

HAND CLEANSE- triclosan 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.

Active Ingredient	Purpose
Triclosan 0.15%.....	Antibacterial

Uses

for the 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 20°C to 25°C (68° to 77°F)

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
- microwave
- add to hot water or any container where heating 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 worsens, 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.

HAND SOAP

Antibacterial

Kills Germs
Eliminates Bacteria on Hands

20 FL OZ (592 mL)

Drug Facts

Active ingredients.....Purpose
Triclosan 0.15%.....Antibacterial

Uses - For handwashing to decrease bacterial on the skin.

Warnings For external use only.

Do not apply around eyes. Do not use in ears & mouth

When using this product, avoid contact with eyes.
In case of contact flush eyes with water.

Stop use and ask a doctor if redness or irritation develop and persist for more than 72 hours.

Keep out of reach of children. Children must be supervised in use of this product. If swallowed, get medical help or contact a Poison Control Center right away.

Directions - wet hands - apply palmful to hands - scrub thoroughly - rinse

Inactive ingredients benzophenone-4, citric acid, cocamide MEA, cocamidopropyl betaine, FD&C red 33, FD&C yellow 5, FD&C yellow 6, fragrance, glycerin, methylchloroisothiazolinone, methylisothiazolinone, sodium chloride, sodium laureth sulfate, tetrasodium EDTA, water.

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DISTRIBUTED BY
GREENBRIER INTERNATIONAL, INC.
500 VOLVO PARKWAY, CHESAPEAKE, VA 23320
MADE IN CHINA

HAND CLEANSE

triclosan gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:33992-1413
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	0.15 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
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WATER (UNII: 059QF0K00R)
SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)
COCO 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:33992-1413-1	444 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	09/11/2013	

Labeler - Greenbrier International, Inc. (610322518)

Establishment

Name	Address	ID/FEI	Business Operations
Ningbo Pulisi Daily Chemical Products Co., Ltd.		529047265	manufacture(33992-1413)

Revised: 9/2013

Greenbrier International, Inc.