LUCKY ANTIBACTERIAL HAND SOAP SUPERSOFT- triclos an 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 can 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

Water, Sodium Laureth Sulfate, Sodium Chloride, Cocamidopropyl Betaine, Cocamide DEA, Polyquaternium-7, Fragrance, Methylchloroisothiazolinone, Methylisothiazolinone, Tetrasodium EDTA, Benzophenone-4, Citric Acid, Alphatocopherol Acetate (Vitamin E), DC Red No. 33, FDC Blue No. 1

Package Label





LUCKY ANTIBACTERIAL HAND SOAP SUPERSOFT

triclosan liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:20276-161
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: BPV390 UAP0)	

SO DIUM CHLO RIDE (UNII: 451W47IQ8X)	
COCAMIDO PRO PYL BETAINE (UNII: 50 CF30 11KX)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 900 KD) (UNII: B70CUU14M9)	
METHYLCHLORO ISOTHIAZO LINO NE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)	
EDETATE SO DIUM (UNII: MP1J8420LU)	
BENZOPHENONE (UNII: 701M4TTV9O)	
CITRIC ACID MONO HYDRATE (UNII: 2968 PHW8 QP)	
ALPHA-TO COPHEROL ACETATE (UNII: 9E8 X80 D2L0)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Pa	ickaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:20276-161-75	222 mL in 1 BOTTLE, SPRAY		
2	NDC:20276-161-08	237 mL in 1 BOTTLE, PUMP		
3	NDC:20276-161-09	266 mL in 1 BOTTLE, PUMP		
4	NDC:20276-161-10	296 mL in 1 BOTTLE, PUMP		
5	NDC:20276-161-11	333 mL in 1 BOTTLE, PUMP		
6	NDC:20276-161-12	355 mL in 1 BOTTLE, PUMP		
7	NDC:20276-161-13	400 mL in 1 BOTTLE, PUMP		
8	NDC:20276-161-14	414 mL in 1 BOTTLE, PUMP		
9	NDC:20276-161-15	444 mL in 1 BOTTLE, PUMP		
10	NDC:20276-161-16	500 mL in 1 BOTTLE, PUMP		
11	NDC:20276-161-32	946 mL in 1 BOTTLE, PLASTIC		
12	NDC:20276-161-40	1183 mL in 1 BOTTLE, PLASTIC		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333	09/01/2010			

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 Ambala	j ve Kimya	Sanayi ve	Ticaret A S
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356694526

manufacture

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

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

Revised: 8/2010 Delta Brands Inc