AS 1278—1982
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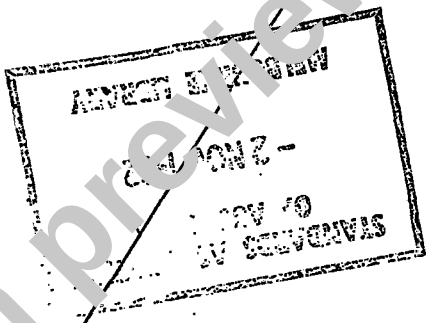
Australian Standard 1278—1982

RESIN-BASED DENTAL RESTORATIVE MATERIALS

The Tariffs, Instruments, Materials and Equipment Committee of the Australian Dental Association has adopted this standard for use in connection with its program for accreditation of certified dental products, lists of which are published periodically. Enquiries regarding this program should be addressed direct to the Australian Dental Association. When used in connection with the program, the standard is known as Australian Dental Standard (ADS) 1278—1982.



[Title allocated by Defence Cataloguing Authority: FILLING MATERIAL, DENTAL (Resin-based)]

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The following interests were represented on the committee responsible for the preparation of this standard:

Australian Dental Association
Australian Dental Standards Laboratory
Australian Dental Trade Association
Confederation of Australian Industry
Dental Schools
Department of Defence
Technical Consultants
Victorian Employers Federation

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PREFACE

This edition of this standard was prepared by the Association's Committee on Synthetic Resins, under the direction of the Dental Materials and Equipment Standards Committee, to supersede AS 1278—1973, Dental Composite Filling Materials. The standard is one of a series of standards intended for use in assessing the quality of dental goods used in Australia.

This edition is based on ISO 4049, Resin-based Dental Filling Materials, and cognizance was also taken of the existing requirements of AS 1278—1973.

Unlike ISO 4049, tests for radiopacity and depth of cure for Type II materials are included so that the manufacturer's claims could be checked. Further, unlike ISO 4049, composite resins are classified into two types because of recent developments with these materials, and, in line with current thinking, the test for colour stability does not involve a heating procedure.

In this edition the title has been changed so that any materials of the resin-based type are not excluded, although most of the materials are normally referred to as composite restorative materials. Also, this edition takes account of recent developments by making provision for radiation-cured materials and has a requirement for radiopacity, if such a claim is made.

The terms 'initial set time' and 'final set time' are used because they are obtained using an oscillating rheometer, and although they are related to what the clinician may consider as the working and setting time respectively, they may not have the same value.

The Australian Dental Standards Laboratory, 240 Langridge Street, Abbotsford, Victoria, 3067, has facilities for testing materials for compliance with this standard.

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STANDARDS ASSOCIATION OF AUSTRALIA

Australian Standard
for
RESIN-BASED DENTAL RESTORATIVE MATERIALS

1 SCOPE. This standard specifies requirements for resin-based dental filling materials intended for use as direct restorations, the polymerization of which is initiated by chemical or external energy sources.

2 REFERENCED DOCUMENTS. The following standards are referred to in this standard:

AS 2193	Methods for Calibration and Grading of Force-measuring Systems of Testing Machines
BS 5828	Methods of Biological Assessment of Dental Materials.

3 DEFINITIONS. For the purpose of this standard, the following definitions apply:

3.1 Initial set time—the time from the start of mixing to the initial change in viscosity, as detected by the oscillating rheometer.

3.2 Final set time—the time from the start of mixing to the time the material becomes rigid when detected by the oscillating rheometer.

3.3 Manipulation time—that period of time measured from the end of mixing during which it is possible to manipulate the material without an adverse effect on its properties.

4 CLASSIFICATION. The material shall be classified according to the method of activation, as follows:

(a) Type I ..... Chemically cured.

(b) Type II ..... Photopolymerized.

5 TEST CONDITIONS. All tests shall be performed at the following conditions:

(a) Temperature ..... 23 ± 1°C.

(b) Relative humidity ..... 50 ± 5 percent.

The test equipment and test material shall be equilibrated at the above conditions prior to testing.

6 MATERIAL REQUIREMENTS.

6.1 General. When used in accordance with the manufacturer's instructions (see Clause 15), the material shall readily produce a stable, aesthetic restoration free from harmful effects.*

Liquid components shall be free from deposits or sediment, and pastes and/or powder shall be free from extraneous matter. Paste or powder components shall show no sign of segregation, unless adequate instructions are given for their homogenization (see Clause 15).

6.2 Shade. If the material is supplied in pre-coloured standard shades, then each shade shall be capable of fulfilling the test requirements. The colour of the hardened material shall closely match the manufacturer's shade guide, if supplied, and shall not vary significantly from one sample to another.

6.3 Tinting and Blending. In the event of a material being supplied for tinting or blending to the user's prescriptions, the test requirements shall apply both when the maximum recommended proportion of tinter and blender (see Clause 15) is used and with the base material itself.

7 STORAGE LIFE. The expiry date shall be marked prominently on the package if the manufacturer cannot guarantee a storage life of at least one year from the date of manufacture, when stored in accordance with the manufacturer's instructions.

8 INITIAL SET TIME OF TYPE I MATERIALS. When determined in accordance with Appendix A, the initial set time of Type I materials shall be more than 90 s.

9 FINAL SET TIME OF TYPE I MATERIALS. When determined in accordance with Appendix B, the final set time of Type I materials shall be not more than 5 min.

10 DEPTH OF CURE FOR TYPE II MATERIALS. When determined in accordance with Appendix C, the depth of cure for Type II materials shall be more than 1.5 mm.

The depth of cure claimed by the manufacturer shall not exceed the measured value by more than 0.5 mm.

11 FLEXURAL STRENGTH. When determined in accordance with Appendix D, the flexural strength of materials shall be more than 50 MPa.

12 RADIOPACITY. If the manufacturer claims that the material is radiopaque, then the radiopacity shall be not less than 1 mm of aluminium equivalent to 1 mm of resin-based restorative material, when determined in accordance with Appendix E.

13 OPACITY. When determined in accordance with Appendix F, the opacity shall be such that the contrast ratio $C_{0.70}$ of a specimen 1 mm thick shall be not less than 0.35 nor more than 0.55, unless the material is intended for specialized application for which aesthetics are not a consideration.

NOTE: The contrast ratio $C_{0.70}$ is the ratio between the daylight apparent reflectance of the restorative material (1 mm thick specimen) when backed by a black backing, and the daylight apparent reflectance of the specimen when backed by a white backing having a daylight apparent reflectance of 70 percent relative to magnesium oxide.

14 COLOUR STABILITY. When the material is tested in accordance with Appendix G, there shall be not more than a slight change in colour.

*BS 5828 may be referred to for guidance.