

Product Information

On

Cavex ProphyPaste

Cavex ProphyPaste Fine
Cavex ProphyPaste Regular

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

Cavex ProphyPaste is a professional prophylaxis paste used to clean the tooth surface, facilitate the removal of all exogenous deposits, and to polish the hard tissue including restorations.

Cavex ProphyPaste is developed and manufactured by Cavex Holland B.V.
Cavex ProphyPaste is in compliance with the provisions of the
Regulation (EU) 2017/745 concerning Medical Devices, against ISO 9001 and ISO 13485.

2. Composition

The overall chemical composition of Cavex ProphyPaste as follows:
sorbitol, hydrated silica, water, glycerine, silica, erythritol, lithium magnesium sodium silicate, laponite, sodium hexametaphosphate, ethoxyethanol, flavour, cellulose gum, sodium saccharine, colour, titanium dioxide, xanthan gum, sodium fluoride.
Contains: 0,22 % sodium fluoride (1000 ppm fluoride)

3. Manufacturing

The manufacturing of Cavex ProphyPaste Fine & Regular is the result of gradually mixing all raw materials into a homogeneous substance, Fine(pink) and Regular(green). Quality controls ensure the good quality of Cavex ProphyPaste after the manufacturing process.

4. Laboratory control

Every single batch of Cavex ProphyPaste Fine & Regular is tested according to an in-house test method. At present, a product standard is not available. Therefore, quality control is carried out according to a number of in-house standards.

The following tests are performed to ensure the good quality of the raw materials on the product Cavex ProphyPaste Fine & Regular:

Characteristic	Internal specifications		Cavex ProphyPaste		Unit
	Fine	Regular	Fine	Regular	
Appearance	Pink paste with cranberry flavour	Blue/Green paste with mint flavour	Pink paste with cranberry flavour	Blue/Green paste with mint flavour	
PH	7 – 8	7 – 8	6.5 – 8.5	6.5 – 8.5	
Viscosity	40 - 100	40 - 100	30 - 110	30 - 110	Pa.s
* Relative Dentin Abrasion (RDA)	Max 250	Max 250	50 – 60	130 -150	
* Relative Enamel Abrasion (REA)	Max 40	Max 40	< 5	< 5	
* Enamel Polishing Potential (EPP)			> 35	> 35	
* Pellicle Cleaning Ration (PCR)	Max 100	Max 100	> 85	> 85	

Test with * results are based on tests performed by Indiana university.

5. Shelf-life test

Based on all this experience, we are able to guarantee the good quality of Cavex ProphyPaste for a period of 3 years, when kept in its original packaging, provided the tube is unopened and stored in a cool and dry place.

6. Quality Control

A batch of Cavex ProphyPaste, 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.

7. Statement of non-toxicity

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

Cavex ProphyPaste 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.