Product Information
On

Cavex ColorChange

Dustfree Alginate Impression Material
With Color Change

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1. Introduction

Cavex ColorChange is an alginate impression material for dental use.
Cavex ColorChange has a setting time that makes it a suitable general purpose alginate impression material, that can also be used by the orthodontist.
It is presented in the form of a homogeneous, light-pink coloured powder with a nice peppermint flavour. A special characteristic of the powder is that it is dustfree: the powder is treated in such a way, that no dust is generated during dosing and mixing. This also facilitates the mixing process through easy absorption of water by the powder, offering both dentist and dental assistant convenient and hygienic handling.
After mixing with water, a smooth paste is formed that is loaded into an impression-tray and placed in the mouth of the patient. After hardening of the paste, due to a chemical reaction, an accurate impression is obtained, that can be taken out of the mouth without any deformation, because of its elastic nature.
A special feature of Cavex ColorChange is a change of color during the processing of the product at all stages that are relevant to the dentist:

- the powder itself is of a light-pink colour;
- upon contact with water and during the mixing time, the colour becomes violet;
- a colour change from violet to pink indicates the end of the mixing time; the mixed paste can now be loaded into the impression tray and the tray placed into the patient's mouth;
- as soon as the colour change from pink to white is completed, the material has set and the impression tray can be taken out of the patient's mouth for further processing.
- After a while the color of the impression will turn back to pink again. The moment that this phenomena will take place can be influenced by the use of disinfecting solutions. This final colorchange will not be of any influence on the physical properties of the impression material.

By pouring the impression with gypsum, or dental stone, a precise model of the situation in the mouth can be prepared, allowing the dental technician to construct a well-fitting dental prosthesis.

Cavex ColorChange impressions have dimensional stability of 9 days when:
- stored in a well-closed container preventing shrinkage by water evaporation and swelling by water absorbtion

Cavex ColorChange is in full compliance with the two most important Specifications for alginate impression material:

- EN 1641 (EN 21563)
- ADA No. 18

Cavex ColorChange is developed and manufactured by Cavex Holland B.V. of Haarlem, The Netherlands, a Company that is certified according to the provisions of the Regulation (EU) 2017/745 concerning Medical Devices, against ISO 9001 and EN ISO13485.

Cavex ColorChange bears the CE-marking of conformity.

2. Composition

The basic composition of Cavex ColorChange is as follows:

alginate	: app. 14% w
calcium sulphate	: app. 10% w
fillers	: app. 70% w
retarder, stabilisers and flavour	: app. 6% w
colour indicators	: trace amount

The alginate, a soluble salt of alginic acid (extracted from brown seaweed), serves as the thickener for water, giving the paste, upon mixing, the correct consistency. It also reacts chemically with calcium sulphate to make the paste harden into a solid impression.
The fillers give the mixture its mechanical strength and proper handling characteristics.
A retarder, sodium pyrophosphate, is used for achieving the proper hardening-time and the stabilisers will improve the surface-smoothness of the gypsum-cast.

3. Manufacturing

It is essential that alginate impression material does not come into contact with water during manufacturing and storage. Especially a combination of elevated temperature and moisture has an adverse effect upon the shelf-life of the material.
Cavex ColorChange is therefore manufactured and handled in an area with a temperature of app. 20 – 25 °C and a humidity below 70% R.H.

A number of the raw materials has to be pre-treated before use:

- some of them have to be dried in order to decrease their water content below an acceptable level
- some have to be sieved for removing undesired coarse particles

The raw materials are then accurately weighed according to the formulation, and the weight of all the raw materials of every single batch recorded and filed. Then they are fed into the mixer in a special, fixed order and mixed according to a standard program. A sample is taken for In-Process Control, which comprises the following points:

- absorption of water by the powder upon mixing
- consistency of the mixed paste
- smoothness of the paste and absence of coarse particles
- colour and flavour
- general appearance
- setting time

With the exception of the setting time, which is measured, these characteristics are judged through visual inspection by a trained and experienced staff, based on many years of experience.
The setting time is determined according to ADA Spec. No. 18, with a powder/water ratio of 23 g/50 ml.
For all tests, demineralized water is used with a temperature of 23 °C. Tests are carried out in an air-conditioned laboratory (temp. 21 – 23 °C, 40 – 60 % R.H.).
The formulation has been chosen such that the setting time is always too short. The laboratory then orders the addition of a certain amount of retarder to be mixed in, and the

mixture is checked again. This procedure is repeated another time until the setting time is within the accepted limits and all the above-mentioned points are considered satisfactory. Only then, the batch is released for packaging and marking with the appropriate batch number and the expiry-date. A large sample is taken to the laboratory for further testing.

4. Laboratory control

Every single batch is tested according to the entire EN 21563 Standard.

In the following Table, all the requirements of the EN 21563 Standard are listed together with the typical values for Cavex ColorChange.

Characteristic	**Colour**	**EN 21563**	**Cavex ColorChange**	
Powder/water ratio		–	23/50	g/ml
Mixing time	Violet → Pink	max. 60	30	sec
Total working time	Pink	*As stated by the manufacturer*	1.30	min
Total setting time	Pink → White		2.30	min
Setting time in the mouth		–	1.00	min
Compressive strength		min. 0.35	1.0	MPa
Recovery from deformation		min. 95	97	%
Strain in compression		5 – 20	17	%
Detail reproduction		50 µm line	complies	
Deterioration acc. to ADA No. 18		Compressive strength after test: min 0.26	0.7	MPa

5. Shelf-life test

The test on "deterioration", that is part of the ADA Specification No. 18, is already a good indication for the shelf-life of Cavex ColorChange.

The second part of our shelf-life test consists of storing a sample of every single batch in an oven at 50 °C. After 2 weeks, the material is tested for consistency and setting time. Normally, the consistency has become slightly thinner, and the setting time 10 – 40 sec. longer.

A sample of one batch out of the alginate-production of 1 week, is kept in the laboratory and tested for the setting time every 2 months over a period of 5 years. Normally, the setting time has become 40 – 60 sec. longer then.

Finally, every two months an unopened, original package is taken out of the alginate-production. At the end of its shelf-life the product is tested according to the entire EN 21563 Standard.
Based on all this experience, we are able to guarantee the good quality of Cavex ColorChange for a period of 5 years, provided the pack is unopened and stored in a cool and dry place.

6. Quality Control

A batch of Cavex ColorChange, that has passed all the tests, is released for sales.
In case of one or more requirements being not in specification, that batch is withdrawn and not sold.

7. Statement of non-toxicity

We hereby declare that Cavex ColorChange can be safely used and is non-toxic to the patient as well as to the dental team.
More specifically, it can be stated that Cavex ColorChange is free of lead (less than 5 ppm) and cadmium (less than 5 ppm).

Cavex ColorChange will also normally not be irritant to oral tissues and does not contain any hazardous ingredients in sufficient concentration to be harmful to human beings when used as directed, or in the event of accidental ingestion of 10 ml.