

Product Information On

Cavex SiliconA Addition-Cured Silicone Impression Material

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- **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 has 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 2017/745 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.

- **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	Cavex SiliconA			
		Putty Type 0	Heavy Body Type 1	Injection Type 3	
colour	<i>Acc. to manufacturer</i>	Yellow	Green	Blue	
mixing time	EN 24823	45	--	--	sec
total working time	<i>Acc to manufacturer</i>	1¼	2	2	min
time in the mouth	<i>Acc to manufacturer</i>	3½	3½	3½	min
Total setting time	<i>Acc to manufacturer</i>	5½	5½	5½	min
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	%
Detail reproduction	EN 24823	75	50	20	µm
Compatibility with gypsum	EN 24823	75	50	50	µm

- **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.

- **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.