SAFEHANDS SQUIRTS- benzalkonium chloride liquid safeHands 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 chlidren

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 temperature.

Inactive Ingredients

Water, Cocamidopropyl PG-Dimonium Chloride Phosphate, Propylene glycol, Triethylene glycol, Polysorbate 20, Fragrance, D&C Red No. 33.

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 SafeThePlanet

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

safeHands® Squirts® 4 Kids Alcohol Free Hand Sanitizer Kills 99.9% of germs.

- Non-toxic
- Non-flammable
- Non-skin drving

Bubble Gum

safeHands

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Drug Facts

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NDC 60867-103-07













Kills 99.99% of germs.

- · Non-toxic
- · Non-flammable
- Non-skin drying

Bubble Gum

7 fl oz (208 mL)

SAFEHANDS SQUIRTS

benzalkonium chloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60867-103
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: 059QF0KO0R)			
CO CAMIDO PRO PYL PG-DIMO NIUM CHLO RIDE PHO SPHATE (UNII: H2KVQ74JM4)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
TRIETHYLENE GLYCOL (UNII: 3P5SU53360)			
POLYSORBATE 20 (UNII: 7T1F30V5YH)			
D&C RED NO. 33 (UNII: 9DBA0SBB0L)			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:60867-103-02	52 mL in 1 BOTTLE	09/27/2014		
2	NDC:60867-103-07	208 mL in 1 BOTTLE	09/27/2014		
3	NDC:60867-103-18	532 mL in 1 BOTTLE	09/27/2014		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	09/27/2014		

Labeler - safeHands LLC (061206060)

Establishment				
Name	Address	ID/FEI	Business Operations	
Products by O2, Inc.		136932444	manufacture(60867-103)	

Revised: 9/2014 safeHands LLC