



TECHNICAL DATA SHEET

Product: Alginate Impression Material

Product Description: Alpha-Dent® Alginate Impression Material is available in a variety of flavors and set types. This heavy body material is designed to produce consistent impressions. Each can includes powder scoop and vial.

Indications for Use: Alpha-Dent® Alginate Impression Materials are indicated for making dental impressions for fabrication of casts, for orthodontic models, opposing models and case study models.

Appearance: Fluffy, off-white powder.

Curing Mechanism: The material sets when mixed with tap or distilled water.

Shelf-Life: 24 months

Filler Type: Not applicable.

Main Composition (%w/w):

Sodium Alginate	5 – 15 %
Diatomaceous Earth	55 – 70 %
Retardant	0.5 – 3.5 %
Accelerator	5 – 15 %
Pigment	2.0 – 5.0 %
Filler	2.0 – 7.0 %
Potassium Titanium Fluoride	0.5 – 1.5 %
Flavor	< 2 %

Physical /Mechanical Properties: (Typical Values)

	<u>Fast Set</u>	<u>Normal Set</u>
Initial setting time (sec.)	90	155
Total working time (mm)	0.04	0.04
Recovery from deformation %	98	98
Strain in compression %	14.5	14.0
Compressive Strength Mpa	0.80	0.85
Compatibility to gypsum	Passes test	Passes test
Reproduction of details	Passes test	Passes test
Deterioration Mpa	0.6	0.5

Regulatory Classification:

This product is in conformity with the following standard(s) or other normative documents:

- Code of Federal Regulations 21 CFR Part 820 – Medical Device Quality System Regulation
- Code of Federal Regulations 21 CFR §872.3660 Impression Material
- International Standard ISO 21563:2013 Hydrocolloid Impression Materials
- ANSI/ADA Specification No. 18: 1992 Specification No. 18 for Dental Alginate Impression Material

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