Product Information On

Cavex Alginate Adhesive
Dust free Alginate Impression Materials

Legal manufacturer:	**Cavex Holland BV** **Fustweg 5** **2031CJ Haarlem**
Regulatory evaluator: **Signature:**	**Danny Stoelinga**
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- **Introduction.**

For an accurate impression of the dental arch one has to be convinced of a good adherence between the impression material and the impression tray. As alginate based materials do not show good or reliable bond to all types of tray materials, it is advised to use perforated or rim lock trays. Besides this the use of an alginate adhesive is propagated.

Cavex Alginate Adhesive improves chemically the adhesion between the impression tray and alginate impression material. Reducing the risk of deformation when removing the impression tray from the mouth.

Cavex Alginate Adhesive is exclusively developed for the use in combination with alginate impression material and not for silicone impression materials.

Cavex Alginate Adhesive is presented in the form of a blue coloured liquid packed in glass bottles. Each bottle cap is equipped with a small applicator brush. This applicator makes it easier to exactly target the adhesive. Every package consists of two bottles of 14 ml each. This is enough for over 50 impressions per bottle.

Cavex Alginate Adhesive is developed and manufactured by Cavex Holland B.V. of Haarlem, The Netherlands, a Company that is certified according to the provisions of the Council Directive 2017/745 concerning Medical Devices, against ISO 9001 and ISO 13485.

Cavex Alginate Adhesive bears the CE-marking of conformity.

- **Composition.**

The basic composition of Cavex Alginate Adhesive is as follows:

Isopropyl alcohol	: app. 60 – 80 % w/w
Polyamide resin	: app. 15 – 20 % w/w
Pigment	: app. < 1.0 % w/w
Toluene	: app. >2,5 - <3.0 % w/w

- **Manufacturing.**

The solvent serves as diluent for the polyamide resin and pigment. The raw materials are accurately weighed according to the formulation and recorded and filed. Then the polyamide resin and pigment are mixed into the diluent.

- **Directions for use.**

The Cavex Alginate Adhesive must be applied as a thin layer on a clean and dry surface of the impression trays.

The blue pigment in Cavex Alginate Adhesive facilitates the easy and exact application by the dentist. After application the diluents mixture needs 3 – 5 minutes to evaporate. Then the alginate impression material is applied and the impressions can be taken.

After the alginate impression material is fully set the Cavex Alginate Adhesive has formed a strong bond between the impression tray and the alginate impression material.
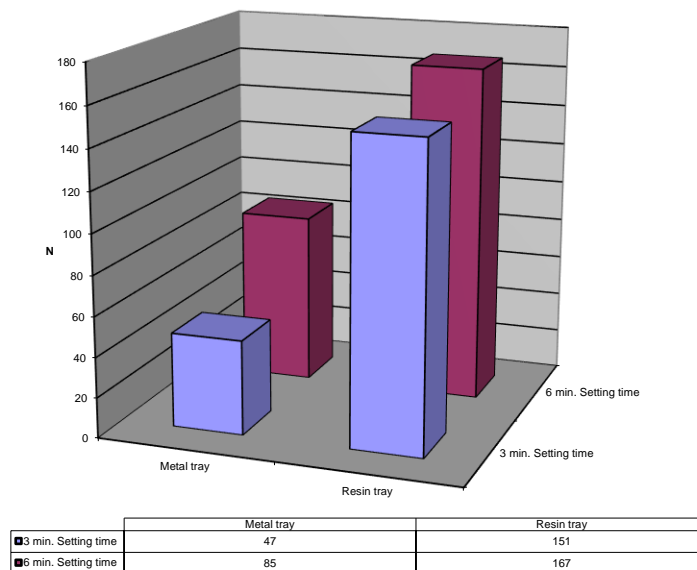Afterwards the trays can be cleaned by removing the alginate impression material, possibly with the use of Cavex GreenClean. The residue of Cavex Alginate Adhesive can simply be removed with isopropyl alcohol or ethanol (95%)

- **Quality Control.**

At present, a product standard for alginate adhesives is not available. Therefore, quality control is carried out according to a number of in-house standards.

The following two graphs show typical values for the adhesion of Cavex CA37 to metal and resin trays.

Cavex Alginate Adhesive adhesion in combination with Cavex CA 37.

	Metal tray	Resin tray
■3 min. Setting time	47	151
■6 min. Setting time	85	167

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- **Shelf-life test.**

Based on all this experience, we are able to guarantee the good quality of Cavex Alginate Adhesive for a period of 3 years, provided the bottle is unopened and stored in a cool and dry place.

- **Statement of non-toxicity.**

Cavex Alginate Adhesive contains toluene and isopropyl alcohol both irritating and flammable liquids. Therefore Cavex Alginate Adhesive is marked with the following warnings:
- Flammable liquid.
- Store in a cool and dry place.
- Do not expose to sources of ignition or temperatures above 49°C.
- Use in well ventilated areas.
- Close bottle immediately after use.
- Vapours may cause drowsiness and dizziness.

Cavex Alginate Adhesive can be safely used and is non-toxic to the patient as well as to the dental team when used according to the directions of the manufacturer.

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