

Product Information On

Cavex Plastic Individual Tray

Thermoplastic Shellac Plates for Making an Individual Impression Tray

Legal manufacturer:	Cavex Holland BV Fustweg 5 2031CJ Haarlem
Regulatory evaluator:	Danny Stoelinga
Signature:	
Regulatory manager:	Richard Woortman
Signature:	
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- **Introduction.**

Cavex Plastic Individual Trays provide a simple way of making excellent quality individual trays, to be used for the second impression and final gypsum model with the highest accuracy.

Based on a gypsum model, obtained from the first impression made with a stock tray, the individual tray is modelled, using a Cavex Dental Base Plate as a spacer. A metal grip, provided with the package, is positioned and fixed for easy handling of the individual tray.

The plates are based on shellac and can be easily softened with a flame, or otherwise, and modelled to the desired shape. Upon cooling, the tray retains its shape and form. Its adequate thickness guarantees a strong and dimensionally stable tray during and after the impression taking.

Cavex Plastic Individual Trays are available as upper or lower plates, plain or perforated. Perforations, for increased retention of the impression material, can also be made after modelling of the tray as the last manufacturing step.

Cavex Plastic Individual Trays comply with an in-house specification, based on Australian Standard 1241-1973.

Cavex Plastic Individual Trays 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 ISO13485.

Cavex Plastic Individual Trays bear the CE marking of conformity.

- **Composition.**

The basic composition of Cavex Plastic Individual Tray is as follows:

shellac	: app. 50 %
mica-powder	: app. 20 %
plasticizer	: app. 10 %
fillers	: app. 20 %
pigments	: trace amount

The most important component of Cavex Plastic Individual Trays is shellac, a resinous substance coming from the lac-insect. It is a thermoplastic material that, in combination with the plasticizer, offers a softening range that allows the plate to be processed by hand. The mica-powder and fillers enhance the strength and prevent sticking.

- **Manufacturing.**

The ingredients are carefully weighed and blended in a mixing-machine into 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 extruded to form a strip, that is rolled out between a number of cylinders, gradually reducing the thickness to 1.9 mm and at the same time smoothing the surface.

Finally, the individual plates are stamped with a die and perforated, or packed as plain plates.

- **Laboratory control.**

The testing-program for individual trays 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 Plastic Individual Trays:

	Cavex Plastic Individual Trays
general inspection: colour	complies
surface	smooth, no cracks
working properties	comply
softening point	90 °C
transverse bending strength	30 N
tensile strength	350 N
adaptability at 70 °C	complies

- **Shelf-life test.**

There is no specific shelf-life test described for base plate or individual trays. Under normal conditions, the quality of Cavex Plastic Individual Trays is hardly impaired upon storage.

It is obvious that storage at a too high temperature and/or load will lead to blocking of the plates. Moreover, storage of shellac plates or individual trays at elevated temperatures for a longer period will lead to polymerisation of the shellac, making the 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 Plastic Individual Trays can be guaranteed for a period of 3 years.

- **Quality Control.**

A batch of Cavex Plastic Individual Trays, 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 Plastic Individual Trays can be safely used and are non-toxic to the patient as well as to the dental team or the dental technician.

Cavex Plastic Individual Trays 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.