# 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.

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#### **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.

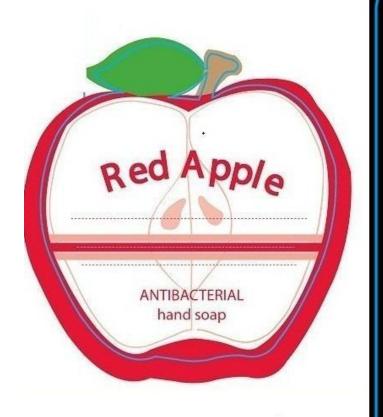
#### **Directions:**

- \* 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



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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

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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
SO DIUM LAURETH SULFATE (UNII: BPV390 UAP0)	2.1 g in 100 g
SO DIUM LAURYL SULFATE (UNII: 368GB5141J)	2.5 g in 100 g
COCAMIDO PRO PYL BETAINE (UNII: 50 CF3 O 11 KX)	2.5 g in 100 g
SO DIUM CHLO RIDE (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
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)	1.1 g in 100 g
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)	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			
1	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	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 monograph 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	<b>Business Operations</b>	
Zhejiang Blue Dream Cosmetics Co., Ltd.		529047234	manufacture	

Revised: 6/2010 Zhejiang Blue Dream Cosmetics Co., Ltd.