

OOSAFE DISINFECTANT- benzalkonium chloride liquid

SparMED ApS

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Oosafe Disinfectant

Purpose

- Purpose:** • Skin disinfectant for preventing and handling bacterial/viral infection.
- Disinfectant for CO₂ incubators and laminar flowhoods.
 - MEA tested for IVF laboratory use.
 - No alcohol, no odour.
 - Easy to apply, no water dilution is required (ready to use).
 - Bactericide (E.Coli), fungicide (Candida) and virucide.
 - Effective against hepatitis B, HIV, Rota virus within 1 minute, Mycobacterium within 5 minutes and bacteria, fungi (Candida) Influenza A virus (H5N1/H1N1) within 15 minutes.
 - Do not contact with embryos, oocytes, sperm and any living samples.

Application

- Application:** • Apply 3 ml disinfectant on skin and let it dry for 30 seconds.
- Apply evenly on the surface, wait 15 minutes to dry out for the best result and clean with a sterile sponge or cloth impregnated sterile water.

Dosage Administration

- Application:** • Apply 3 ml disinfectant on skin and let it dry for 30 seconds.
- Apply evenly on the surface, wait 15 minutes to dry out for the best result and clean with a sterile sponge or cloth impregnated sterile water.

Active Ingredients

Active ingredients: • Quaternary ammonium compounds:
Benzyl-alkyldimethyl chloride 1,3 mg/g.

Inactive Ingredients

Inactive ingredients: • Water.

Warning

**Please keep out of the reach children.
For external use only.**

Keep Out of Reach

**Please keep out of the reach children.
For external use only.**

Oosafe 250 ml label

**Oosafe® Disinfectant / OODIH-250
For Human use in the
laboratory / hospital / private sectors
and for Co. Incubators and**

and for CO₂ incubators and laminar Flow Hoods

Purpose: • Skin disinfectant for preventing and handling bacterial/viral infection.

- Disinfectant for CO₂ incubators and laminar flowhoods.
- MEA tested for IVF laboratory use.
- No alcohol, no odour.
- Easy to apply, no water dilution is required (ready to use).
- Bactericide (E.Coli), fungicide (Candida) and virucide.
- Effective against hepatitis B, HIV, Rota virus within 1 minute, Mycobacterium within 5 minutes and bacteria, fungi (Candida) Influenza A virus (H5N1/H1N1) within 15 minutes.
- Do not contact with embryos, oocytes, sperm and any living samples.

Application: • Apply 3 ml disinfectant on skin and let it dry for 30 seconds.

- Apply evenly on the surface, wait 15 minutes to dry out for the best result and clean with a sterile sponge or cloth impregnated sterile water.

Active ingredients: • Quaternary ammonium compounds: Benzyl-alkyldimethyl chloride 1,3 mg/g.

Inactive ingredients: • Water.

Please keep out of the reach children.

For external use only.

Manufactured by IC Products SA exclusively for Sparmed Aps.



Toppevadvej 34-38, DK-3660 Stenløse / Denmark
Phone: +45 39 40 25 03 • Fax: +45 39 40 25 64
e-mail: info@sparmed.dk • web: www.sparmed.dk

250 ml

Expiry date/Lot No

2014 2015 2016 2017 01 02 03 04 05 06 07 08 09 10 11 12

OOSAFE DISINFECTANT

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52759-922
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 g in 1 L

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	99.1 g in 1 L
SODIUM NITRITE (UNII: M0KG633D4F)	4 g in 1 L
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	3.7 g in 1 L

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52759-922-01	1 L in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2012	11/30/2020
2	NDC:52759-922-05	5 L in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2012	11/30/2020
3	NDC:52759-922-10	10 L in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2012	11/30/2020
4	NDC:52759-922-00	0.25 L in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2012	11/30/2020

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/30/2012	11/30/2020

Labeler - SparMED ApS (311811306)