TRICLOSAN FREE ANTIBACTERIAL 7.5 OZ (OCEAN) ANTIBACTERIAL-chloroxylenol liquid

China Ningbo Shangge Cosmetic Technology Corp.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Purpose

Antibacterial

Active Ingredient

Chloroexylenol, 0.3%

USAGE

For hand washing to decrease bacteria on the skin

Directions

Pump into hands

Lather vigorously for at least 15 seconds

Rinse and dry thoroughly

Keep out of reach of children

If swallowed get medical help or contact a poison control center right away.

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

WATER, SODIUM LAURETH SULFATE, COCAMIDE MEA, SODIUM C14-16 OLEFIN SULFONATE, SODIUM CHLORIDE, PEG-150 DISTEARATE, FRAGRANCE, CITRIC ACID, GLYCERIN, PEG-40 HYDROGENATED CASTOR OIL, DISODIUM EDTA, TOCOPHERYL ACETATE, METHYLCHLOROTHIAZOLINONE, METHYLISOTHIAZOLINONE, FD&C YELLOW NO.5, D&C RED NO. 33; FD&C BLUE NO. 1





NORTHVILLE, MI 48168, USA MADE IN CHINA

TRICLOSAN FREE ANTIBACTERIAL 7.5 OZ (OCEAN) ANTIBACTERIAL

chloroxylenol liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58503-102	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)	CHLOROXYLENOL	0.3 g in 100 mL

Inactive Ingredients			
Ingredient Name	Strength		
D&C RED NO. 33 (UNII: 9DBA0SBB0L)			
WATER (UNII: 059QF0KO0R)			
GLYCERIN (UNII: PDC6A3C0OX)			

PROPYLENE GLYCOL (UNII: 6DC9Q167V3) SODIUM LAURETH SULFATE (UNII: BPV390 UAP0) CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) DISODIUM EDTA-COPPER (UNII: 6V475AX06U) COCO MONOETHANOLAMIDE (UNII: C80684146D) SODIUM CHLORIDE (UNII: 451W47IQ8 X) .ALPHATOCOPHEROL ACETATE (UNII: 9E8 X80 D2L0) METHYLCHLORO ISOTHIAZOLINONE (UNII: DEL7T5QRPN) PEG-150 DISTEARATE (UNII: 6F36Q010 AC) POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F) METHYLISOTHIAZOLINONE (UNII: 229 D0E1QFA) FD&C YELLOW NO. 5 (UNII: 1753WB2F1M) FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) DISODIUM EDTA-COPPER (UNII: 6V475AX06U) COCO MONOETHANOLAMIDE (UNII: C80684146D) SODIUM CHLORIDE (UNII: 451W47IQ8 X) .ALPHATOCOPHEROL ACETATE (UNII: 9E8 X80 D2L0) METHYLCHLORO ISOTHIAZOLINONE (UNII: DEL7T5QRPN) PEG-150 DISTEARATE (UNII: 6F36Q010 AC) POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F) METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA) FD&C YELLOW NO. 5 (UNII: 1753WB2F1M)	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
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SODIUM CHLORIDE (UNII: 451W47IQ8X) .ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0) METHYLCHLORO ISO THIAZOLINO NE (UNII: DEL7T5QRPN) PEG-150 DISTEARATE (UNII: 6F36Q0I0AC) POLYOXYL 40 HYDRO GENATED CASTOR OIL (UNII: 7YC686GQ8F) METHYLISO THIAZOLINO NE (UNII: 229D0E1QFA) FD&C YELLOW NO. 5 (UNII: 1753WB2F1M)	DISODIUM EDTA-COPPER (UNII: 6 V475AX06U)	
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FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
	METHYLISO THIAZO LINO NE (UNII: 229 D0 E1QFA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
	FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58503-102-01	221 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/06/2017	
Marketing Information				

Marketing information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/06/2017	

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

Establishment				
Name	Address	ID/FEI	Business Operations	
China Ningbo Shangge Cosmetic Technology Corp.		529287434	manufacture (58503-102)	

Revised: 9/2019 China Ningbo Shangge Cosmetic Technology Corp.