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

Warning

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 and 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

Direction

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

Water (Aqua), Sodium Laureth Sulfate, Sodium Chloride, Cocamidopropyl Betaine, Fragrance (Parfum), Sodium Lauroamphoacetate, Polyquaternium 7, Glycerin, Citric Acid, Tocopheryl Acetate (Vit E Actetate), Methylchloroisothiazolinone, Methylisothiazolinone, Red 33 (Cl 17200), Blue 1 (42090)

BACK LABEL
SIZE: 4.5" X 2.5"
SUBSTRATE: CLEAR FILM
FINISH: GLOSSY UV
COLORS: 2 + 1 VARNISH (WHITE RS & BLACK)

ANTIBACTERIAL

triclosan liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50157-203
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	1.15 mg in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM LAUROAMPHOACETATE (UNII: SLK428451L)	
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600 KD) (UNII: 0L414VCS5Y)	
GLYCERIN (UNII: PDC6A3C0OX)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50157-203-14	414 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(50157-203)

Revised: 5/2016 Brands International Corp