# **Product Information On**

## **Cavex Base Plate Pink and Cavex Base Plate Mica Free**

Intermediates in the Process of Making a Prosthesis

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#### Introduction.

Cavex Dental Base Plates are used as an intermediate in making a prosthesis: a base plate is modelled over a gypsum model, built-up with a wax-rim and artificial teeth and molars. After checking in the patient's mouth and possible corrections, the base plate (and wax) is replaced by synthetic resin.

Cavex Dental Base Plates are available in the form of pink-coloured plates of a special form to fit the average form of the mouth (upper or lower).

A recent development is the Cavex Dental Base Plate Mica Free, pink-coloured and also available as both uppers and lowers. The advantages of this new formula Base Plate can be summarised as follows:

- a crack-free, very smooth surface
- less porosity's
- · reduced risk of burning during processing
- less damage to cutting tools

The base plates can be easily softened over a flame, or otherwise, and modelled to the desired shape. Upon cooling, the base plate retains its shape to form a strong and dimensionally stable intermediate base for the prosthesis.

Cavex Dental Base Plate Pink and Cavex Dental Base Plate Mica Free are 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 ISO13485.

Cavex Dental Base Plate Pink and Cavex Dental Base Plate Mica Free bear the CE marking of conformity.

#### • Composition.

The basic composition of the various types of Cavex Dental Base Plates is approximately as given in the following table:

Raw material	Pink	Mica Free	
shellac	50	50	%
mica powder	30	-	%
talcum	-	20	%
wood resins	7.5	7.5	%
pigments and fillers	12.5	22.5	%

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The most important component of the Cavex Dental Base Plates is shellac, a resinous substance coming from the lac-insect. It is a thermoplastic material with a softening range that allows the base plate to be processed by hand. The mica-powder or fillers enhance the strength and prevent sticking, and the wood-resins serve as softeners.

### • Manufacturing.

The ingredients are carefully weighed and blended in a mixing-machine to form a homogeneous mixture. This mixture is fed into an extruder and transformed into a warm, plastic mass with the shellac molten. This plastic mass is pressed through a slit to form a strip, that is rolled out between a number of cylinders, gradually reducing the thickness to the desired value of 1.4 mm or 2.8 mm.

Finally, the individual plates are stamped with a die.

## • Laboratory control.

The testing-program for base plate comprises the following tests, mainly coming from the Australian Standard 1241-1973 for Dental Shellac Baseplates:

- general inspection of the plates (colour, surface smoothness)
- working properties (ease of softening with a flame, modelling over a gypsum model)
- softening point, (ASTM D 3461-76, which is essentially the same method as described in ASTM D 566-64, but using a sample cup with an orifice of 5.0 mm instead of 2.8 mm)
- transverse bending strength (Australian Standard 1241-1973)
- adaptability at 70°C (Australian Standard 1241-1973).

All these tests are carried out on a daily basis for every batch produced. The following Table gives typical values for the Cavex Dental Base Plates:

	Cavex Dental Base Plate Pink	Cavex Dental Base Plate Mica Free
general inspection: colour	complies	complies
surface		
working properties	comply	comply
softening point	100 - 110 °C	95 – 105°C
transverse bending strength	21 N	17 N
tensile strength	350 N	320 N
adaptability at 70 °C	complies	complies

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#### Shelf-life test.

There is no specific shelf-life test described for base plates. Under normal conditions, the quality of Cavex Dental Base Plates is hardly impaired upon storage.

It is obvious that storage at a too high temperature and/or load will lead to blocking of the base plates. Moreover, storage of shellac base plates at elevated temperatures for a longer period will lead to polymerisation of the shellac, making the base plates flexible and rubber-like.

It is therefore recommended that the product should be stored at cool to moderate temperatures. Prevent stocking the packs too high, in particular at elevated temperatures.

Under these conditions, the good quality of Cavex Dental Base Plate Pink and Cavex Dental Base Plate Mica Free can be guaranteed for a period of 3 years.

#### Quality Control.

A batch of Cavex Dental Base Plate Pink and Cavex Dental Base Plate Mica Free 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 Dental Base Plate Pink and Cavex Dental Base Plate Mica Free can be safely used and is non-toxic to the patient as well as to the dental team or the dental technician.

Cavex Dental Base Plate Pink and Cavex Dental Base Plate Mica Free 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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