

ANTIBACTERIAL FOAMING HAND SP LEMONGRASS - triclosan liquid
AMERICAN SALES

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 DECREASE 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 THOROUGHLY WITH WATER.

STOP USING THIS PRODUCT AND ASK DOCTOR IF

IRRITATION AND REDNESS DEVELOP.

DIRECTIONS

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

OTHER INFORMATION

STORE AT ROOM TEMPERATURE.

INACTIVE INGREDIENTS

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ANTIBACTERIAL FOAMING HAND SP LEMONGRASS

triclosan liquid

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:41520-172 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-------------------|
| TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X) | TRICLOSAN | 0.60 mL in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| WATER (UNII: 059QF0KO0R) | |
| SODIUM XYLENESULFONATE (UNII: G4LZF950UR) | |
| DIPROPYLENE GLYCOL (UNII: E107L85C40) | |
| AMMONIUM LAURYL SULFATE (UNII: Q7AO2R1M0B) | |
| COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX) | |
| SODIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: 94255I6E2T) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) | |
| EXT. D&C VIOLET NO. 2 (UNII: G5UX3K0728) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--------------------------|----------------------|--------------------|
| 1 | NDC:41520-172-08 | 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 | |

Labeler - AMERICAN SALES (809183973)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------------|---------|-----------|---------------------|
| APOLLO HEALTH AND BEAUTY CARE | | 201901209 | manufacture |

Revised: 5/2011

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