

OOSAFE - 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.

Active Ingredient

Benzalkonium Chloride 1.3 gram/liter.

Purpose

Disinfectant

Warnings

Harmful to health in case of inappropriate utilisation. Keep out of reach of children.

Inactive Ingredients

Water

Keep Out of Reach of Children

Keep out of reach of children

Dosage and Administration

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

Indication and Usage

Disinfectant -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.

Package Label Principal Display Panel

Oosafe[®] Disinfectant / OODIH-250 For Human use in the laboratory / hospital / private sectors 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 compound: 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.



Torngade 24-28 DK-2660 Sønderborg / Denmark

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250 ml

Expiry Date / Lot No

2014	2015	2016	2017	01	02	03	04	05	06	07	08	09	10	11	12
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Oosafe® Disinfectant / OODIH-1000

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Expiry Date / Lot No 2014 2015 2016 2017 01 02 03 04 05 06 07 08 09 10 11 12 1 Liters

Oosafe® Disinfectant / OODIH-5000

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Expiry Date / Lot No 2014 2015 2016 2017 01 02 03 04 05 06 07 08 09 10 11 12 5 Liters

OOSAFE

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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52759-922-01	1 L in 1 BOTTLE		
2	NDC:52759-922-05	5 L in 1 BOTTLE		
3	NDC:52759-922-10	10 L in 1 BOTTLE		
4	NDC:52759-922-00	0.250 L in 1 BOTTLE		

Marketing Information

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

Labeler - SPARMED ApS (311811306)

Revised: 9/2012

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