

SBS ULTRAPINK - triclosan gel
Deb USA, Inc.

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.

Drug Facts

Active Ingredient

Triclosan, 0.15%

Purpose

Antibacterial

Uses

For handwashing to reduce bacteria on the skin

Warnings

Avoid contact with eyes

Keep out of reach of children

Consult with a physician or poison control center if ingested

Directions

Apply soap to dry hands

Add water

Lather for 15-20 seconds

Rinse and dry

Inactive Ingredients

Water, Sodium Laureth Sulfate, Cocamide DEA, Propylene Glycol, Sodium Chloride, Chloroxylenol, Acrylic Copolymer, Tetrasodium EDTA, Citric Acid, Glycol Distearate, Cocamide MEA, Sodium Hydroxide, Fragrance, Laureth-10, Magnesium Nitrate, Methylchloroisoithiazolinone, Magnesium Chloride, Methylisothiazolinone, Red 40 (CI16035).

SBS UltraPink

Pearlescent Antibacterial Gel

Ideal for Healthcare, Food Services, Office Environments, Schools, Professional Buildings

Proudly made in the USA

77127-01-116

1 Liter - 33.8 Fluid Ounces

triclosan gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11084-077
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	0.15 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
CHLOROXYLENOL (UNII: 0F32U78V2Q)	
EDETATE SODIUM (UNII: MP1J8420LU)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
MAGNESIUM NITRATE (UNII: 77CBG3UN78)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11084-077-27	1000 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	01/01/2010	

Labeler - Deb USA, Inc. (607378015)

Establishment

Name	Address	ID/FEI	Business Operations
Deb USA, Inc.		607378015	manufacture

