HAND CLEANSE REFILL- triclosan gel China Ningbo Shangge Cosmetic Technology Corp.

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.

Purpose

Hand Cleanse

Active Ingredient

Triclosan 0.15%......Antibacterial

Uses

forthe temporary relief of minor aches and pains of muscles and joints.

Keep out of reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

□Other information

store at 20oC to 25oC (68o to 77oF)

□Warnings

For external use only. Avoid contact with eyes.

Ask a doctor before use if you have cough associated with

- smoking
- excessive phlegm
- asthma
- emphysema
- persistent or chronic cough

When using this product do not

- heat
- microwafe
- add to hot water or any container where healing water may cause splattering and result in burns
- use in eyes or directly on mucous membranes
- take by mouth or place in nostrils
- apply to wounds or damaged skin
- bandage skin

Consult a doctor and discontinue use if condition worsesn, persists for more than 1 week or tends to recur.

Directions

- see important warnings under "When using this product"
- adults & children 2 years of age & older: apply to the affected area not more than 3 to 4 times daily.
- children under 2 years of age: consult a physician.

□Inactive Ingredients

camphor, carbomer, ethyl alcohol, fd&c blue no.1, isopropyl alcohol, methylchloroisothiazolinone, methylisothiazolinone, sodium hydroxide, water.

Antibacterial Hand Soap Drug Facts Active ingredient Purpose Triclosan 0.15%..... .Antibacterial **Uses** for hand washing to decrease bacteria on the skin. Warnings for external use only. When using this product avoid contact with eyes. in case of eye contact, flush with water. Stop use and ask a doctor if irritation and redness develops. Keep out of reach of children if swallowed, get medical help or contact a poison control center right away. **Directions** • pump into hands • lather vigorously for at least 15 seconds • rinse and dry thoroughly. **Other information** • store at room temperature Inactive ingredients water, sodium c14-16 olefin sulfonate, sodium laureth sulfate, cocamide DEA, sodium chloride, PEG-150 distearate, fragrance, citric acid, glycerin, disodium EDTA, tocopheryl acetate, methylchloroisothiazolinone, fd&c yellow no.5, d&c red no.33, methylisothiazolinone. 183852-14454-002-1305 DISTRIBUTED BY GREENBRIER INTERNATIONAL, INC. 500 VOLVO PARKWAY, CHESAPEAKE, VA 23320 MADE IN CHINA



HAND CLEANSE REFILL

triclosan gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58503-008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	7.5 mg in 500 mg	

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)		
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)		
COCO DIETHANOLAMIDE (UNII: 92005F972D)		
SODIUM CHLORIDE (UNII: 451W47IQ8X)		
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)		
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)		
GLYCERIN (UNII: PDC6A3C0OX)		
EDETATE DISODIUM (UNII: 7FLD91C86K)		
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)		
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)		
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)		
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)		

l	Packaging				
	# Item Code Package Description		Marketing Start Date	Marketing End Date	
	1	NDC:58503-008- 500 mg in 1 BOTTLE; Type 0: Not a Combination 05/24/2013 Product			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	05/24/2013		

Labeler - China Ningbo Shangge Cosmetic Technology Corp. (529287434)

Establishment				
Name	Address	ID/FEI	Business Operations	
China Ningbo Shangge Cosmetic Technology Corp.		529287434	manufacture(58503-008)	

Revised: 11/2022 China Ningbo Shangge Cosmetic Technology Corp.