



American National Standard/American Dental Association
Specification No. 62

Dental Abrasive Pastes

ADA American
Dental
Association®
Council on
Scientific Affairs

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AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 62 FOR DENTAL ABRASIVE PASTES

American Dental Association Specification No. 62 for Dental Abrasive Pastes has been approved by the Council on Scientific Affairs of the American Dental Association. This and other specifications for dental materials, instruments and equipment are being formulated by working groups of the American Dental Association's Standards Committees on Dental Products. The Council acts as administrative sponsor of that committee, which 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. Approval of ADA specification No. 62 as an American National Standard was granted by the American National Standards Institute on February 17, 2005. This standard becomes effective February 17, 2006.

The Council thanks the working group members and the organizations with which they were affiliated at the time the specification was developed: Bruce Schemehorn (Chairman), Indiana University, Indianapolis, IN; Ramon Baez, University of Texas Health Science Center, San Antonio, TX; Larry Farrell, John O. Butler Co., Chicago, IL; Paul Hammesfahr, Dentsply Caulk, Milford, DE; John Hefferren, University of Kansas, Lawrence, KS; Mark Putt, Indiana University, Indianapolis, IN; George Stookey, Indiana University, Indianapolis, IN.

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FOREWORD

(This foreword does not form a part of ANSI/ADA Specification No. 62 for Dental Abrasive Pastes).

For many years dental abrasive pastes have been extensively used by the dental profession to remove exogenous deposits from teeth.

Commercially-available preparations of dental abrasive pastes vary considerably in their particular abrasive distribution in order to fulfill the wide range of needs expected of such materials. Unfortunately, there is no uniformity of labeling of such preparations and a given "grade" from one supplier is typically quite different from the same "grade" provided by another supplier. This lack of uniformity presents obvious problems to both dental practitioners and dental laboratories.

This specification includes a test which addresses the relative abrasivity of these products but does not directly relate to the clinical application of cleaning the tooth surface. To distinguish the abrasivity of prophylactic pastes from dentifrices, a different nomenclature will be used. The enamel abrasivity will be known as Prophylactic Paste Enamel Abrasion (PPEA) and the dentin abrasivity will be known as Prophylactic Paste Dentin Abrasion (PPDA).

In view of the foregoing, this specification has been developed by the Subcommittee to fulfill the following objectives.

1. To provide a degree of assurance of the absence of gross contaminants in such preparations; and,
2. To provide at least minimal assurance of the safety of abrasive prophylactic pastes for intraoral use.

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DENTAL ABRASIVE PASTES**

1 SCOPE AND CLASSIFICATION

1.1 Scope

This specification is for in-office abrasive pastes used in dentistry for removing stains and other exogenous materials from natural tooth structures and prostheses.

2 APPLICABLE SPECIFICATIONS

2.1 Specifications

American National Standard Z210.1 (ASTM 380) (1974) has been used as a guide in selecting symbols, units of measurement, procedures for SI Style and Usage, and for procedures for conversion and rounding in this specification. ANSI/ADA Document No. 41 for Recommended Standard Practices for Biological Evaluation of Dental Materials contains the following procedures and acceptance criteria for dental abrasive powders (Type I only); 4.4.6 Oral LD 50 and 4.4.9 Mucus Membrane Irritation. Copies of ANSI/ADA Specifications may be obtained from the American Dental Association, Department of Standards Administration, 211 E. Chicago Avenue, Chicago, IL 60611.

3 REQUIREMENTS

3.1 Total fluoride

The total fluoride concentration (if fluoride is present) shall not exceed the limits set by national laws and regulations and in no case shall the total fluoride concentration exceed 1.23 % by weight. Test in accordance with one of the procedures given in Appendix A. The EC (European Community) method¹ or other validated methods of similar sensitivity and accuracy^{2,3} may be used (see Appendix B).

3.2 Material

The abrasive system of the product shall be indicated on the label of the immediate container.

3.3 Foreign material

When tested according to 4.3.1 the material shall be free of foreign material.

3.4 Heavy metals

The maximum concentration, when tested according to 4.3.2, shall not exceed the limits set by national laws and regulations. In no case shall the total heavy metal concentration in the prophylactic paste be greater than 20 ppm.

3.5 The abrasivity of the product to enamel and/or dentin should not exceed the limits for the specified abrasion level outlined below: