ANSI/ADA Specification No. 30
Reaffirmed by ANSI: October 2010

American National Standard/
American Dental Association
Specification No. 30

Dental Zinc Oxide – Eugenol and Zinc Oxide – Non-Eugenol Cements

Modified adoption of ISO 3107:1988, Dental zinc oxide — eugenol cements and dental zinc oxide — non-eugenol

American Dental Association
Council on Scientific Affairs 2000

Reaffirmed: October 2010

AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 30 FOR DENTAL ZINC OXIDE–EUGENOL AND ZINC OXIDE–NON-EUGENOL CEMENTS

American Dental Association Specification No. 30 for Dental Zinc Oxide–Eugenol and Zinc Oxide–Non-Eugenol Cements 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 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. Approval of ADA Specification No. 30 as an American National Standard was granted by the American National Standards Institute on September 21, 2000. This standard becomes effective September 21, 2001.

The Council thanks the working group members and the organizations with which they were affiliated at the time the specification was developed: John M. Powers (Chairman), University of Texas Health Sciences Center at Houston, Houston; Keith Moore (Secretary), Indiana University, Indianapolis; Stephen Bayne, University of North Carolina, Chapel Hill; Richard Bennett, Dentsply/Caulk, Milford, DE; James Forbes, Unitek Corporation, Monrovia, CA; Trenholm Meyer, T.N. Meyer and Associates, Cincinnati, OH; and Sophia Jose, American Dental Association, Chicago, IL.

Reaffirmed: October 2010

AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 30 FOR DENTAL ZINC OXIDE–EUGENOL AND ZINC OXIDE–NON-EUGENOL CEMENTS

FOREWORD

(This foreword does not form a part of the ANSI/ADA Specification No. 30 for Dental Zinc Oxide–Eugenol and Zinc Oxide–Non-Eugenol Cements)

This specification is essentially identical (exceptions noted below) to the ISO Standard 3107, Dental Zinc Oxide–Eugenol Cements and Zinc Oxide–Non-Eugenol Cements, which was approved by Technical Committee ISO TC106, Dentistry, of the International Organization of Standardization (ISO).

This specification mainly differs from ISO 3107 in the following:

1) The minimum setting time at 37 °C for Type III materials has been lowered from 3 minutes to 2 minutes. This change was made so that otherwise acceptable commercial products could meet the specification.

2) Film thickness for type I cements has been changed from 25 to 40 µm. This change was made because materials currently marketed as type I cements do not meet the 25 µm requirement. The working group agreed that there was no clinical justification for a temporary luting cement to be so restricted.

The change in film thickness is the only revision made in the Revised American National Standard/American Dental Association Specification No. 30 for Dental Zinc Oxide-Eugenol Cements and Zinc Oxide-Non-Eugenol Cements, which was approved in March 1990. As the title implies, this specification covers non-eugenol cements containing oxide and aromatic oils intended for temporary cementation. In addition, it also includes a paste/paste category for temporary restorations.

INTRODUCTION

Specific qualitative and quantitative requirements of freedom from biological hazard are not included in this national standard but it is recommended that, in assessing possible biological or toxicological hazards, reference should be made to ISO/TR 7405 Biological Evaluation of Dental Materials.

Reaffirmed: October 2010

AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 30 FOR DENTAL ZINC OXIDE–EUGENOL AND ZINC OXIDE–NON-EUGENOL CEMENTS

1. SCOPE

This standard specifies the requirements and test methods for zinc oxide–eugenol or zinc oxide–non-eugenol cements supplied as two separate components that may be either powder/liquid or paste/paste and are suitable for use in the oral cavity. These non-aqueous cements may contain eugenol or an aromatic oil, compounds capable of reacting with zinc oxide—such as accelerators—and gums, resins and inert inorganic fillers.

2. FIELD OF APPLICATION

This standard covers commercially manufactured zinc oxide–eugenol and modified zinc oxide–eugenol cements suitable for use in restorative dentistry for temporary cementation, for permanent cementation—such as temporary restorations and bases—and as cavity liners. This standard also covers non-eugenol cements containing zinc oxide and aromatic oils suitable for temporary cementation.

3. REFERENCES

ISO 2590 General Method for the Determination of Arsenic-Silver Diethyldithiocarbamate Photometric Method

ISO/TR 7405 Biologic Evaluation of Dental Materials

4. CLASSIFICATION

For the purposes of this standard, zinc oxide–eugenol cements are classified, according to their intended use in restorative dentistry, into the following types:

Type I: For temporary cementation—Setting and non-setting

Class 1: Powder and liquid
Class 2A: Setting paste and paste containing eugenol
Class 2B: Setting paste and paste not containing eugenol
Class 3: Non-setting paste and paste

Type II: For permanent cementation

Class 1: Powder and liquid

Type III: For temporary restorations and bases

Class 1: Powder and liquid
Class 2: Paste and paste

Type IV: For cavity liners

Class I: Powder and liquid
Class II: Setting paste and paste

Zinc oxide–non-eugenol cements covered by this standard are indicated as such.

5. REQUIREMENTS

5.1 Material

The components of the material, when mixed in accordance with the manufacturer's instructions, shall produce a material with characteristics suitable for its intended use within a given time.