

CLEAN31- benzalkonium chloride liquid
S3 Surface Solutions, 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 Ingredients

Benzalkonium Chloride 0.13%

Drug Facts

Active Ingredients	Purpose
Benzalkonium Chloride	Skin Antiseptic

Uses
For hand and skin sanitizing to decrease microbes on skin.

Warnings
For external use only. Do not use in the eyes. In case of eye contact, flush thoroughly with water & seek medical attention.

Stop use and ask a doctor if irritation or redness develops, or if condition persists for more than 72 hours.

Keep out of reach of children. If swallowed, get help, or contact a Poison Control Center at 1-800-527-0899.

Directions
Dispense an adequate amount in palm to cover hands. Rub hands together to cover skin thoroughly until dry. Supervise young children while using this product.

Other Information
Skin cells may be shed naturally or by abrasion prior to 4 hours, exposing fresh, unprotected skin. Reapply as needed.

Inactive Ingredients
Water, Colloidal Silicon Dioxide

Questions?
info@S3surfaces.com
www.S3surfaces.com
S3 Surface Solutions, LLC
3239 S. Dixie Hwy
Dalton, GA 30720
NDC# 81300-100-05

81300 100 05

MADE IN U.S.A.



HAND SANITIZER

Kills 99.9% of Germs

Country of Origin: United States

Sample



Alcohol Free

Fragrance Free

Kills 99.9% of Germs

***Up to 4 Hours of Protection**

Net Contents 3785.41 ml
(128 oz)

Purpose

Skin Anticeptic

Uses

For hand and skin sanitizing to decrease microbes on skin

Warnings

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seek medical attention

Stop use and ask a doctor

If irritation or redness develops, or if condition persists 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

Dispense an adequate amount in palm to cover hands. Rub hands together to cover skin thoroughly until dry. Supervise young children while using this product.

Other Information

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Inactive Ingredients

Water, Colloidal Silicon Dioxide

Questions?

email info@S3Surfaces.com

Alcohol-Free Formulation

S3 Surface Protect, Quality branded Clean31 Protection, Hand Sanitizer, Sanitizes, Protects up to 4 hours, Alcohol-Free, Fragrance-free, Up to 4 hours of Protection, Kills over 99.9% of Germs




Hand Sanitizer Label

Product label picture

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Net Contents 3785.41 ml
(128 oz)

CLEAN31

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81300-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	99.67 g in 100 mL
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	0.2 g in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81300-100-01	50 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	12/08/2020	
2	NDC:81300-100-02	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/08/2020	
3	NDC:81300-100-03	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/08/2020	
4	NDC:81300-100-04	1000 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	12/08/2020	
5	NDC:81300-100-05	3785.41 mL in 1 JUG; Type 0: Not a Combination Product	12/08/2020	
6	NDC:81300-100-06	18927.1 mL in 1 PAIL; Type 0: Not a Combination Product	12/08/2020	
7	NDC:81300-100-07	208198 mL in 1 DRUM; Type 0: Not a Combination Product	12/08/2020	
8	NDC:81300-100-08	1249000 mL in 1 CONTAINER; Type 0: Not a Combination Product	12/08/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	12/08/2020	

Labeler - S3 Surface Solutions, LLC (087784389)

Registrant - S3 Surface Solutions, LLC (087784389)

Establishment

Name	Address	ID/FEI	Business Operations
Polyventive LLC		116722770	manufacture(81300-100)

Establishment

Name	Address	ID/FEI	Business Operations
Guide Energy Solutions		117045830	manufacture(81300-100)

Establishment

Name	Address	ID/FEI	Business Operations
Emerald 66 Enterprises LLC		117386196	manufacture(81300-100)