HAND CLEANSE REFILL- triclos an gel 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.

Hand Cleanse

Active Ingredient Purpose

Triclosan 0.15%......Antibacterial

Uses

forthe temporary relief of minor aches and pains of muscles and joints.

□ **Keep out of reach of children.** □ In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

Other information

• store at 20oC to 25oC (68o to 77oF)

□ Warnings

For external use only. Avoid contact with eyes.

Ask a doctor before use if you have cough associated with

- smoking
- excessive phlegm
- asthma
- emphysema
- persistent or chronic cough

When using this product do not

- heat
- microwafe
- add to hot water or any container where healing water may cause splattering and result in burns
- use in eyes or directly on mucous membranes
- take by mouth or place in nostrils
- apply to wounds or damaged skin
- bandage skin

Consult a doctor and discontinue use if condition worsesn, persists for more than 1 week or tends to recur.

Directions

- see important warnings under "When using this product"
- adults & children 2 years of age & older: apply to the affected area not more than 3 to 4 times daily.
- children under 2 years of age: consult a physician.

Inactive Ingredients

camphor, carbomer, ethyl alcohol, fd&c blue no.1, isopropyl alcohol, methylchloroisothiazolinone, methylisothiazolinone, sodium hydroxide, water.

Antibacterial Hand Soap

Drug Facts

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 eye 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, d&c red no.33, methylisothiazolinone.



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HAND CLEANSE REFILL

triclosan gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:33992-3008

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength
TRICLOSAN (UNII: 4NM5039 Y5X) (TRICLOSAN - UNII:4NM5039 Y5X)

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Inactive Ingredients					
Ingredient Name	Strength				
WATER (UNII: 059QF0KO0R)					
SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)					
SODIUM LAURETH SULFATE (UNII: BPV390 UAP0)					
COCO DIETHANOLAMIDE (UNII: 92005F972D)					
SODIUM CHLORIDE (UNII: 451W47IQ8X)					
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)					
CITRIC ACID MONO HYDRATE (UNII: 2968 PHW8 QP)					
GLYCERIN (UNII: PDC6A3C0OX)					
EDETATE DISO DIUM (UNII: 7FLD9 1C8 6 K)					
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)					
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)					
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)					
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)					

Packaging							
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
	1	NDC:33992-3008-1	500 mg in 1 BOTTLE; Type 0: Not a Combination Product	05/24/2013			

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not final	part333E	05/24/2013				

Labeler - Greenbrier International, Inc. (610322518)

Establishment						
Name	Address	ID/FEI	Business Operations			
China Ningbo Shangge Cosmetic Technology Corp.		529287434	manufacture(33992-3008)			

Revised: 4/2019 Greenbrier International, Inc.