

CALBENIUM LIQUID

Disinfection product for dental unit



The CALBENIUM® is a disinfectant for dental unit water systems

The CALBENIUM® has been formulated to be compatible with all dental units and not entail any alteration of the internal components.

The CALBENIUM® is CE marked a Class IIa medical device compliant with European Directive 93/42/EEC requirements.

PRODUCT REFERENCES

SURGICAL

Reference	Storage
2910.013	1 Liter
2910.023	2 Liters

FRUITY

Reference	Storage
2910.012	1 Liter
2910.022	2 Liters

FRUITY MINT

Reference	Storage
2910.011	1 Liter
2910.021	2 Liters

COMPOSITION

The CALBENIUM® contains: CTAB - EDTA - Chloramine - Bronidox - Ethyl Alcohol - Aspartam – Allantoïn – Foamaster

PHYSICAL AND CHEMICAL CHARACTERISTICS

	CALBENIUM® Surgical	CALBENIUM® Fruity	CALBENIUM® Fruity Mint
Appearance	Clear and transparent liquid	Clear and transparent liquid	Clear and transparent liquid
pH	5 ± 0.5	5 ± 0.5	5 ± 0.5
Density	1,020 - 1,040	1,020 - 1,040	1,020 - 1,040



CALBENIUM LIQUID

Disinfection product for dental unit



STORAGE CONDITIONS

- Keep in the original packaging
- Store the vial upright
- Storage at ambient temperature
- Expiry date before opening: 2 years from the date of manufacturing
- Shelf life after opening: 2 months after opening and with cap back on or if it is directly connected to a system

CALBENIUM PERFORMANCES

The CALBENIUM® 2% is efficient against *Pseudomonas Aeruginosa* and *Staphylococcus Aureus* population (minimum 5 log¹⁰ CFU reduction) after a 5 min contact at 20°C as per NF EN 1040: 2006

The CALBENIUM® 2% is efficient against *Staphylococcus Aureus*, *Pseudomonas Aeruginosa*, *Enterococcus Hirae* and *L.pneumophila* after a 60 min contact at 20°C as per NF EN 13727+A2:2015

The CALBENIUM® 2% is efficient against *human coronavirus E229*, *adenovirus type 5* and *Norovirus murin* after 60 min contact at 20°C as per NF EN 14476+A2 :2019

PRECAUTION OF USE

- Use safety eyewear designed to protect against liquid splashes.
- Wear suitable protective gloves if prolonged or repeated contact with skin.
- In case of contact with eyes, rinse with running water.
- In case of skin contact, rinse with running water.
- Do not reject pure in environment.
- May cause allergic reaction

INSTRUCTION FOR USE

The CALBENIUM® must be stored in recommended storage conditions: room temperature for maximum 2 years. Once the bottle is opening and with cap back on or if it is directly connected to the system the product can be stored at room temperature for maximum 2 months.



Do not throw the pure CALBENIUM® in wastewater, the product must be discarded by an approved collector.

We recommend users to perform a regular control of microbiologic contamination of the water.





CALBENIUM® Dilution procedure

The product must be diluted at 2% : 20 mL of pure product completed with 1L of water.

Once diluted at 2%, the product can be discarded in wastewater.

If completely empty container or the validity date is exceeded, keep the label on the container. Return the container and its contents to a certified disposer.

Safety Symbols

A description of the pictograms found in this user manual and/or on the material labels is given in the table below.



Warning



Class IIa medical device compliant with requirements of the European directive 93/42/EEC

The CE marking authorization has been delivered by the notified body SZUTEST.



Read the user manual before using



Contact details of the medical device manufacturer



Lot number



Product reference



Environmental hazard



Date of expiry



Date of manufacture

IFU Version 05 – Last revision date 14/10/2021

