GUNK GETTER SANITIZING- benzalkonium chloride spray PeerBasics LLC

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

Lauramide Propyl Dimethyl Oxide Amine

Purpose

Antimicrobial Agent

Surfactant

Antifugal

Use

Use to decrase bacteria on the skin.

Warnings

For external use only

Do not use

Do not use it you are allergic to any of the ingredients.

When using this product

- keep out of eyes. In case of contact with eyes, flush thoroughly with water.
- avoid contact with broken skin.
- do not inhale or ingest.

Stop use and ask a doctor if

irritation or rash develops and continues for more than 72 hours.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

adults and children 2 years and over:

- apply to hands.
- allow skin to dry without wiping.
- children under 2 years: ask a doctor before use.

Other information

- do not store above 105F(41C).
- may discolor some fabrics.
- harmful to wood finishes and plastics.

Inactive Ingredients

Water

Glycerol

Fungicide



GUNK GETTER SANITIZING

benzalkonium chloride spray

LUMAN OTO DDUG		
HUMAN OTC DRUG	Item Code (Source)	NDC:83590-002
TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength Strength		
LAURAMIDOPROPYLAMINE OXIDE (UNII: I6KX160QTV) (LAURAMIDOPROPYLAMINE OXIDE - UNII:I6KX160QTV)	LAURAMIDOPROPYLAMINE 1.5 mg OXIDE in 100 mL		
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM UNII: 7N6JUD5X6Y)	- BENZ ALKONIUM 0.5 mg CHLORIDE in 100 mL		

Inactive Ingredients		
Ingredient Name	Strength	
TRIETHOXYSILYLPROPYL STEARDIMONIUM CHLORIDE (UNII: XGN40YQC7B)		
WATER (UNII: 059QF0KO0R)		
GLYCERIN (UNII: PDC6A3C0OX)		

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83590- 002-01	80 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/20/2023	
2	NDC:83590- 002-02	98 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/20/2023	
3	NDC:83590- 002-03	473 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/20/2023	
4	NDC:83590- 002-04	828 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/20/2023	
5	NDC:83590- 002-05	946 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/20/2023	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/20/2023	
	part333A	07/20/2023	

Labeler - PeerBasics LLC (087291627)

Establishment				
Name	Address	ID/FEI	Business Operations	
Hangzhou Huiji Biotechnology Co.,Ltd		526893497	manufacture(83590-002)	

Revised: 8/2023 PeerBasics LLC