ANTIBACTERIAL FOAMING HAND SP CUCUMBER AND MELON - triclos an liquid AMERICAN SALES COMPANY

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 0.60 PERCENT

PURPOSE

ANTIBACTERIAL

USES

FOR HAND WASHING TO REDUCE BACTERIA ON THE SKIN.

WARNINGS

FOR EXTERNAL USE ONLY.

KEEP OUT OF REACH OF CHILDREN

IN CASE OF ACCIDENTAL INGESTION, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

WHEN USING THIS PRODUCT

AVOID CONTACT WITH EYES. IF CONTACT OCCURS, RINSE EYES THROUGHLY WITH WATER.

STOP USING THIS PRODUCT AND ASK DOCTOR IF

IRRITATION AND REDNESS DEVELOP.

DIRECTIONS

PUMP ONTO DRY HANDS, WORK INTO LATHER AND RINSE THOROUGHLY.

OTHER INFORMATION

STORE AT ROOM TEMPERATURE.

INACTIVE INGREDIENTS

WATER, SODIUM XYLENESULFONATE, DIPROPYLENE GLYCOL, AMMONIUM LAURYL SULFATE, COCAMIDOPROPYL BETAINE, FRAGRANCE, DISODIUM PHOSPHATE, CITRIC ACID, BLUE 1, YELLOW 5, RED 40.





ANTIBACTERIAL FOAMING HAND SP CUCUMBER AND MELON

triclosan liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:41520-167

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

TRICLOSAN (UNII: 4NM5039 Y5X) (TRICLOSAN - UNII:4NM5039 Y5X)

TRICLOSAN (0.6 mL in 100 mL

| Inactive Ingredients | | |
|---|----------|--|
| Ingredient Name | Strength | |
| WATER (UNII: 059QF0KO0R) | | |
| SODIUM XYLENESULFONATE (UNII: G4LZF950 UR) | | |
| DIPROPYLENE GLYCOL (UNII: E107L85C40) | | |
| AMMO NIUM LAURYL SULFATE (UNII: Q7AO2R1M0B) | | |
| COCAMIDO PRO PYL BETAINE (UNII: 50 CF3 O 11 KX) | | |
| SO DIUM PHO SPHATE, DIBASIC, DIHYDRATE (UNII: 9425516E2T) | | |
| CITRIC ACID MONOHYDRATE (UNII: 2968 PHW8 QP) | | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | | |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) | | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | | |

| Packaging | | | | | | |
|-----------|-----------------|--------------------------|----------------------|--------------------|--|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | | |
| 1 N | DC:41520-167-08 | 221 mL in 1 BOTTLE, PUMP | | | | |

| Marketing Information | | | | | | |
|-------------------------|--|----------------------|--------------------|--|--|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | | | |
| OTC monograph not final | part333E | 05/24/2011 | | | | |
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Labeler - AMERICAN SALES COMPANY (809183973)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

| Establishment | | | | | |
|-------------------------------|---------|----------------|---------------------|--|--|
| Name | Address | ID/FEI | Business Operations | | |
| APOLLO HEALTH AND BEAUTY CARE | | 20 19 0 12 0 9 | manufacture | | |

Revised: 5/2011 AMERICAN SALES COMPANY