

LUCKY ANTIBACTERIAL HAND SOAP SUPERSOFT- 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 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, Methylchloroisoethiazolinone, Methylisothiazolinone, Tetrasodium EDTA, Benzophenone-4, Citric Acid, Alphanatocopherol Acetate (Vitamin E), FDC Yellow No. 5

Package Label



LUCKY ANTIBACTERIAL HAND SOAP SUPERSOFT
 triclosan liquid

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:20276-164 |
| 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: 059QF0K00R) | |
| SODIUM LAURETH SULFATE (UNII: BPV390UAP0) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |

| | |
|--|--|
| COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX) | |
| COCO DIETHANOLAMIDE (UNII: 92005F972D) | |
| POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 900 KD) (UNII: B70CUU14M9) | |
| METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN) | |
| METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA) | |
| EDETATE SODIUM (UNII: MPIJ8420LU) | |
| BENZOPHENONE (UNII: 701M4TTV9O) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----|------------------|------------------------------|----------------------|--------------------|
| 1 | NDC:20276-164-75 | 222 mL in 1 BOTTLE, SPRAY | | |
| 2 | NDC:20276-164-08 | 237 mL in 1 BOTTLE, PUMP | | |
| 3 | NDC:20276-164-09 | 266 mL in 1 BOTTLE, PUMP | | |
| 4 | NDC:20276-164-10 | 296 mL in 1 BOTTLE, PUMP | | |
| 5 | NDC:20276-164-11 | 333 mL in 1 BOTTLE, PUMP | | |
| 6 | NDC:20276-164-12 | 355 mL in 1 BOTTLE, PUMP | | |
| 7 | NDC:20276-164-13 | 400 mL in 1 BOTTLE, PUMP | | |
| 8 | NDC:20276-164-14 | 414 mL in 1 BOTTLE, PUMP | | |
| 9 | NDC:20276-164-15 | 444 mL in 1 BOTTLE, PUMP | | |
| 10 | NDC:20276-164-16 | 500 mL in 1 BOTTLE, PUMP | | |
| 11 | NDC:20276-164-32 | 946 mL in 1 BOTTLE, PLASTIC | | |
| 12 | NDC:20276-164-40 | 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 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: 8/2010

Delta Brands Inc