

# Product Information On

## **Cavex Outline** Impression Paste Eugenol Free

|                              |  |
|------------------------------|--|
| <b>Legal manufacturer:</b>   | <b>Cavex Holland BV</b><br>Fustweg 5<br>2031CJ Haarlem                               |
| <b>Regulatory evaluator:</b> | <b>Danny Stoelinga</b>   |
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| <b>Version:</b>              | <b>2021-09</b>   |

- **Introduction.**

Cavex Outline Impression Paste Eugenol Free is intended for making accurate impressions of soft tissues, in particular the second impression with the individual tray technique for the edentulous mouth, and for rebasing of dentures.

Cavex Outline is presented as a two-paste system: a white paste, containing metallic oxides (such as zinc and magnesium) as the base component and a blue paste, containing fatty acid as the reactive component. Upon mixing homogeneously (controlled by a uniform blue colour), a very smooth paste with a soft consistency is formed, that easily flows under light pressure: an important characteristic for an impression paste to be used on soft tissues in the mouth.

Through a reaction between the metallic oxides and fatty acid, a chelate-network is formed, that makes the paste harden. The resulting impression is stable and non-sticky. It shows little or no elasticity so that any undercuts present have to be blocked out first. Due to its smooth consistency and the fine structure of the fillers, Cavex Outline shows a very good detail reproduction, even on soft tissues in the mouth.

Cavex Outline is free of eugenol and therefore highly patient-friendly.

Cavex Outline is in full compliance with the ANSI MD156-16 (1975) Standard.

Cavex Outline 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 Outline bears the CE marking of conformity.

- **Composition.**

The basic composition of Cavex Outline is as follows:

The white paste

|                 |        |      |
|-----------------|--------|------|
| metallic oxides | : app. | 80 % |
| vegetable oil   | : app. | 20 % |

The dark blue paste

|               |        |      |
|---------------|--------|------|
| fatty acid    | : app. | 69 % |
| fillers       | : app. | 21 % |
| natural waxes | : app. | 3 %  |
| organic acid  | : app. | 6 %  |
| pigment       | : <    | 1 %  |

- **Manufacturing.**

The white paste is manufactured as follows:

The powders are gradually added to the oil in a kneading machine, in which an extremely homogeneous, fine-textured paste can be manufactured.

The dark blue paste is manufactured as follows:

The ingredients are molten together by gently heating. Then, by adding a small amount of organic acid, the hardening time of that particular batch of blue paste is adjusted to match a batch of white paste, together forming a batch of Cavex Outline. Upon cooling, a soft paste is obtained, that can be easily extruded from the tube.

- **Laboratory control.**

Of every single batch of Cavex Outline, the working time and viscosity is tested according to in-house test methods. One combination out of a production series is tested according to the entire ANSI Standard.

In the following Table, typical values for Cavex Outline are listed, together with the requirements of ANSI MD156-16 (1975):

| Characteristic           | ANSI MD156-16<br>Type II (Soft) | Cavex Outline |     |
|--------------------------|---------------------------------|---------------|-----|
| Mixing ratio, blue:white |                                 | 1,0 : 2,2     | g/g |
| mixing time              | –                               | 45            | sec |
| working time             | –                               | 2.15 – 3.30   | min |
| initial setting time     | 3 – 6                           | 3             | min |
| final setting time       | max. 15                         | 4             | min |
| Consistency              | 20 – 45                         | 33            | mm  |
| cast surface             | smooth gypsum surface           | complies      | –   |
| penetration hardness     | 0,8 – 1,5                       | 1.3           | mm  |

- **Shelf-life test.**

There is no specific shelf-life test described for dental impression pastes.

Out of every production-run, we keep a combination of a white and a dark blue paste back in our laboratory for regular checks on the quality. In a period of 3 years, hardly any change in setting time is observed.

Based on this experience, we can guarantee the good quality of Cavex Outline for a period of 3 years when stored in the original containers in a cool place.

- **Quality Control.**

A batch of Cavex Outline, 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 Outline can be safely used and is non-toxic to the patient as well as to the dental team.

Cavex Outline 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.