

ISO

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION

ISO RECOMMENDATION R 1563

ALGINATE IMPRESSION MATERIAL

1st EDITION

June 1970

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Printed in Switzerland

Also issued in French and Russian. Copies to be obtained through the national standards organizations.

BRIEF HISTORY

The ISO Recommendation R 1563, *Alginate 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. 1563, 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.

ALGINATE IMPRESSION MATERIAL

INTRODUCTION

This ISO Recommendation is technically indetical with F.D.I.* Specification No. 9, 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 classification of and requirements for alginate 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 powder form containing an alginate as the gel-forming ingredient.

3. CLASSIFICATION

Alginate impression materials may be classified into the following types :

- **Type I** : Fast setting (see clause 4.2.6);
- **Type II** : Normal setting (see clause 4.2.6).

* Fédération Dentaire Internationale.

4. REQUIREMENTS

4.1 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 4.3), the material should form a smooth plastic mass suitable for taking impressions in the mouth.

4.2 Special requirements

- 4.2.1 *Odour and flavour.* The material when used in accordance with the manufacturer's instructions should not have an unpleasant odour or flavour.
- 4.2.2 *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 the accidental ingestion of 10 ml (see clause 8.3).
- 4.2.3 *Irritation.* The material used in accordance with the manufacturer's instructions should not normally cause visible evidence of irritation of the normal oral mucosa.
- 4.2.4 *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 alginate impression in accordance with clause 7.2.2.5 should for the full width of the specimen reproduce the line 0.075 mm wide on the test block illustrated in Figure 1.
- 4.2.5 *Mixing time.* The time of mixing, as stated in the manufacturer's directions, to obtain a smooth working consistency should be not more than 1 minute.
- 4.2.6 *Setting time.* The setting time when tested as in clause 7.2.3 should not be less than 60 seconds nor more than 120 seconds, for Type I – Fast setting – and should be not less than 120 seconds nor more than 4 minutes and 30 seconds for Type II – Normal setting.
- 4.2.7 *Working time.* The working time when tested as in clause 7.2.4 should be not less than 1 minute 15 seconds for Type I – Fast setting – and should be not less than 2 minutes for Type II – Normal setting.
- 4.2.8 *Uniformity.* The ingredients, after mixing, should not segregate. The mixed material should be homogeneous, have a smooth surface, and should be free from lumps and granules.
- 4.2.9 *Permanent deformation.* The permanent deformation should be not more than 3.0 % after 10.0 % strain is applied for 30 seconds when tested in accordance with clause 7.2.5.
- 4.2.10 *Compressive strength.* The compressive strength should be not less than 0.34 MN/m² (3.5 kgf/cm²) when tested in accordance with clause 7.2.6.
- 4.2.11 *Strain in compression.* The strain should be not less than 10 % nor more than 20 % 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 7.2.7.
- 4.2.12 *Deterioration.* The compressive strength of the material when tested as in clause 7.2.6 after storage as described in clause 7.2.8 should be not less than 0.25 MN/m² (2.6 kgf/cm²).

4.3 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 :

- 4.3.1 *Powder-water ratio.* The powder-water ratio in grammes of powder and millilitres of water.
- 4.3.2 *Mixing.* The time and method of mixing.
- 4.3.3 *Temperature.* The temperature of the water and the material.
- 4.3.4 *Set.* The time in the mouth for proper set.
- 4.3.5 *Special treatment.* Any special treatment of the impression, such as use of fixative solution, in the interval between withdrawal from the mouth and preparation of the gypsum cast.