

Product Information On
**CAVEX SET UP SOFT, CAVEX SET UP REGULAR,
CAVEX SET UP HARD AND CAVEX SET XHARD**
General Purpose Modelling Wax for Dentist and Dental Technician

Introduction

Cavex Set Up form a series of waxes for the dentist and the dental technician. Their main application is the construction of the wax rim in which the artificial teeth and molars are placed, in the process of preparing a prosthesis.

The four types: Cavex Set Up Soft, Cavex Set Up Regular, Cavex Set Up Hard and Cavex Set Up XHard in particular differ in their flow properties at different temperatures, thus making the (X)Hard type more stable at higher temperatures than the Regular and Soft type.

All types: Cavex Set Up are tenacious, do not break easily and have exceptionally good handling properties.

They are presented in the form of red-coloured sheets, that can be easily softened over a flame, or otherwise, and modelled to the desired shape. Upon cooling, the wax retains its shape with great dimensional stability and excellent adhesiveness to the other dental materials involved.

Cavex Set Up Soft, Cavex Set Up Regular, Cavex Set Up Hard and Cavex Set Up XHard 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 93/42/EEC as amended by Directive 2007/47/EC concerning Medical Devices, against ISO 9001 and ISO 13485.

Cavex Set Up Soft, Cavex Set Up Regular, Cavex Set Up Hard and Cavex Set Up XHard bear the CE marking of conformity.

Composition

The basic composition of Cavex Set Up is approximately as given in the following Table:

Raw material	Cavex Set Up			
	Soft	Regular	Hard	XHard
paraffin waxes (high- and low melting)	64 %	61 %	70 %	70%
micro-crystalline paraffin waxes (high- and low melting)	31 %	39 %	25 %	25%
natural waxes	5 %	–	5 %	5%
pigment	trace amount			

The various types of paraffin's form the basic components of modelling waxes. In order to obtain the desired properties, the macro-crystalline paraffin waxes are blended with much softer and more ductile micro-crystalline paraffin waxes, and natural waxes.

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 on an endless belt and cooled down below the solidification point to form a strip of wax.

This strip is then rolled out between two cylinders to obtain the desired thickness of 1.5 mm, and individual sheets (18.6 x 8.9 cm) are cut off and packed, separated by sheets of greaseproof paper.

Laboratory control

At this moment, there is no valid ISO Standard for modelling waxes. All Cavex modelling waxes comply with the requirements for Type 1 products of ADA 24/24A and Type 2, Class 1 products of the ISO15854(2005) Our own testing-program comprises of the following tests:

1. General inspection of the sheets (colour, dimensions, surface smoothness).
2. Working properties (ease of softening over a flame, modelling over a gypsum-model).
3. Dropping point, which is a fast way of determining the melting-characteristic (ASTM D 566-64).
4. Penetration, which is a measure for the hardness of a wax (ASTM D 1321-65).
5. Congealing point (ASTM D 938-60).
6. Flow (ADA 24a + ISO15854)

For quality control, tests nr. 1-4 are carried out on a daily basis for every single batch produced. Tests nr. 5 and 6 are carried out regularly, but not daily (typical analysis).

The following Table gives typical values for Cavex Set Up Soft, Cavex Set Up Regular and Cavex Set Up Hard:

Test	Cavex Set Up			
	Soft	Regular	Hard	XHard
1. general inspection	colour and dimensions: comply surface: smooth, no cracks, no gross porosity's			
2. working properties	comply	comply	comply	comply
3. dropping point	63 °C	60 °C	61 °C	75°C
4. penetration, unit of 0.1 mm	23	18	17	12
5. congealing point	62 °C	58 °C	61 °C	73°C
6. flow at 23 °C	0.5%	0.4 %	0.3 %	0.1%
32 °C	10 %	5 %	4 %	0.2%
37 °C	65 %	60 %	47 %	22 %
45 °C	86 %	86 %	84 %	82 %

Note

The difference between the types is expressed particularly in the values for the flow (Test nr. 6), indicating that Cavex Set Up Hard and Cavex Set Up XHard are more stable at higher temperatures than Cavex Set Up Regular and Cavex Set Up Soft.

Shelf-life test

There is no specific shelf-life test described for modelling wax. Under normal conditions, the quality of Cavex Set Up 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 Set Up can be guaranteed for a period of at least 5 years.

Quality Control

A batch of Cavex Set Up, 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 Set Up Soft, Cavex Set Up Regular, Cavex Set Up Hard and Cavex Set Up XHard can be safely used and are non-toxic to the patient as well as to the dental team or the dental technician.

Cavex Set Up Soft, Cavex Set Up Regular, Cavex Set Up Hard and Cavex Set Up XHard 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.

Haarlem,

CAVEX HOLLAND B.V.