

ANTIBACTERIAL HAND - triclosan soap

Greenbrier International, Inc.

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 Hand Soap

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Active Ingredient

Triclosan 0.15%

Purpose

Antibacterial

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 contact, flush with water.

Stop use and ask a doctor if irritation and redness develops.

Keep out of reach of children if swallowed, get medical help or contact a poison control center right away.

Directions

- pump into hands
- lather vigorously for at least 15 seconds
- rinse and dry thoroughly

Other Information

- store at room temperature

Inactive Ingredients

water, sodium c14-16 olefin sulfonate, sodium laureth sulfate, cocamide DEA, sodium chloride, PEG-150 distearate, fragrance, citric acid, glycerin, disodium EDTA, tocopheryl acetate, methylchloroisothiazolinone, fd c yellow no.5, methylisothiazolinone.

Antibacterial Hand Soap 16oz/500ml (33992-0100-0)



ANTIBACTERIAL HAND

triclosan soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:33992-0100
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 OLEFIN SULFONATE (UNII: N816E2SOKI)	
SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	
CO CO 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:33992-0100-0	500 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333E	12/05/2012	

Labeler - Greenbrier International, Inc. (610322518)

Registrant - Ningbo Unichem Household Products Co., Ltd. (528196956)

Establishment

Name	Address	ID/FEI	Business Operations
Ningbo Unichem Household Products Co., Ltd.		528196956	manufacture(33992-0100)

Revised: 12/2012

Greenbrier International, Inc.