

PACIFIC ANTI-BACTERIAL HAND CLEANSE BLUEBERRY ESSENCE- triclosan gel
Filo America

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.

Active Ingredient

Purpose

Triclosan 0.15%.....Antibacterial

Uses

for handwashing to eliminate bacteria and germs on the skin.

Keep away from children, except if under adult supervision. If swallowed, get medical help or contact a Poison Control Center right away.

Wet hand, apply palmful to hands, scrub thoroughly, Rinse.

Warnings

For external use only.

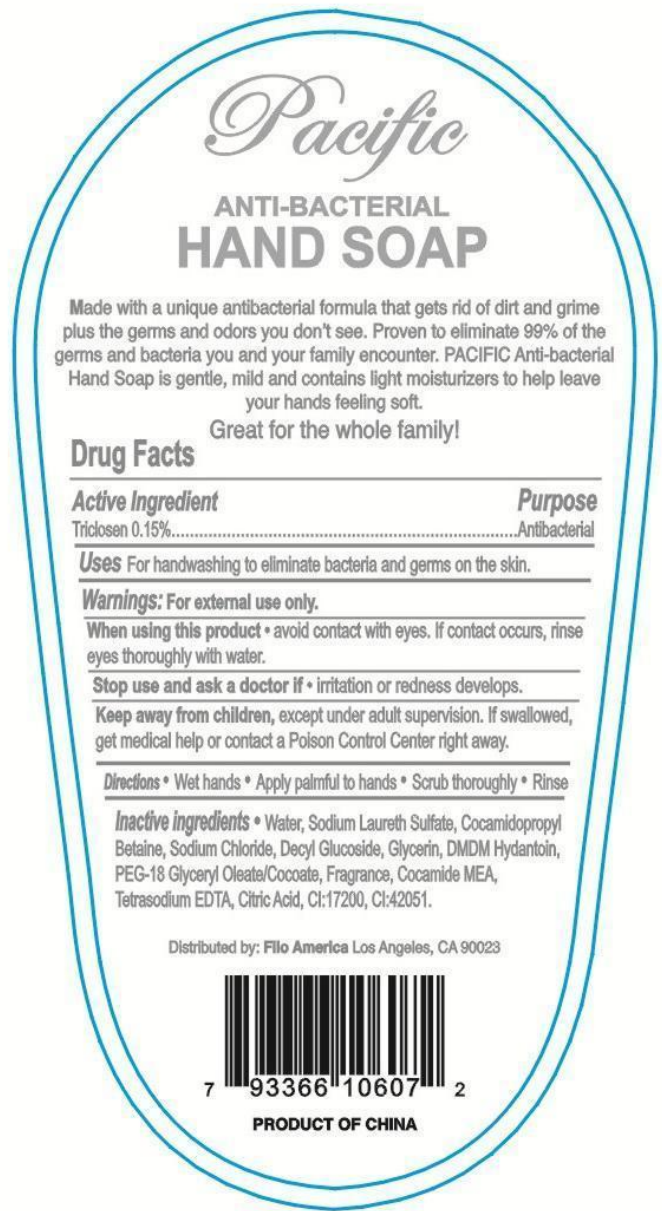
When using this product, avoid contact with eyes, if contact occurs, rinse eyes thoroughly with water.

Stop use and ask a doctor, if irritation or redness develops

Wet hand, apply palmful to hands, scrub thoroughly, Rinse.

Inactive Ingredients

camphor, carbomer, ethyl alcohol, fd&c blue no.1, isopropyl alcohol, methylchloroisothiazolinone, methylisothiazolinone, sodium hydroxide, water, cocamide MEA, PEG-18 glyceryl



PACIFIC ANTI-BACTERIAL HAND CLEANSE BLUEBERRY ESSENCE			
triclosan gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50438-102
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	1.5 mg in 1 mL
Inactive Ingredients			

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50438-102-01	500 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	08/08/2013	

Labeler - Filo America (943873703)

Establishment

Name	Address	ID/FEI	Business Operations
Ningbo Pulisi Daily Chemical Products Co., Ltd.		529047265	manufacture(50438-102)

Revised: 8/2013

Filo America