# ANTIBACTERIAL FOR THE KITCHEN- triclosan solution TOPCO ASSOCIATES 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.

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#### **DRUG FACTS**

#### **ACTIVE INGREDIENT**

TRICLOSAN 0.46%

#### **PURPOSE**

ANTIBACTERIAL

#### **USES**

HELPS REDUCE BACTERIA ON THE SKIN

#### **WARNINGS**

FOR EXTERNAL USE ONLY

#### WHEN USING THIS PRODUCT

AVOID CONTACT WITH EYES. IF CONTACT OCCURS, RINSE EYES THOROUGHLY WITH WATER.

#### STOP USING THIS PRODUCT AND ASK DOCTOR

IF IRRITATION AND REDNESS DEVELOP

#### KEEP OUT OF REACH OF CHILDREN

IN CASE OF ACCIDENTAL INGESTION, GET MEDICAL HELP OR CONTACT POISON CONTROL CENTER IMMEDIATELY

#### **DIRECTIONS**

PUMP ONTO DRY HANDS, WORK INTO LATHER AND RINSE THOROUGHLY.

#### OTHER INFORMATION

STORE AT ROOM TEMPERATURE

#### **INACTIVE INGREDIENTS**

WATER (AQUA), SODIUM XYLENE SULFONATE, DIPROPYLENE GLYCOL, GLYCERIN, SODIUM PCA, AMMONIUM LAURYL SULFATE, COCAMIDOPROPYL BETAINE, POLYQUATERNIUM-10, FRAGRANCE (PARFUM), DISODIUM PHOSPHATE, CETYL ALCOHOL, ALOE BARBADENSIS LEAF JUICE, CITRIC ACID, METHYLPARABEN, PROPYLPARABEN, YELLOW 5 (CI 19140), YELLOW 6 (CI 15985)

#### LABEL COPY



#### ANTIBACTERIAL FOR THE KITCHEN

triclosan solution

Product Type HUMAN OTC DRUG Item Code (Source) NDC:36800-160

Route of Administration TOPICAL

#### **Active Ingredient/Active Moiety**

Ingredient NameBasis of StrengthStrengthTRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)TRICLOSAN0.46 mL in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM XYLENESULFONATE (UNII: G4LZF950 UR)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM PYRROLIDONE CARBO XYLATE (UNII: 469 OTG57A2)	
AMMO NIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)	
COCAMIDO PRO PYL BETAINE (UNII: 50 CF3 O 11 KX)	
POLYQUATERNIUM-10 (400 CPS AT 2%) (UNII: HB1401PQFS)	

SODIUM PHO SPHATE, DIBASIC ANHYDRO US (UNII: 22ADO53M6F)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)	
METHYLPARABEN (UNII: A2I8 C7HI9 T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

ı	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:36800-160-08	222 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	08/03/2011			

## Labeler - TOPCO ASSOCIATES LLC (006935977)

### Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture	

Revised: 8/2011 TOPCO ASSOCIATES LLC