

LIQUID HAND CLEANSE- triclosan gel
Great Lakes Wholesale & Marketing, 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 Purpose

Triclosan 0.2%.....Antiseptic

Health Care Instant Hand Sanitizer - Ice Clear - Extra Enriched with Vitamin E Bead & Aloe

Kills 99.9% of Germs without water or towels!

☐**Keep out of reach of children.** ☐If swallowed, get medical help or contact a Poison Control Center right away.

☐**USE:**

- handwashing to decrease bacteria on the skin

☐**Warnings:**

for external use only.

Flammable. Keep away from heat and flame.

☐**Do not use**☐ in the eyes. In case of contact, rinse eyes thoroughly with water.

☐**Stop use and ask a doctor if**☐ irritation and redness develop and persist for more than 72 hours.

☐**Directions:**

- wet hands thoroughly with product
- briskly rub hands together until dry
- supervise children in the use of this product

☐**Inactive ingredients:**

aloe vera leaf juice, carbomer, glycerin, propylene glycol, tocopheryl acetate (vitamin E), triethanolamine, water.



LIQUID HAND CLEANSE

triclosan gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64092-316
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	10 mg in 500 mg

Inactive Ingredients

Ingredient Name	Strength
CETETH-7 (UNII: 4ST6952Q67)	
ETHYL SULFATE (UNII: P3LK0HF3B7)	
COCONUT OIL (UNII: Q9L0O73W7L)	
DIETHANOLAMINE (UNII: AZE05TDV2V)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
OCTHLINONE (UNII: 4LFS24GD0V)	
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64092-316-01	500 mg in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/05/2013	

Labeler - Great Lakes Wholesale & Marketing, LLC (361925498)

Establishment

Name	Address	ID/FEI	Business Operations
China Ningbo Shangge Cosmetic Technology Corp.		529287434	manufacture(64092-316)