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ALGINATE FOR DENTAL IMPRESSION

Intended use:
Alginate for dental impression. Gluten free. Comply with ISO 21563:2013 DENTISTRY – Hydrocolloid impression materials. Packaging: bag 453 gr

Product description:
ALGINMAX: fast setting dust free chromatic alginate with chromatic phase indicator. Color variations indicate the respective work for simple and precise use: violet during mixing, pink during working phase and positioning on the tray, pale blue during the time in mouth while setting. Suitable in general clinical practice for the creation of study models. Aroma: Vanilla-Mint or mixed Fruits
ALGINMAJOR: dust free fast setting alginate for general clinical practice. Aroma: Orange
ALGINPLUS and **ALGINPLUS TROPICAL:** high consistency, dust free chromatic alginate chromatic phase indicator. Color variations indicate the respective work for simple and precise use: dark orange during mixing, orange during the working phase and positioning on the tray, yellow during the time in mouth while setting. Suitable in general clinical practice for the creation of study models. Aroma: Tropical Fruits.
ALGINPLUS: fast setting **– ALGINPLUS TROPICAL:** normal setting
ALGINKID: high elastic, dust free fast setting alginate suitable for orthodontic practices. Aroma: Orange
ALGENIUX NORMAL: high consistency dust free alginate for maximum precision impressions with normal setting times. Aroma: Mint
ALGENIUX FAST: high consistency dust free alginate for maximum precision impressions with fast setting times. Aroma: Mint.

Area of application:
For any patient. The device is intended for use by dental professionals such as dentists and dental technicians**.**

Dosing accessories:
measuring spoons for water and powder

Mixing ratio:
(1 spoon= 9.5 g powder)
9,5 g powder: 20 ml Water
19 g powder: 40 ml Water
28.5g powder: 60 ml Water
38g powder: 80 ml Water

Procedure:
Avoid moisture contamination: open the refill package and transfer its contents into an air-tight container, like MAJOR ALGINBOX, immediately after opening. Before any use, shake appropriately the container to loosen the alginate powder. Moisture and other contaminations lead to incorrect chemical reactions (working times, viscosity) and eventually to unacceptable impressions results. Use only well dry and clean equipment (mixing bowl, spatula, mixer, etc).

Directions:
Dispense the alginate powder from the container using the spoon provided and level the powder in the spoon with a spatula. Place the powder into a mixing bowl and add the corresponding water. Two spoons of alginate and two spoons of water are generally required for a complete impression. Mix the powder and water to a homogeneous consistency using a mixing spatula. Refer to the manufacturer's instructions when using automatic mixers.

	ALGINMAX	ALGINMAJOR	ALGINPLUS	ALGINPLUS TROPICAL	ALGINKID	ALGENIUX NORMAL	ALGENIUX FAST
Mixing time	35 sec.	35 sec.	35 sec.	35 sec.	30 sec.	35 sec.	35 sec.
Working time*	80 sec.	80 sec.	80 sec.	120 sec.	70 sec.	100 sec.	90 sec.
Minimum time in the mouth	40 sec.	40 sec.	40 sec.	80 sec.	40 sec.	80 sec.	60 sec.
Initial Setting time*	80 sec.	80 sec.	80 sec.	120 sec.	70 sec.	100 sec.	90 sec.
Total Setting time*	120 sec.	120 sec.	120 sec.	200 sec.	110 sec.	180 sec.	150 sec.

*Times with * apply from the start of mixing at a temperature of 23°C/73°F for both powder and water with deionized water. These times are reduced by higher temperatures and lengthened by lower temperature. Variations in water hardness may also result in deviations from these times. If tap water is preferred, some practical tests will give the needed information on times.*

Model fabrication:
Best results are achieved by rinsing the impression thoroughly after removal from the mouth, pouring it immediately after cleaning.
Impression storage: If longer storage is required, the impression should be kept in a firmly sealed plastic bag (relative humidity of 100%). This is essential for optimum results. The impression has a dimensional stability (without significant shrinking) of 5 days or 120 hours. Store or pack in a way to avoid contamination and deformation.

Disinfection:
Impressions may be treated with standard disinfectant solutions. After removal from the mouth and before disinfection thoroughly clean the impression with water, to remove biological residuals. Use a hospital-level disinfectant or high-level disinfectant intended for alginate impressions disinfecting. Use disinfectants with short-term contact time (max 10 min). No specific products or brands are recommended.
Procedure: Proceed by immersing in the disinfecting solution for the prescribed time. Alternatively, spray accurately the impression with disinfectant solution and then put the impression in a sealed plastic bag for the prescribed time, then clean with water. As a general recommendation, it is approved the use of water solutions releasing chlorine (for instance: sodium hypochlorite), with a Chlorine concentration of 5000 ppm. The approved procedures are by immersion or by spraying; in both cases with a recommended contact time of 10 min. Please follow the respective manufacturer's instructions for disinfection and processing.

