

SPA ORIGINALS ANTIBACTERIAL GOLD HAND - triclosan soap
Custom Solutions, Inc

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.

Spa Originals Antibacterial Gold Hand Soap

Active Ingredient

Triclosan 0.12%

Purpose

Antibacterial

Uses

For hand washing, sanitizing and to decrease bacteria on the skin

Caution

For external use only.

When using this product

avoid contact with the eyes

Discontinue use and seek medical attention if

skin irritant and redness develops

Keep out of reach of children

Children under six years should be supervised by an adult when using this product. If swallowed, get medical help or contact a Poison Control Center right away.

Directions for use

Proper usage: Wet hands with water. Pump small amount into hands. Lather vigorously for 15 seconds. Rinse and dry thoroughly.

Inactive Ingredients

Water, Sodium Alcohol Ether Sulphate, Coconut Diethanolamide, Sodium Dodecyl Sulfate, Dodecyl Dimethyl Betaine, Citric Acid, Sodium Chloride, Disodium EDTA, DMDM Hydantoin, Fragrance, Vitamin E, FDandC Yellow 5, Yellow 6

MADE IN CHINA

Distributed by Custom Solutions, Inc.

Lee's Summit, MO 64064

www.customsolutionsinc.com

Spa Originals

Antibacterial Gold

HAND SOAP

enriched with vitamin e

Kills Germs, Neutralizes Odors

7.5 fl. oz. (221mL)

Package Labeling



SPA ORIGINALS ANTIBACTERIAL GOLD HAND			
triclosan soap			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76405-011
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	0.12 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76405-011-02	221 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	08/22/2011	

Labeler - Custom Solutions, Inc (966678240)

Revised: 9/2011

Custom Solutions, Inc