

DUROKLEEN SANITIZER- benzalkonium chloride liquid

NuGenTec

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.

DuroKleen Sanitizing Spray

Active Ingredient(s)

Benzalkonium Chloride 0.10%

Purpose

Antiseptic, Hand Sanitizer, Antibacterial

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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Directions

- Spray product on hands to cover and wet all surfaces. Rub thoroughly. Allow to dry without wiping
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

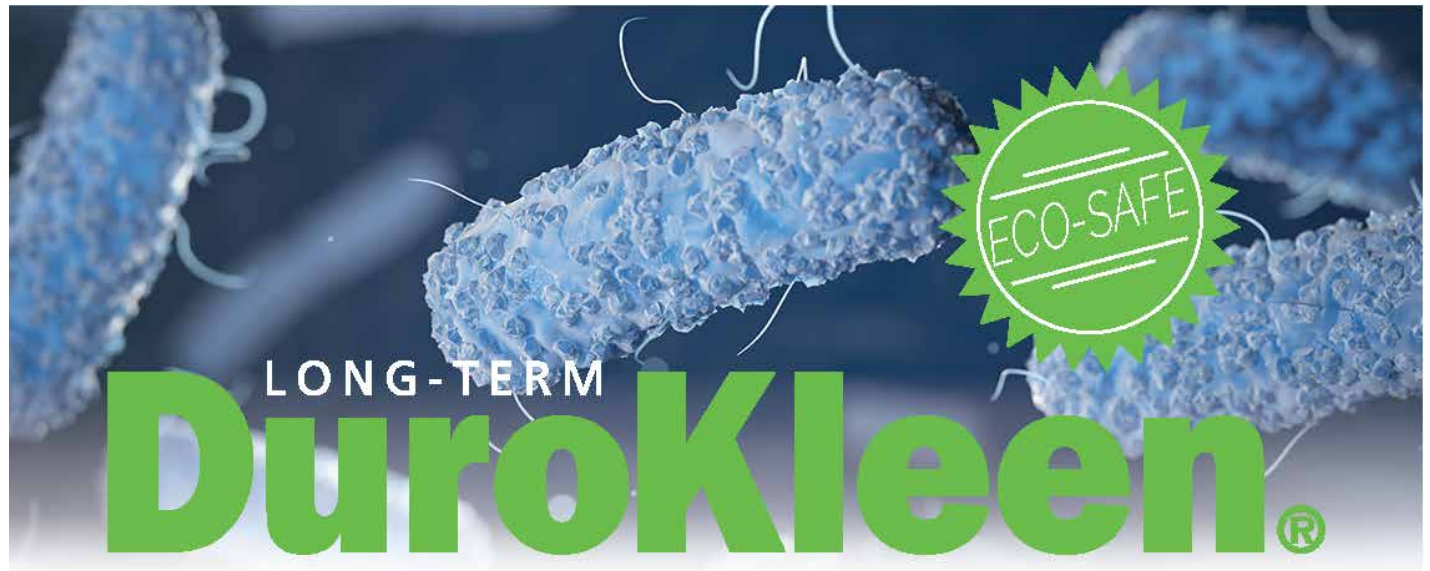
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Ztrex 72 MUP, purified water USP

Package Label - Principal Display Panel

750mL is one bottle NDC: 77368-901-75



Hospital Grade Spray Disinfectant

- | | |
|---|--|
| <input checked="" type="checkbox"/> No Volatile Organic Compounds | <input checked="" type="checkbox"/> No Harsh Chemicals |
| <input checked="" type="checkbox"/> Eliminates Odor | <input checked="" type="checkbox"/> Won't Stain or Burn |
| <input checked="" type="checkbox"/> Long-term Protection | <input checked="" type="checkbox"/> Controls 99.9% of Microbes |

Long-term DuroKleen provides a long-lasting invisible biostatic barrier that prevents the growth of molds, mildew, fungus, algae, bacteria and viruses on skin or soft surface, including masks and fabric.

Highly effective as a durable surface protection for the long-term elimination and control of a wide spectrum of microbial life forms, including fungi that produce communicable infections or appear as mould or mildew, and bacteria that may cause disease, odor and discoloration.

FOR USER AND SAFETY INSTRUCTIONS, REFER TO THE LABEL ON REVERSE SIDE OF CONTAINER

Benzalkonium chloride 0.1% %w/v



PRODUCED FOR: Durokleen Global Pty Ltd
ACN 630 884 105 Suite 401, 55 Plaza Parade,
Maroochydore QLD 4558 Australia.
Ph 1300 911 695 www.durokleen.com

NET CONTENTS
750mL

LONG-TERM DuroKleen®

NET CONTENTS
750mL

DIRECTIONS FOR USE

FOR SKIN SURFACE PROTECTION: DuroKleen is formulated ready for use. Shake the container and then spray the area to be protected with the nozzle 10-15cm from the skin surface, making sure the surface is completely covered. Rub in thoroughly for 20 seconds. Let stand until dry.

FOR MASKS: Shake the container and then spray the area to be protected with the nozzle 10-15cm from the surface, making sure the surface is completely covered. Let stand until dry.

COLOR FASTNESS: If concerned, test fabric for staining and color-fastness by treating and drying a small, concealed area prior to application.

CAUTION: Avoid contact with eyes; may cause moderate eye irritation. Do Not Ingest.

Manufactured by: NuGenTec 1155 Park Avenue, Emeryville, CA 94608
Made in the USA

FDA NDC Code: 77368-901-75

DuroKleen_DK-750-1_Label_TGA-3.1



ACTIVE INGREDIENTS	Benzalkonium chloride 0.1% (%w/v).
FIRST AID	If poisoning occurs, contact a medical doctor or call the Poison Control Center Hotline 24/7 (800)222-1222. Have the container with you when phoning or seeking treatment.
IF IN EYES	Hold affected eyes open and rinse gently with clean water for 15-20 minutes. If you are wearing contact lenses, remove them after rinsing eyes for 5 minutes, then continue rinsing eyes 10-15 minutes.
STORAGE	Store in original container between 41°F and 104°F

Durokleen Global Pty Ltd, 401 / 55 Plaza Pde, Maroochydore QLD 4558 Australia. Ph 1300 911 695 www.durokleen.com

DUROKLEEN SANITIZER

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77368-902
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.1 mg in 100 mL
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Inactive Ingredients

Ingredient Name	Strength
DIMETHYL TETRADECYL(3-(TRIMETHOXY S I L Y L) P R O P Y L) A M M O N I U M C H L O R I D E (UNII: N7BH1NTV97)	0.2 mL in 100 mL
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77368-902-75	750 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	01/14/2021	
2	NDC:77368-902-02	60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	01/14/2021	
3	NDC:77368-902-10	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/14/2021	
4	NDC:77368-902-05	18927 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/14/2021	
5	NDC:77368-902-01	3786 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/14/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - NuGenTec (090331927)

Registrant - NuGenTec (090331927)

Establishment

Name	Address	ID/FEI	Business Operations
NuGenTec		090331927	manufacture(77368-902)