

RED APPLE ANTIBACTERIAL HAND - triclosan soap
Zhejiang Blue Dream Cosmetics Co., Ltd.

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 FACT

Active Ingredient

Triclosan 0.115%

Purpose:

Antibacteria

Uses:

For hand washing to decrease bacteria on skin

Warnings:

For external use only

When using this product, avoid contact with eyes. In case of contact, flush with water

Keep out of reach of children, except under adult supervision. If swallowed, get medical help or contact a Poison Control Center right away.

Directions:

- * Wet hands
- * Apply small amount to hands
- * Scrub thoroughly
- * Rinse
- * For children under 6, use only under adult supervision.

Inactive Ingredient:

Water (aqua), Sodium Laureth Sulfate, Sodium Lauryl Sulfate, Cocamidopropyl Betaine, Sodium Chloride, Decyl Glucoside, Cocamide DEA, Fragrance (Parfum), DMDM Hydantoin, Citric Acid, Disodium EDTA, FD and C Red No. 40

label



Drug Facts

| | |
|---------------------------|----------------|
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Formulated Exclusively and Distributed By:
Enchanté Accessories, Inc., New York, NY 10016
Not Tested On Animals. For Adult Use Only.
Designed in the USA. Made in China.

9 FL. OZ/265ML

RED APPLE ANTIBACTERIAL HAND

triclosan soap

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:34460-6001 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|------------------|
| TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X) | TRICLOSAN | 0.115 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------|----------|
| | |

| | |
|---|-------------------|
| WATER (UNII: 059QF0KO0R) | 84.034 g in 100 g |
| SODIUM LAURETH SULFATE (UNII: BPV390UAP0) | 2.1 g in 100 g |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | 2.5 g in 100 g |
| COCAMIDO PROPYL BETAINE (UNII: 5OCF3O11KX) | 2.5 g in 100 g |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | 2.0 g in 100 g |
| COCO DIETHANOLAMIDE (UNII: 92005F972D) | 1.5 g in 100 g |
| DMDM HYDANTOIN (UNII: BYR0546TOW) | 1.3 g in 100 g |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | 1.1 g in 100 g |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | 1.25 g in 100 g |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | 0.001 g in 100 g |
| APPLE (UNII: B423VGH5S9) | 0.3 g in 100 g |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:34460-6001-1 | 265 g in 1 BOTTLE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------------|--|----------------------|--------------------|
| OTC mono graph not final | part333A | 07/07/2010 | |

Labeler - Zhejiang Blue Dream Cosmetics Co., Ltd. (529047234)

Registrant - Zhejiang Blue Dream Cosmetics Co., Ltd. (529047234)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---------|-----------|---------------------|
| Zhejiang Blue Dream Cosmetics Co., Ltd. | | 529047234 | manufacture |

Revised: 6/2010

Zhejiang Blue Dream Cosmetics Co., Ltd.