PERSONAL CARE ANTIBACTERIAL HAND - FRESH MELON - 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 - Fresh Melon

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, blue#1, yellow #5

Personal Care

Antibacterial

Washes Away Germs

Hand soap

Fresh Melon 7.5 fl oz (221ml)

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





PERSONAL CARE ANTIBACTERIAL HAND - FRESH MELON

triclosan soap

Product	Inform	ation
Product	Intorn	lation

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:29500-9079

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)

AMMO NIUM CHLO RIDE (UNII: 01Q9PC255D)

LAURIC DIETHANO LAMIDE (UNII: I29 I2VHG38)

DMDM HYDANTO IN (UNII: BYR0546 TOW)

CITRIC ACID MONOHYDRATE (UNII: 2968 PHW8 QP)

EDETATE SO DIUM (UNII: MP1J8420LU)

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

FD&C YELLOW NO. 5 (UNII: I753WB2F1M)

Packaging # Item Code Package Description Marketing Start Date Marketing End Date 1 NDC:29500-9079-9 221 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	0 4/11/20 11		

Labeler - Personal Care Products, LLC (966155082)

Establishment				
Name	Address	ID/FEI	Business Operations	
Ningbo United Group Co Ltd		544900137	manufacture	

Establishment			
Name	Address	ID/FEI	Business Operations
Ningbo Pulisi Daily Chemical Products		529047265	manufacture

Establishment			
Name	Address	ID/FEI	Business Operations
Ningbo Unichem Household Products Co Ltd		528196956	manufacture

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

Revised: 11/2011 Personal Care Products, LLC