

MANDARIN ORANGE 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, FD and C Yellow No. 5

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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.	
8.1 FL. OZ/240ML	

MANDARIN ORANGE ANTIBACTERIAL HAND

triclosan soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:34460-6004
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: 059QF0K00R)	84.033 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
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	2.5 g in 100 g
SODIUM CHLORIDE (UNII: 451W47IQ8X)	2.0 g in 100 g
COCAMIDE DIETHANOLAMINE (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
ORANGE (UNII: 5EVU04N5QU)	0.3 g in 100 g
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	0.001 g in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:34460-6004-1	240 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333	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.