Product II	Product Information On		
	Cavex Temporary Cement Temporary Cement – Eugenol Free		
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1. Introduction

Cavex Temporary Cement is intended for the cementation of temporary crowns and bridges. It is free of eugenol and will therefore, after its removal, not inhibit the polymerisation of a luting cement on composite basis.

Cavex Temporary Cement is presented as a two-paste system: a white BASE paste, containing metallic oxides (zinc and magnesium) as the reactive component and a yellow CATALYST paste, containing a fatty acid dimer as the reactive component. These two pastes can be mixed into a homogeneously light-yellow coloured cement in app. 30 seconds.

Through a reaction between the metallic oxides and the fatty acid dimer, a chelate-network is formed, that makes the cement harden. The set cement is sufficiently stable to hold the provisional prosthesis in situ for the time, needed for the manufacturing of the final prosthesis, crown or bridge, in the dental laboratory. After that period, the temporary crown or bridge can be removed without any problem for the dentist or discomfort for the patient and without damaging the tooth stump. The light-yellow colour of the cement, distinct from the colour of dentine, is a guide for easy removal of cement traces.

Cavex Temporary Cement is free of eugenol and therefore highly patient-friendly. It will also not inhibit the setting of composite cements or composite filling materials.

Cavex Temporary Cement is in full compliance with EN 1641 (ISO 3107) "Dental zinc oxide/eugenol cements and zinc oxide non-eugenol cements" as Type I.

Cavex Temporary Cement 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 Temporary Cement bears the CE marking of conformity.

2. <u>Composition.</u>

The basic composition of Cavex Temporary Cement is as follows:

The white BASE paste

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

The yellow CATALYST paste

fatty acid dimer : app. 69 % natural and modified resins : app. 21 % natural waxes : app. 3 % organic acid : app. 6 % pigment : < 1 %

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3. Manufacturing.

The white BASE 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, that can be easily extruded from the tube.

The yellow CATALYST paste is manufactured as follows:

The waxes and part of the fatty acid dimer are melted together by gentle heating. Then, the different resins are added under stirring, followed by the rest of the fatty acid dimer. By adding a small amount of organic acid, the hardening time of that particular batch of yellow paste is adjusted to match a batch of white paste, together forming a batch of Cavex Temporary Cement.

Upon cooling, a soft paste is obtained, that can be easily extruded from the tube.

4. <u>Laboratory control.</u>

Of every single batch of Cavex Temporary Cement, the working time is tested according to an in-house test method. Also, the viscosity of the white and yellow paste is measured as an in-process control. One combination out of a production series is tested according to the entire ISO 3107 Specification.

In the following table, typical values for Cavex Temporary Cement are listed, together with the requirements of ISO 3107 Specification:

Characteristic	ISO 3107	Cavex Temporary Cement	
pastes	homogeneous	homogeneous	
setting time	1.30 - 10	4 - 5	min
compressive strength	max. 35	8	Мра
acid-soluble content	max. 2	< 2	ppm
film thickness	max. 25	< 10	μm

5. Shelf-life test.

There is no specific shelf-life test described for dental temporary cements.

Out of every production-run, we keep a combination of a white and a yellow paste back in our laboratory for regular checks on the quality. After a period of 3 years, the product is still in full compliance with ISO 3107.

Based on this experience, we can guarantee the good quality of Cavex Temporary Cement for a period of 3 years when stored in the original containers (storage temperature: 5-25 °C).

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6. **Quality Control.**

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

Cavex Temporary Cement 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.

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