HAND CLEANSE - OCEAN FRESH- 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 - Ocean Fresh

Active Ingredient Purpose

Triclosan 0.15%......Antibacterial

\Box 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.





Drug Facts

Active ingredient

Purpose

Triclosan 0.15%..

.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 blue no.1, methylisothiazolinone.



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HAND CLEANSE - OCEAN FRESH

triclosan gel

Product Information

Product Type HUMAN OTC DRUG

Item Code (Source)

NDC:33992-3010

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
	EDICI OCANI	

TRICLOSAN (UNII: 4NM5039 Y5X) (TRICLOSAN - UNII:4NM5039 Y5X)

TRICLOSAN

7.5 mg in 500 mg

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)

 $\textbf{SODIUM LAURETH SULFATE} \hspace{0.1cm} \textbf{(UNII: BPV390UAP0)} \\$

COCO DIETHANOLAMIDE (UNII: 92005F972D)

SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
METHYLCHLORO ISO THIAZO LINO NE (UNII: DEL7T5QRPN)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)	

Packaging							
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:33992-3010-1	500 mg in 1 BOTTLE; Type 0: Not a Combination Product	05/24/2013				
Marketing Information							
	Marketing Catego	ry Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
О	TC monograph not fi	nal part333E	05/24/2013				

$\boldsymbol{Labeler} \text{ - } \textbf{Greenbrier International, Inc. (610322518)}$

Establishment						
Name	Address	ID/FEI	Business Operations			
China Ningbo Shangge Cosmetic Technology Corp.		529287434	manufacture(33992-3010)			

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