

ANTIBACTERIAL- triclosan liquid
Brands International 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.

Active Ingredient - Triclosan 0.115%

Purpose - Antibacterial

Use for handwashing to decrease bacteria on the skin

Warnings

For external use only - hands only

When using this product avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water

Stop use and ask a doctor if irritation or redness develops n condition persists for more than 72 hours

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

Directions

- wet hands
- apply palmful to hands
- scrub thoroughly
- rinse thoroughly

Inactive Ingredients - Water (Aqua), Sodium Laureth Sulfate, Sodium Chloride, Cocamidopropyl Betaine, Fragrance (Parfum), Sodium Lauroamphoacetate, Polyquaternium 7, Glycerin, Citric Acid, Aloe Barbadensis Leaf Extract, Tocopheryl (Vitamin E) Acetate, Methylchloroisothiazolinone, Methylisothiazolinone, Yellow 5 (Cl 19140), Red 4 (Cl 14700)

WHITE FILM
5.75" X 2.375"



CLEAR FILM
5.75" X 2.375"



ANTIBACTERIAL

triclosan liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50 157-201
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRICLOSAN (UNII: 4NM50 39 Y5X) (TRICLOSAN - UNII:4NM50 39 Y5X)	TRICLOSAN	1.15 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
METHYLISOTHIAZOLINONE (UNII: 229D0 E1QFA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C RED NO. 4 (UNII: X3W0 AM1JLX)	
METHYLCHLOROISO THIAZOLINONE (UNII: DEL7T5QRPN)	

WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
SODIUM LAUROAMPHOACETATE (UNII: SLK428451L)	
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600 KD) (UNII: 0L414VCS5Y)	
GLYCERIN (UNII: PDC6A3C0OX)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50157-201-24	709 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/06/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/06/2016	

Labeler - Brands International Corp (243748238)

Establishment

Name	Address	ID/FEI	Business Operations
Brands International Corp		243748238	manufacture(50157-201)

Revised: 5/2016

Brands International Corp