



American National Standard/
American Dental Association
Specification No. 39

Pit and Fissure Sealants

ANSI/ADA Specification No. 39/ISO 6874:2005, *Dentistry —
Polymer-based pit and fissure sealants* (ISO 6874:2005, IDT)



American Dental Association
Council on Scientific Affairs 2006

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**AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 39 FOR
PIT AND FISSURE SEALANTS**

The Council on Scientific Affairs of the American Dental Association has approved American Dental Association Specification No. 39 for Pit and Fissure Sealants. This and other specifications for dental materials, instruments and equipment are being formulated by working groups of the ADA Standards Committee on Dental Products (formerly Accredited Standards Committee MD156 for Dental Materials, Instruments and Equipment). The Committee has representation from all interests in the United States in the standardization of materials, instruments and equipment in dentistry. The Council has adopted the specifications, showing professional recognition of their usefulness in dentistry, and has forwarded them to the American National Standards Institute with a recommendation that the specifications be approved as American National Standards. The American National Standards Institute granted approval of ADA Specification No. 39 as an American National Standard on July 26, 2006.

The Council thanks the working group members and the organizations with which they were affiliated at the time the specification was developed: Frederick Eichmiller (chairman), American Dental Association Health Foundation Paffenbarger Research Center, Gaithersburg, MD; Wallace F. Chong, Hilo, HI; Scott Erickson, 3M ESPE Dental Products, St. Paul, MN; Ros Randall, 3M ESPE Dental Products, St. Paul, MN; Gary Severance, Ivoclar North America, Amherst, NY; and Paulette Spencer, UMKC School of Dentistry, Kansas City, MO.

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FOREWORD

(This Foreword does not form a part of ANSI/ADA Specification No. 39 for Pit and Fissure Sealants).

This revised specification is an adoption of ISO 6874: 2005, Dentistry – Polymer-based pit and fissure sealants. The ADA SCDP working group examined the standard and found it acceptable for adoption as revised ANSI/ADA Specification No. 39. The efficacy of pit and fissure sealants for the prevention of dental caries is widely accepted. The polymer-based materials intended for this purpose and covered by this specification harden by a free-radical polymerization reaction that is either initiated by mixing components or by external energy, e.g. visible light.

In this revision of ANSI/ADA Specification No. 39, the test for depth of cure has been aligned with ISO 4049:2000. The requirements and tests for uncured film thickness, sensitivity to ambient light and curing time for Type 2 sealants have been deleted.

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1 SCOPE

This Specification specifies requirements and test methods for polymer-based materials intended for sealing pits and fissures in teeth. This Specification covers both self-cured and external-energy-activated materials.

2 NORMATIVE REFERENCES

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 8601, Data elements and interchange formats — Information interchange — Representation of dates and times.

(ISO standards are available from the American National Standards Institute, 25 W. 43rd St., New York, NY 10036).

3 CLASSIFICATION

For the purposes of this Specification, polymer-based pit and fissure sealants are classified, according to the method of curing, as follows:

Class 1: Materials whose setting is effected by mixing an initiator and activator ("self-curing" materials).

Class 2: Materials whose setting is effected by the application of energy from an external source, such as visible light ("external-energy-activated" materials).

4 REQUIREMENTS

4.1 Biocompatibility

See ISO 7405 and ISO 10993-1 for guidance on biocompatibility.

4.2 Physical properties

4.2.1 Working time, Class 1 sealant

The working time for Class 1 sealants, determined in accordance with 6.4, shall not be less than 40 s.

4.2.2 Setting time, Class 1 sealant

The setting time for Class 1 sealants, determined in accordance with 6.5, shall not be greater than 5 min.

4.2.3 Depth of cure, Class 2 sealant

The depth of cure for Class 2 sealants, determined in accordance with 6.6, shall not be less than 1.5 mm. If the material is supplied in more than one shade, each shade shall comply with this requirement.

5 SAMPLING

The test sample shall consist of a retail package, or packages, from the same batch containing sufficient material (a minimum of 20 g) to carry out the specified tests and repeat tests, if necessary.

6 TEST METHODS