

PERSONAL CARE ANTIBACTERIAL HAND - triclosan soap

Personal Care Products, LLC

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.

Personal Care Antibacterial Hand Soap

Active Ingredient

Triclosan 0.2%

Purpose

Antibacterial

Uses

for handwashing to decrease bacteria on the skin

Warnings

For external use only

When using this product

Avoid contact with eyes. In case of eye contact, flush with water.

Stop use and ask a doctor

if irritation and redness develops

Keep out of reach of children

If swallowed get medical help or contact a Poison Control Center right away.

Directions

pump into hands

lather vigorously for at least 15 seconds

rinse and dry thoroughly

Inactive Ingredients

water (aqua), ammonium lauryl sulfate, ammonium chloride, lauramide DEA, DMDM hydantoin, fragrance, citric acid, tetrasodium EDTA, yellow #5, red #40

Personal Care

Antibacterial

Washes Away Germs

Soap

7.5 fl oz

(221ml)

Distributed by Personal Care Products, Inc.
Bingham Farms, MI 48205-3463
Made In China

Drug Facts

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PERSONAL CARE ANTIBACTERIAL HAND

triclosan soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:29500-9038
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	0.2 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
AMMONIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)	
AMMONIUM CHLORIDE (UNII: 01Q9PC255D)	
LAURIC DIETHANOLAMIDE (UNII: I29I2VHG38)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE SODIUM (UNII: MP1J8420LU)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:29500-9038-6	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	04/11/2011	

Labeler - Personal Care Products, LLC (966155082)**Establishment**

Name	Address	ID/FEI	Business Operations
Ningbo Liyuan Daily Chemical Products Co Ltd		530766098	manufacture

Revised: 6/2011

Personal Care Products, LLC