

**WATERLESS ANTI-BACTERIAL HAND CLEANSER - ethyl alcohol liquid**  
**Tri-Coastal Design Company 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.*

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**Drug Facts**

**Active Ingredient**

Ethyl Alcohol 62%

**Purpose**

Antiseptic

**Uses**

- For handwashing to decrease bacteria on the skin
- Recommended for repeated use

**Warnings**

- For external use only
- Flammable, keep away from fire and flame
- Does not contain grain alcohol; do not drink, if taken internally will produce serious gastric disturbances

**When using this product**

- avoid the eyes and mucous membranes
- in the case of eyes or mucous membrane contact; rinse area thoroughly with water

**Stop use and ask a doctor if**

- condition worsens
- redness or irritation develops
- if condition persists for more than 3 days

**Keep out of reach of children**

If swallowed contact a doctor or Poison Control Center immediately.

**Directions**

- rub quarter sized amount between hands until dry
- supervise children in the use of this product
- in the case of eye contact, rinse eyes thoroughly with water

**Other information**

- store below 105F
- may discolor some fabrics

## Inactive Ingredients

Benzophenone-4, Carbomer, DC Orange 4, Fragrance, Glycerin, PEG-40 Hydrogenated Castor Oil, Propylene Glycol, Tocopherol, Jojoba Oil, Triethanolamine, Water

## Package Label

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<b>Drug Facts</b>	
<b>Active Ingredient</b>	<b>Purpose</b>
Ethyl Alcohol 62%.....	Antiseptic
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<ul style="list-style-type: none"> <li>For handwashing to decrease bacteria on the skin</li> <li>Recommended for repeated use</li> </ul>	
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<b>Inactive Ingredients</b>	
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Manufactured for and Distributed by ©2010 Tri-Coastal Design East Hanover, NJ 07936 www.tricoastaldesign.com All rights reserved. Made in China 8.4 fl oz / 250 ml	

## WATERLESS ANTI-BACTERIAL HAND CLEANSER

ethyl alcohol liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49852-015
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
D&C ORANGE NO. 4 (UNII: Q1LIY3BO0U)	

<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYOXYL 40 HYDROGENATED CASTOR OIL</b> (UNII: 7YC686GQ8F)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>ALPHA-TOCOPHEROL</b> (UNII: H4N855PNZ1)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>WATER</b> (UNII: 059QF0KO0R)	

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49852-015-08	250 mL in 1 BOTTLE, PLASTIC		
2	NDC:49852-015-60	60 mL in 1 BOTTLE, PLASTIC		
3	NDC:49852-015-45	45 mL in 1 BOTTLE, PLASTIC		

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333	12/01/2009	

**Labeler** - Tri-Coastal Design Company Inc. (609734900)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Guangzhou St Eva Fine Chemical Co Ltd		528039793	manufacture

Revised: 11/2009

Tri-Coastal Design Company Inc.