

# Product Information On

## Cavex ImpreSafe

|                              |  |
|------------------------------|--|
| <b>Legal manufacturer:</b>   | <b>Cavex Holland BV</b><br>Fustweg 5<br>2031CJ Haarlem                               |
| <b>Regulatory evaluator:</b> | <b>Danny Stoelinga</b>   |
| <b>Signature:</b>            |    |
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| <b>Signature:</b>            |  |
| <b>Version:</b>              | <b>2021-09</b>   |

- **Introduction.**

Due to growing concern on the threat of micro organisms like HIV, Hepatitis, Asian Birdflu, SARS and many others, the disinfection procedures have become increasingly important in the medical field over the last few years. As a result the disinfection of dental impressions are now an integral part of the daily routine in a dental office. The protection of the patient and the praxis personnel against infections through bacteria, viruses or fungus is of highest priority.

Aside from disabling or removing any pathogenic microorganisms over a reasonably short time period the application of chemicals should not affect the treated impression materials. Especially the sensitive precision alginate impression materials which are used in every prosthetic and orthodontic treatment are in danger of possible chemical reactions with the substances in the disinfectant bath. The accuracy of the impression should remain unaltered (25 – 50 µm) under the influence of any disinfectant.

After years of carefully reviewing all available disinfectants Cavex Holland has developed Cavex ImpreSafe, a dental impression disinfectant which is able to kill bacteria, viruses and fungi within three minutes without changing the properties of the high quality impression. Cavex ImpreSafe is delivered as a blue concentrate liquid packed in 1 litre dosing bottles. After dilution to a 3 % solution the alginate and silicone impressions can be disinfected by immersion in only 3 minutes contact time.

Cavex ImpreSafe is developed and manufactured by Cavex Holland B.V., a Company that is certified according to the provisions of the Council Directive 2017/745 concerning Medical Devices, against ISO 9001 and ISO13485.

Cavex ImpreSafe bears the CE-Mark of conformity.

- **Composition.**

The basic ingredients of Cavex ImpreSafe are:

|                          |        |     |
|--------------------------|--------|-----|
| Quaternair ammonium salt | 30     | % w |
| Surfactant               | < 1 %  | % w |
| Cleaning Booster         | < 1 %  | % w |
| Pigment Blue             | spores | % w |
| Water                    | 70     | % w |

- **Manufacturing.**

Basically, the ingredients are carefully weighed, blended in a high-performance mixing device and automatically packed in bottles.

- **Laboratory control.**

Every batch Cavex ImpreSafe is in compliance with the following specification:

|  | <b>Cavex ImpreSafe</b>  |
|--|---|
| Appearance   | Clear, light blue liquid  |
| Density (20°C)   | 1.0 g/ ml   |
| pH value (3% solution)   | 9 – 11  |
| Biological properties:   | 3 % solution, 3 minutes contact time<br>Under clean and dirty conditions  |
| EN1040 / EN1276<br>EN13727 / EN14561<br>Bactericidal activity<br>5 log reduction | Staphylococcus aureus (-)<br>Pseudomonas aeruginosa (+)<br>Enterococcus hirae (+)<br>MRSA   |
| EN1650 / EN 1275<br>EN13624 / EN14562<br>Fungicidal Activity<br>4 log reduction  | Candida Albicans (+)  |
| EN14476<br>Limited virucidal activity<br>Log 4 reduction                         | Bovine Viral Diarrhea Virus (BVDV)<br>Hepatitis C<br>Hepatitis B<br>Vaccinia Virus strain Elstree<br>Human Immunodeficiency Virus (HIV)<br>Herpes Simplex Virus type 1<br>Human Influenza Virus (H3N2)<br>Human Rotavirus Strain<br>Noro virus<br>Feline Corona virus |

- **Shelf-life test.**

There is no official shelf-life test described for dental disinfectant liquids. Based on the results of internal tests, we can guarantee the good qualities of Cavex ImpreSafe for a period of 3 years, provided the product is stored below 25 °C/77 °F when not in use.

- **Quality Control.**

A batch of Cavex ImpreSafe, 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 ImpreSafe can be safely used and is non-toxic to the patient as well as to the dental team.

Cavex ImpreSafe will also normally not be irritant to oral tissues and it does not contain any hazardous ingredients in sufficient concentration to be harmful to human beings, when used as directed.