Product Information On **CAVEX SILICONA** Addition-Cured Silicone Impression Material

Introduction

Cavex SiliconA is based on addition curing elastomeric polysiloxane suitable for inlays, crown and bridges, partial and edentulous impressions utilising the common impression techniques.

Cavex SiliconA impression material is composed of a kneadable yellow Soft Putty with a very high consistency, a medium consistency green paste (Monophase), and a medium consistency blue paste (Injection Type).

The **Cavex SiliconA** is a variable consistency system that can be combined individually for the desirable impression techniques: either Single-step (Sandwich) or Two-step technique.

Cavex SiliconA shows excellent hydrophilic properties, thus improving wettability and leading to better reproduction of subgingival areas.

Pouring of the impressions can take place 60 minutes after the impression is removed from the mouth and all commercially available modeling stones can be used. The impressions are dimensionally stable for at least 7 days.

Cavex SiliconA Soft Putty is available in 2 x 250 ml containers, **Cavex SiliconA Heavy Body Type** and **Cavex SiliconA Injection Type** is available in 2 x 50 ml Cartridges.

Cavex SiliconA have a dosing ratio 1:1 . **Cavex SiliconA** should not be used together with any other competitor material.

Cavex SiliconA is in full compliance with the most important specifications for Silicone impression material and the harmonised specification for Medical Devices in Dentistry:

- EN 24823 = ISO4823
- EN 1641

Cavex SiliconA is developed and manufactured by Cavex Holland BV in 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 SiliconA bears the CE-marking of conformity.

Composition					
The basic ingredients of Cavex SiliconA are as follows:					
Cavex SiliconA Soft Putty	Poly dimethylsiloxane				
	Paraffine				
	Calciumcarbonate				
	Siliciumdioxide				
	Catalyst				
	Pigment				
Cavex SiliconA Heavy Body	Polydimethylsiloxane				
	Siliciumdioxide				
	Catalyst				
	Pigment				
Cavex SiliconA Injection Type	Polydimethylsiloxane				
	Siliciumdioxide				
	Catalyst				

Manufacturing

Basically, all ingredients are carefully weighed and thoroughly mixed.

Shelf-life test

There is no official shelf-life test described for silicone impression materials. But it is well known that these materials may show some deterioration upon storage, in particular at elevated temperature. Therefore, care should be taken to protect the product from a decrease in quality.

Extensive shelf-life studies have been carried out at different temperatures, recording any change in product qualities related to storage conditions.

Based on all this experience, we are able to guarantee the good quality of **Cavex SiliconA Soft Putty**, **Cavex SiliconA Heavy Body and Cavex SiliconA Injection Type** for a period of 3 years, provided that the packaging is unopened and stored in a cool and dry place.

Quality control

A batch of **Cavex SiliconA**, 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.

Laboratory control

Every single batch is tested according to the entire EN 24823 Standard. In the following Table, all the requirements of the EN 24823 Standard are listed together with the typical values for **Cavex SiliconA**.

Characteristic	EN 24823	Putty Type 0	Cavex Silicon Heavy Body Type 1	A Injection Type 3	
colour	Acc. to manufacturer	Yellow	Green	Blue	
mixing time	EN 24823	45			sec
total working time	Acc to manufacturer	1¼	2	2	min
time in the mouth	Acc to manufacturer	31/2	31/2	31/2	min
Total sotting time	Acc to manufacturar	51/	51/	51/	min
	Act to manufacturer	J/2	J/2	J/2	111111
shore-A hardness (24hrs)	Internal specifications	60	60	57	
Consistency	EN 24823	< 35	< 35	> 36	mm
strain in compression	EN 24823	2.6	2,2	2,5	%%
recovery from deformation	EN 24823	99,7	99,7	99,6	%
lineair dimensional change	EN 24823	0.22	0,15	0,17	%
	EN 24922	75	50	00	
Detail reproduction	EIN 24023	/5	50	20	μm
Compatibility with avecure	EN 24823	75	50	50	
Compatibility with gypsum		10	50	50	μπ

Statement of non-toxicity

We hereby declare that **Cavex SiliconA** can be safely used and is non-toxic to the patient as well as to the dental team.

Cavex SiliconA 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. However, the product can be irritating to eyes and eye contact must be avoided.

Haarlem CAVEX HOLLAND BV