

Product Information On

Cavex Yellow Wax

General Purpose Modelling Wax for Dentist and Dental Technician

Legal manufacturer:	Cavex Holland BV Fustweg 5 2031CJ Haarlem
Regulatory evaluator:	Danny Stoelinga
Signature:	
Regulatory manager:	Richard Wootman
Signature:	
Version:	2021-09

- **Introduction.**

Cavex Yellow Wax is a soft wax for the dentist and the dental technician. The main application is for blocking out undercuts and adjusting edge of impression trays.

Cavex Yellow Wax is presented in the form of yellow-coloured sheets.

Cavex Yellow Wax is developed and manufactured by Cavex Holland B.V. of Haarlem, The Netherlands, a Company that is certified according the provisions of the Council Directive 2017/745 concerning Medical Devices, against ISO 9001 and ISO 13485.

Cavex Yellow Wax bears the CE marking of conformity.

- **Composition.**

The basic composition of Cavex Yellow Wax is approximately as given in the following table:

Raw material	Cavex Yellow Wax
paraffin waxes (high- and low melting)	86.5%
micro-crystalline paraffin waxes (high- and low melting)	8.0%
Paraffin Oil	5.0%
Modifiers	0.5%
pigment	trace amount

Various types of paraffin's form the basic components of modelling waxes. In order to obtain the desired properties, the macro-crystalline paraffin waxes and modifiers are blended.

- **Manufacturing.**

The ingredients are carefully weighed and melted in a kettle. The molten wax is then homogenised by stirring, the pigment is added and the mixture is cooled to the desired temperature.

At that temperature, the wax is poured out and cooled down below the solidification point to produce sheets.

- **Laboratory control.**

At this moment, there is no valid ISO Standard for soft modelling waxes. Our own testing-program comprises of the following tests:

- General inspection of the sheets (colour, dimensions, surface smoothness).
- Working properties (ease of softening over a flame, modelling over a gypsum-model).
- Dropping point, which is a fast way of determining the melting-characteristic (ASTM D 566-64).
- Penetration, which is a measure for the hardness of a wax (ASTM D 1321-65).

The following table gives typical values for Cavex Yellow Wax:

Test	Cavex Yellow Wax
general inspection	colour and dimensions: comply
	surface: smooth, no cracks, no gross porosity's
working properties	comply
dropping point	70-80
penetration, unit of 0.1 mm	25 - 35

- **Shelf-life test.**

There is no specific shelf-life test described for modelling wax. Under normal conditions, the quality of Cavex Yellow Wax is hardly impaired upon storage. It is obvious that storage at a too high temperature and/or load will lead to blocking of the wax sheets.

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 Yellow Wax can be guaranteed for a period of at least 5 years.

- **Quality Control.**

A batch of Cavex Yellow Wax 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 Yellow Wax can be safely used and are non-toxic to the patient as well as to the dental team or the dental technician.

Cavex Yellow Wax will also normally not be irritant to oral tissues and do not contain any hazardous ingredients in sufficient concentration to be harmful to human beings when used as directed.