SAFEHANDS- benzalkonium chloride liquid safeHands Distribution Ne, 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, 0.13%

Purpose

Antiseptic hand sanitizer

Uses

To decrease bacteria on the skin.

Warnings

For external use only.

Do not use

in eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor

if skin irritation develops.

Keep out of reach of children

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

Directions

Liberally apply product to skin by gently massaging until absorbed. Supervise children in the use of this product.

Other Information

Avoid extreme temperatures.

Inactive Ingredients

Water, Cocamidolpropyl PG-Dimonium Chloride Phospate, Propylene glycol, Triethylene glycol, Polysorbate 20, Fragrance, FD&C Blue No. 1

Questions/Comments?

Call toll free 888-338-1338

safeHands® Next Generation Hand Sanitizer Kills 99.9% of germs while pampering your hands Learn more at: www.safehands.com

A percentage of profits is donated to Safe Kids Worldwide to "keep all kids safe from preventable injuries"

#1 Alcohol Free Brand

Manufactured for safeHands, LLC, Boca Raton, FL Patent Pending 61/473 385 Made in the USA

safeHands® Alcohol Free Hand Sanitizer Kills 99.9% of germs.

- Non-toxic
- Moisturizing Clean Linen

safeHands

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Manufactured for safeHands, LLC, Boca Raton, FL Patent Pending 61/473 358 MDC 60867-102-07

SAFEHANDS

benzalkonium chloride liquid

Product Information								
Product Type	HUMAN OTC DRUG	Item Code (Source) ND		NDC:6	2:60867-102			
Route of Administration	TOPICAL							
Active Ingredient/Active Moiety								
Ingredient Name Basis of Strength					Strength			
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - BENZALKO UNII: 7N6JUD5X6Y) BENZALKO			BENZ ALKONIUM CHLORIDE		0.13 g in 100 mL			
Inactive Ingredients								
Ingredient Name								
Water (UNII: 059QF0K00R)								
COCAMIDOPROPYL PG-DIMONIUM CHLORIDE PHOSPHATE (UNII: H2KVQ74JM4)								
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)								
TRIETHYLENE GLYCOL (UNII: 3P5:	SU53360)							
POLYSORBATE 20 (UNII: 7T1F30V	5YH)							

ALCOHOL FREE BRAND



ALCOHOL FREE HAND SANITIZER Kills 99.99% of germs.

Non-toxic
Moisturizing

Clean Linen

7 fl oz (208 mL)

FC	FD&C BLUE NO. 1 (UNII: H3R47K3TBD)									
Ρ	Packaging									
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date						
1	NDC:60867-102- 02	52 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2023							
2	NDC:60867-102- 07	208 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2023							
3	NDC:60867-102- 18	532 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2023							
Marketing Information										
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date						
OTC monograph not final		t part333A	01/01/2023							

Labeler - safeHands Distribution Ne, LLC (080026877)

Establishment								
Name	Address	ID/FEI	Business Operations					
Vintage Chemical Inc		116949970	manufacture(60867-102)					

Revised: 6/2023

safeHands Distribution Ne, LLC