Compatible plasters (ISO 6873: 2013):
it is recommended the use of the following gypsum products: Whip Mix Microstone -Type 3, Whip Mix Prima-Rock-Type 4, Whip Mix Hard-Rock -Type 5

Product storage:
The alginates shall be conserved into an air-tight container (as MAJOR ALGINBOX) in a cool and dry area, protected by excess heat.
Shelf-life: the product in a sealed bag has a shelf life of 6 years from the date of production, as printed on the package.

Contraindication and directions for patient safety:
In case of allergy to one of the components, irritation, redness, or signs of hypersensitivity may occur.
Before using, a possible existing allergy potential of the patient should be clarified as well as an allergic reaction to the current product components in the past. In these cases, the product must not be used. After removal of the impression, ask the patient to rinse well his mouth and check for any possible residuals left.
Taking multiple impressions of the same jaw (more than 3 or 4 in the same session) can cause mucosal irritation

CPL SAFETY INFORMATION FOR USERS

The product is not subject to the classification and labeling requirements as it is a medical device in its final state, destined for professional use (EU Regulation No. 1272/2008, Art. 1.5 d). The product is, therefore, also excluded from obligations of information (Material Safety Data Sheet, downstream safety information) as it is excluded from the application of Title IV EU Regulation No. 1907/2006 Art. 2.6.c.
This preparation contains dust that up to 5% may be composed of respirable crystalline silica (Cristobalite, CAS 14464-64-1); prolonged and massive inhalation of crystalline silica respirable dust may cause pulmonary fibrosis. In applying the following instructions, the quantity of dust released during daily dental practice should be such as to ensure the exposure levels below the risk thresholds are maintained. The material is, nevertheless, pretreated with binding agents in order to avoid the release of dust during measuring out and mixing processes.

Precautions and hygiene advice:
When measuring out the material, avoid dust formation and dispersion in the air. Do not inhale any dust that may be released. Close the containers immediately after use. Ensure that the measuring and mixing area is well-ventilated. Collect any material that may have been spilled with mechanical or suction devices. If mixed with water, the material may form slippery films

In the event of exposure:
Powders can cause skin irritation or allergic responses. Wear protective gloves and clothing. Remove the eventually resting powder from the skin and the clothing after the use of the product. Powders can cause serious eye irritation or mechanical corneal damage. Wear protective eyewear or mask; pay special attention if you are wearing contact lenses. In case of contact, do not rub or scratch; thoroughly flush with water or eye solutions for 10-15 minutes. Do not swallow. If swallowed, drink a lot of water. The ingestion of limited quantities is not dangerous.
The inhalation of alginate powders can be dangerous. Powders can cause irritation or increase susceptibility to respiratory illnesses. Do not breathe the dusts. Avoid generating airborne powders and dusts while dosing and mixing the material. Close containers immediately after use. In case of massive inhalation move the victim to fresh air and facilitate the respiration. Blow the nose, rinse with water the mouth and the throat to eliminate the resting material.

Occupational exposure limits:
The preparation does not contain powdered ingredients for which European Union exposure limits in the workplace exist. However, such limits do exist in some countries in Europe and around the world. For information, the following are some of the occupational exposure limits highlighted:

Exposure limits/ingredients	Quantiy	In some EU countries	In the USA (ACGIH 2013)
Powder		TLV 10 mg/m3 (inhalable) TLV 3 mg/m3 (respirable)	
Crystalline silica —Cristobalite	< 5.0% (respirable fraction)	0.05 mg/m3 or above	TWA 0.025 mg/m3
Zinc oxide	< 2.0%	2 mg/m3 (Zn, inhalable) 0.1 mg/m3 (Zn, respirable)	TWA 2 mg/m3 (respirable) STEL 10 mg/m3 (respirable)
Calcium sulfate dihydrate	< 20.0%	4 mg/m3 (inhalable) 1.5 mg/m3 (respirable)	TWA 10.0 mg/m3 (inhalable)
Talc	< 0.5%	0.5 mg/m3 or above	2.0 mg/m3 (inhalable)

Disposal information:
Discard damaged containers. Do not mix or use in combination with different products. Avoid contamination and cross-use. Dispose following local laws. Patient-contacted materials are at infection risk (CER cod 18.01.03*).

Waste classification (2014/955/ CEE)

Item	Material	Code	Name
Primary bags and container	PET - ALU -PE	150106	Packaging for waste – mixed packaging
Packages	Paper/cardboard	150101	Packaging for waste – paper/cardboard
Alginate container and contaminated material	Alginates and Fillers	180107	Waste of chemical products and medicines
Dental impressions	Alginates and Fillers	180103 *	Waste whose collection and disposal are subject to special requirements to prevent infections

NOTE: The General Safety and Performance Requirements suggest that any serious incident that led or might led to the death of a patient or other person, to the temporary or permanent serious deterioration of a patient's or other person's health, or to a public health threat, should be reported to the National Competent Authority and to the manufacturer.

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CE

MD
Medical device