

ANTIBACTERIAL HAND SOAP - triclosan liquid

Delta Brands 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 0.1%

Purpose

Antibacterial

Uses

For handwashing to decrease bacteria on the skin. Recommended for repeated use.

Warnings

For external use only

When using this product

avoid contact with eyes. In case of eye contact immediately flush eyes with water, call a doctor. Avoid contact with broken skin.

Discontinue use if irritation or redness develops. If condition persists for more than 72 hours, consult a doctor.

Keep out of reach of children

Children should only use this product with adult supervision. Do not drink. Not edible. In case of accidental ingestion seek professional assistance or contact Poison Control Center immediately.

Directions

Wet hands. Apply palmful to hands. Scrub thoroughly. Rinse. Recommended for repeated use

Deionized Water, Sodium Laureth Sulfate, Cocamidopropyl Betaine, Sodium Chloride, Cocamide DEA, Glycerin*, Polyquaternium-7*, Fragrance, Tetrasodium EDTA, Methylchloroisothiazolinone, Methylisothiazolinone, Citric Acid, Benzophenone-4, FDC Yellow No. 6, DC Red No 33

*May contain one or more of these ingredients

Product Label



ANTIBACTERIAL HAND SOAP

triclosan liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:20276-165
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	0.1 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
GLYCERIN (UNII: PDC6A3C0OX)	
EDETATE SODIUM (UNII: MP1J8420LU)	
METHYLCHLOROISO THIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISO THIAZOLINONE (UNII: 229D0E1QFA)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:20276-165-75	221 mL in 1 BOTTLE, PUMP		
2	NDC:20276-165-08	237 mL in 1 BOTTLE, PUMP		
3	NDC:20276-165-09	266 mL in 1 BOTTLE, PUMP		
4	NDC:20276-165-10	296 mL in 1 BOTTLE, PUMP		
5	NDC:20276-165-11	325 mL in 1 BOTTLE, PUMP		
6	NDC:20276-165-12	355 mL in 1 BOTTLE, PUMP		
7	NDC:20276-165-13	384 mL in 1 BOTTLE, PUMP		
8	NDC:20276-165-35	400 mL in 1 BOTTLE, PUMP		
9	NDC:20276-165-14	414 mL in 1 BOTTLE, PLASTIC		
10	NDC:20276-165-15	444 mL in 1 BOTTLE, PLASTIC		
11	NDC:20276-165-16	500 mL in 1 BOTTLE, PUMP		
12	NDC:20276-165-20	592 mL in 1 BOTTLE, PLASTIC		
13	NDC:20276-165-24	710 mL in 1 BOTTLE, PLASTIC		
14	NDC:20276-165-32	946 mL in 1 BOTTLE, PLASTIC		

15	NDC:20276-165-33	1000 mL in 1 BOTTLE, PLASTIC		
16	NDC:20276-165-48	1420 mL in 1 BOTTLE, PLASTIC		
17	NDC:20276-165-64	1890 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	09/30/2011	

Labeler - Delta Brands Inc (102672008)

Establishment

Name	Address	ID/FEI	Business Operations
Ningbo Pulisi Daily Chemical Co. Ltd.		529047265	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Delta Dis Ticaret A.S.		643703853	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Primo Ambalaj ve Kimya Sanayi ve Ticaret A S		356694526	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Delta Kozmetik Sanayi Ve Ticaret-Selim Yesil		566220234	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Marmara Temizlik Maddeleri Sanayi Ve Ticaret Ltd STI		356082250	manufacture

Revised: 9/2011

Delta Brands Inc