contains a fungicide that will effectively prevent mould growth.

4. SAMPLING

The method of procurement and the amount of impression material required for the tests should be the subject of agreement between the parties concerned.

5. PREPARATION OF TEST SPECIMENS

The specimens should be prepared in accordance with the manufacturer's instructions accompanying the package (see clause 3.3).