

Product Information On
Cavex Orthotrace
Dust free Alginate Impression Materials

Introduction

Cavex Orthotrace is an alginate impression material for dental use.

Cavex Orthotrace has an extra fast setting time, high elasticity, high tear resistance, can be poured twice with gypsum and is presented in a attractive fuchsia-coloured powder with a red-fruit flavour. Therefore, Cavex Orthotrace is particularly suited for orthodontics.

Cavex Orthotrace is also dust free: the powder is treated in such a way, that no dust is generated during dosing and mixing. This facilitates the mixing process through easy absorption of water by the powder, offering the orthodontist 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.

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 orthodontic appliance.

Cavex Orthotrace is in full compliance with the two most important specifications for alginate impression material:

- EN 21563
- ADA No. 18

Cavex Orthotrace 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 93/42/EEC as amended by Directive 2007/47/EC concerning Medical Devices, against ISO 9001 and ISO 13485.

Cavex Orthotrace bears the CE-marking of conformity.

Composition

The basic composition of Cavex Orthotrace is as follows:

alginate	: app. 14% w
calcium sulphate	: app. 10% w
fillers	: app. 70% w
retarder, stabilisers, pigment and flavour	: app. 6% w

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, the stabilisers will improve the surface-smoothness of the gypsum-cast and the pigment facilitates the "reading" of the impression by the dentist for a good judgement of its quality.

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 Orthotrace 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 have 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, demineralised 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.

End 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 Orthotrace.

Characteristic	EN 21563	Cavex Orthotrace	
powder/water ratio	–	23/50	g/ml
mixing time	max. 60	30	sec
total working time	<i>as stated by the</i>	1.10	min
total setting time	<i>manufacturer</i>	2.10	min
setting time in the mouth	–	1.00	min
compressive strength	min. 0.35	> 1.1	MPa
recovery from deformation	min. 95	> 96	%
strain in compression	5 – 20	14 – 16	%
detail reproduction	50 µm line	Complies	
deterioration acc. to ADA No. 18	compressive strength after test: min 0.26	0.6	MPa

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 Orthotrace.

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 – 30 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 20 – 40 sec. longer then.

Finally, every two months an unopened, original package is taken out of the alginate-production. At the end of it's 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 Orthotrace for a period of 5 years, when packed in a refill bag, provided the pack is unopened and stored in a cool and dry place.

Quality control

A batch of Cavex Orthotrace, 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.

Statement of non-toxicity

We hereby declare that Cavex Orthotrace 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 Orthotrace is free of lead (less than 5 ppm) and cadmium (less than 5 ppm).

Cavex Orthotrace 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.

Haarlem
CAVEX HOLLAND B.V.