

ANTIBACTERIAL - 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.

Antibacterial

Active Ingredient

Triclosan 0.2%

Purpose antibacterial

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

Uses

for hand washing 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.

Directions

Pump into hands

Lather vigorously for at least 15 seconds

Rinse and dry thoroughly

Inactive ingredients

Water (aqua), sodium laureth sulfate, sodium chloride, coamide DEA, DMDM hydantoin, fragrance, citric acid, tetrasodium EDTA, yellow #5, red #40

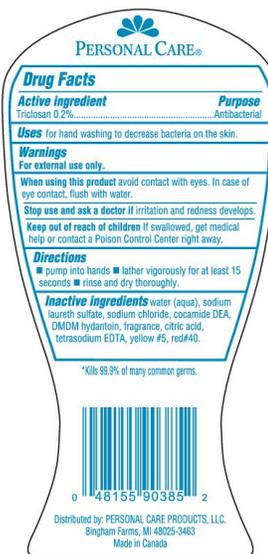
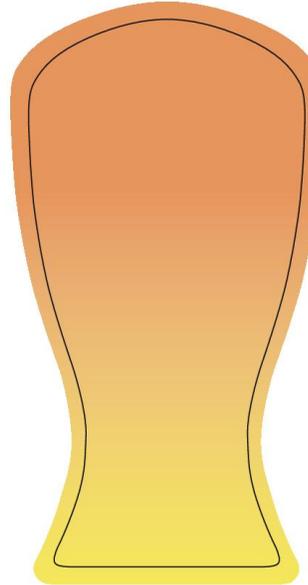
FRONT LABEL PRINTS ON CLEAR LABEL STOCK
WITH WHITE INK SILK SCREEN AS SHOWN

BACK LABEL PRINTS ON PAPER LABEL STOCK
PRINTED ON BOTH SIDES

FRONT LABEL
CLEAR LABEL STOCK

FRONT LABEL
WHITE INK FOR SCREEN

BACK LABEL
BOTTLE/GLUE SIDE



Kills 99% of germs
Antibacterial soap
Moisterizing hand soap
15 fl oz (444 ml)

ANTIBACTERIAL

triclosan soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:29500-903
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	.888 mL in 444 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
CO CO DIETHANOLAMIDE (UNII: 92005F972D)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	

CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)				
EDETATE SODIUM (UNII: MP1J8420LU)				
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:29500-903-85	444 mL in 1 BOTTLE, PUMP		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	01/01/2011		

Labeler - Personal Care Products LLC (966155082)

Registrant - Personal Care Products LLC (966155082)

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

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

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