

**HAND CLEANSE - OCEAN FRESH- triclosan gel**  
**China Ningbo Shangge Cosmetic Technology Corp.**

*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

**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°F 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.



The back of the bottle features a white label with black text and a black border. At the top, it says "ANTIBACTERIAL" in a banner, "LIQUID Hand Soap" in large letters, and "Cleanse & Moisturize with Vitamin E" in smaller text. A black bar at the top right contains the text "OCEAN FRESH SCENT". The main label is divided into sections: "Drug Facts" with a table of active ingredients and purposes; "Uses" for hand washing; "Warnings" for external use only; "Directions" for use; "Other information" about storage; and "Inactive ingredients" list. At the bottom, there is a barcode with the number "6 39277 31579 3" and the product ID "111579-14454-001-1301". The distributor information "DISTRIBUTED BY GREENBRIER INTERNATIONAL, INC. 500 VOLVO PARKWAY, CHESAPEAKE, VA 23320 MADE IN CHINA" is printed at the very bottom.

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.

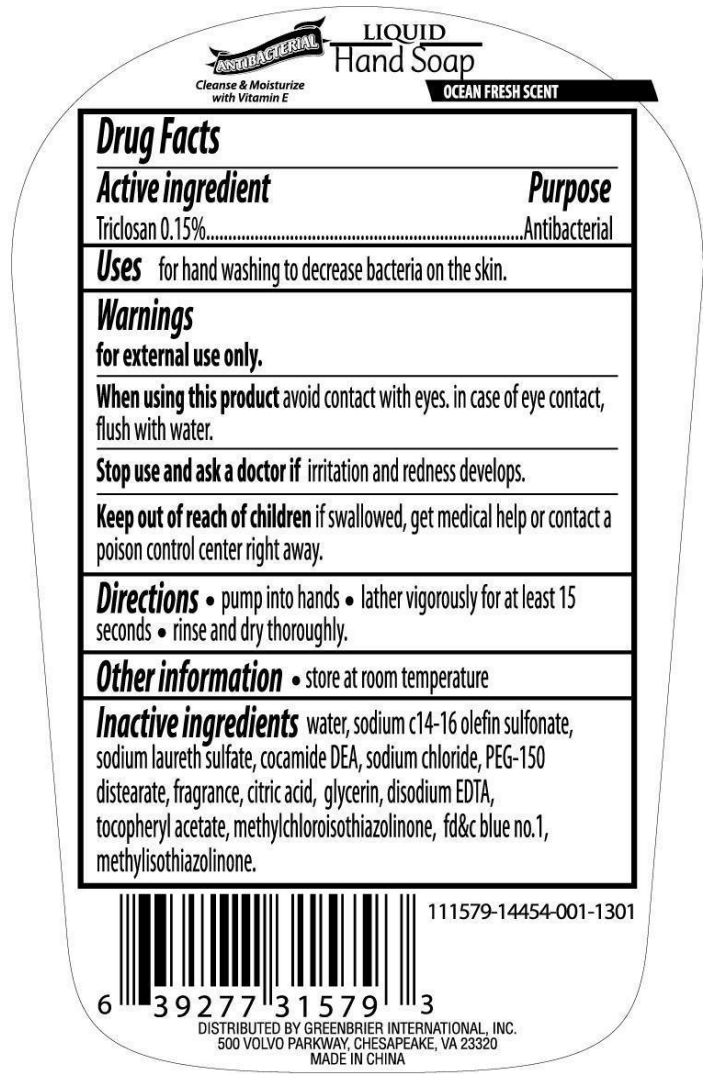
**Other information** • store at room temperature

**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.

111579-14454-001-1301

6 39277 31579 3

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



## HAND CLEANSE - OCEAN FRESH

triclosan gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58503-010
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TRICLOSAN</b> (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	7.5 mg in 500 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM C14-16 OLEFIN SULFONATE</b> (UNII: O9W3D3YF5U)	
<b>SODIUM LAURETH SULFATE</b> (UNII: BPV390UAP0)	
<b>COCO DIETHANOLAMIDE</b> (UNII: 92005F972D)	

<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>PEG-150 DISTEARATE</b> (UNII: 6F36Q0I0AC)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>METHYLCHLOROISOTHIAZOLINONE</b> (UNII: DEL7T5QRPN)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>METHYLISOTHIAZOLINONE</b> (UNII: 229D0E1QFA)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58503-010-01	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** - China Ningbo Shangge Cosmetic Technology Corp. (529287434)

### Establishment

Name	Address	ID/FEI	Business Operations
China Ningbo Shangge Cosmetic Technology Corp.		529287434	manufacture(58503-010)

Revised: 11/2022

China Ningbo Shangge Cosmetic Technology Corp.