

**ROYAL ANTIBACTERIAL TROPICAL FRUIT 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.*

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***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***

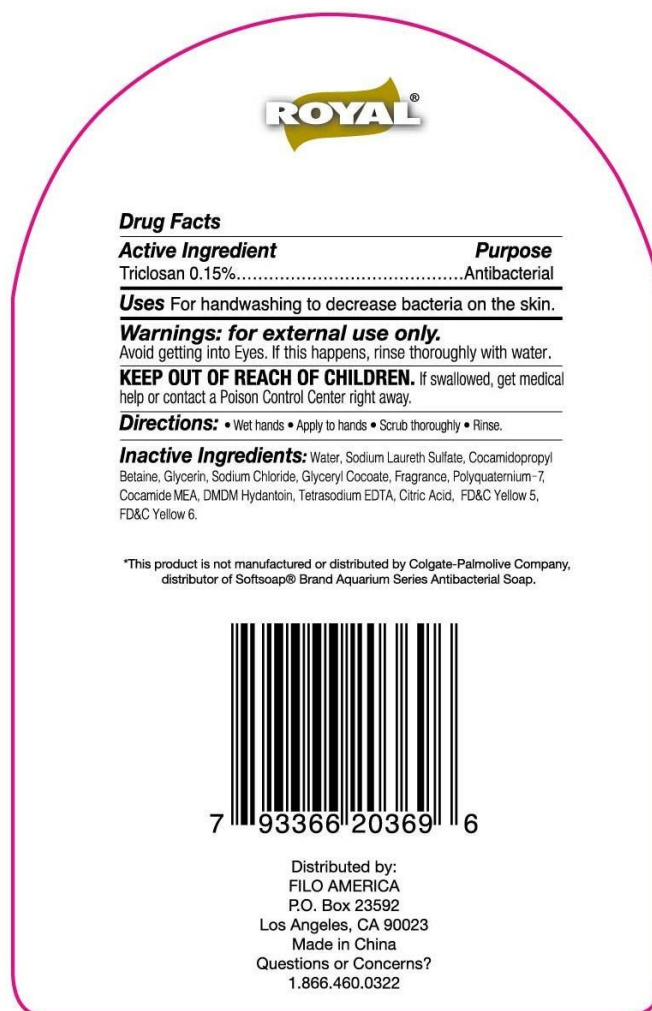
For external use only.

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 ANTIBACTERIAL TROPICAL FRUIT HAND CLEANSE			
triclosan gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50438-108
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)			

<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>PEG-150 DISTEARATE</b> (UNII: 6F36Q0I0AC)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>METHYLCHLOROISOTHIAZOLINONE</b> (UNII: DEL7T5QRPN)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	
<b>METHYLISOTHIAZOLINONE</b> (UNII: 229D0E1QFA)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50438-108-01	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(50438-108)

Revised: 9/2013

Filo America