



American National Standard/
American Dental Association
Standard No. 128

Hydrocolloid Impression Materials

Identical adoption of ISO 21563:2013, *Dentistry-Hydrocolloid Impression Materials*

ADA American
Dental
Association®
Council on
Scientific Affairs

2015

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**AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION STANDARD NO. 128
FOR HYDROCOLLOID IMPRESSION MATERIALS**

The Council on Scientific Affairs of the American Dental Association has approved revised American Dental Association Standard No. 128 for Hydrocolloid Impression Materials. This and other standards for dental materials, instruments and equipment are being formulated by working groups of the ADA Standards Committee on Dental Products. 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 standards, showing professional recognition of their usefulness in dentistry, and has forwarded them to the American National Standards Institute with a recommendation that the standards be approved as American National Standards. The American National Standards Institute granted approval of revised ADA Standard No. 128 as an American National Standard on January 29, 2015.

The ADA Standards Committee on Dental Products thanks the members of Working Group 2.10 and the organizations with which they were affiliated at the time the standard was developed:

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FOREWORD

(This Foreword does not form a part of ANSI/ADA Standard No. 128 for Hydrocolloid Impression Materials).

ANSI/ADA Standard No. 128 is an identical adoption of ISO 21563:2013, Dentistry – Hydrocolloid impression materials. ADA SCDP Working Group No. 2.10 on Impression Materials examined the International Standard and found it acceptable for identical adoption as ANSI/ADA Standard No. 128.

ANSI/ADA Standard No. 128:2015 cancels and replaces ADA Standard No. 18 for Dental Alginate Impression Material and ANSI/ADA Standard No. 82 for Combined Reversible/Irreversible Hydrocolloid Impression Materials.

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INTRODUCTION

Parties seeking clarification of any provisions of this document, or desiring to recommend improvements for the next edition, are encouraged to do so by contacting the ADA Standards Committee on Dental Products, American Dental Association, 211 East Chicago Ave., Chicago, IL 60611 or standards@ada.org.

AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION STANDARD NO. 128 FOR HYDROCOLLOID IMPRESSION MATERIALS

1 SCOPE

This standard specifies the requirements and tests for helping determine whether the elastic aqueous agar and alginate hydrocolloid dental impression materials, as prepared for retail marketing, are of the quality needed for their intended purposes. It also specifies requirements for labelling and instructions for use.

NOTE This standard specifies no requirements or tests for freedom from unacceptable biological hazards. However, it is recommended that, to address possible biological hazards associated with the use of hydrocolloid impression materials, interested parties should refer to ANSI/ADA Standard No. 41^[1], ISO 7405^[2] and ISO 10993^[3]

2 NORMATIVE REFERENCES

The following referenced documents are indispensable for 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 1942 Dentistry — Vocabulary

ISO 6873 Dentistry — Gypsum products

ISO 3696 Water for analytical laboratory use — Specifications and test methods

(Copies of ISO Standards for dentistry may be obtained from the American Dental Association, Department of Standards Administration, 211 E. Chicago Ave., Chicago, IL, or <http://catalog.ada.org>. Other ISO Standards may be obtained from the American National Standards Institute, 25 West 43 St., New York, NY 10036; or www.ansi.org).

3 TERMS AND DEFINITIONS

For the purposes of this document, the terms and definitions given in ISO 1942 and the following apply.

3.1

bonding

adherence of the reversible and non-reversible impression material components constituting a single impression after each of the separate but interfacing materials has reached the level of elasticity and effective setting required for successful removal from the mouth.

3.2

bulk container

labelled consumer packaging or primary packaging container holding a greater amount of otherwise unpackaged granular, liquid, powder, or other loose substance than is usually needed for a single dental clinical or laboratory procedure

3.3

combined reversible/non-reversible impression material system

system of impression making in which a light bodied agar material is first syringed around selected teeth so that it can bond with the non-reversible alginate material that will be forced over it later during the formation of an impression

3.4

consumer packaging

retail packaging

sales packaging