

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 children.

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

Directions

Liberal 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, Cocamidopropyl PG-Dimonium Chloride Phosphate, Propylene glycol, Triethylene glycol, Polysorbate 20, Fragrance, FD&C Blue No. 1, FD&C Yellow No. 5.

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 drying
 Tooty Fruity

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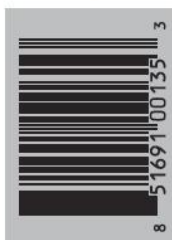
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Manufactured for safeHands, LLC, Boca Raton, FL
 Patent Pending 61/473 358

Made in the USA
 NDC 60867-105-07



safeHands®

SQUIRTS®
 4 Kids

ALCOHOL FREE
HAND SANITIZER
 Kills 99.99% of germs.

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

Tooty Fruity

7 fl oz (208 mL)

SAFEHANDS SQUIRTS

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60867-105
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)	
COCAMIDO PROPYL PG-DIMONIUM CHLORIDE PHOSPHATE (UNII: H2KVQ74JM4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TRIETHYLENE GLYCOL (UNII: 3P5SU53360)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60867-105-02	52 mL in 1 BOTTLE	09/27/2014	
2	NDC:60867-105-07	208 mL in 1 BOTTLE	09/27/2014	
3	NDC:60867-105-18	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(60867-105)