

ROYAL ANTIBACTERIAL ORANGE BERRY HAND CLEANSE- 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 decrease bacteria on the skin.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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

Warnings

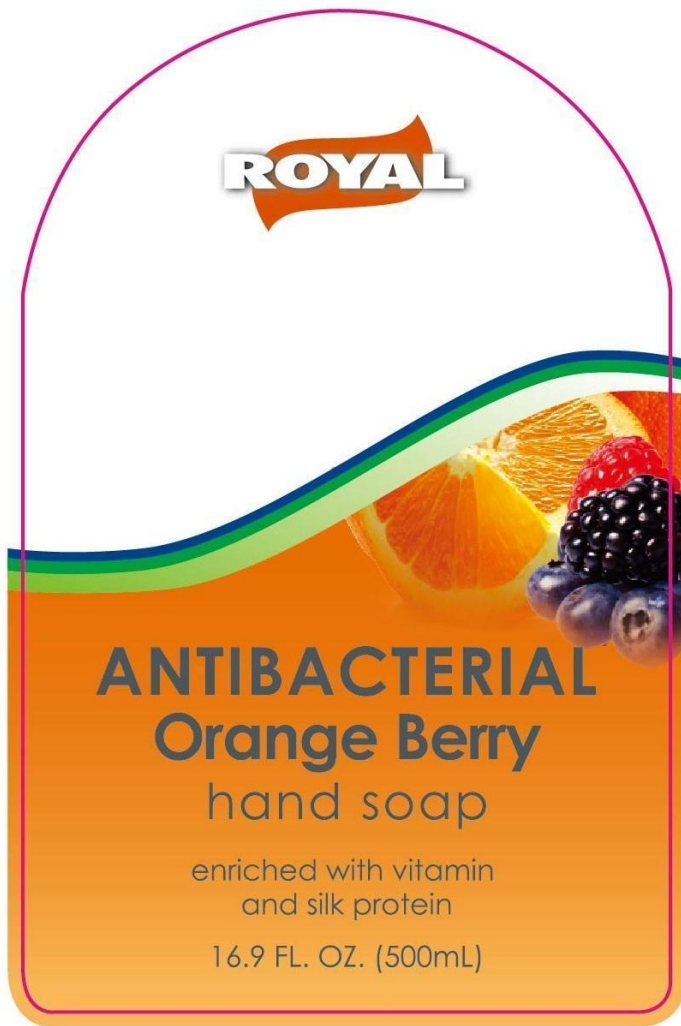
For external use only.

Avoid getting into eyes. If this happens, rinse thoroughly with water.

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



ROYAL

Drug Facts

Active Ingredient	Purpose
Triclosan 0.15%	Antibacterial

Uses For handwashing to decrease bacteria on the skin.

Warnings: for external use only.
Avoid getting into Eyes. If this happens, rinse thoroughly with water.

KEEP OUT OF REACH OF CHILDREN. If swallowed, get medical help or contact a Poison Control Center right away.

Directions: • Wet hands • Apply to hands • Scrub thoroughly • Rinse.

Inactive Ingredients: Water, Sodium Laureth Sulfate, Cocamidopropyl Betaine, Glycerin, Sodium Chloride, Glyceryl Cocoate, Fragrance, Polyquaternium-7, Cocamide MEA, DMDM Hydantoin, Tetrasodium EDTA, Citric Acid, FD&C Red 40, FD&C Yellow 5, FD&C Yellow 6.

*This product is not manufactured or distributed by Colgate-Palmolive Company, distributor of Softsoap® Brand Aquarium Series Antibacterial Soap.



7 93366 20366 5

Distributed by:
FILO AMERICA
P.O. Box 23592
Los Angeles, CA 90023
Made in China
Questions or Concerns?
1.866.460.0322

ROYAL ANTIBACTERIAL ORANGE BERRY HAND CLEANSE
triclosan gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50438-105
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: 059QF0KO0R)			
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:50438-105-01	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	09/17/2013	

Labeler - Filo America (943873703)

Establishment

Name	Address	ID/FEI	Business Operations
Ningbo Pulisi Daily Chemical Products Co., Ltd.		529047265	manufacture(50438-105)

Revised: 9/2013

Filo America