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.

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 an 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, FDC Blue 1, Fragrance, Glycerin, Jojoba Oil, PEG-40 Hydrogenated Castor Oil, Propylene Glycol, Tocopherol, Triethanolamine, Water

Package Label

Package Label



Drug Facts Active Ingredient Purpose Ethyl Alcohol 62%..... - For handwashing to decrease bacteria on the skin Recommended for repeated use Warnings For external use only Flammable, keep away from fire & flame = Does not contain grain alcohol; do not drink if taken internally will produce serious 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 105°F * may discolor some fabrics inactive ingredients Benzophenone-4, Carbomer, FD&C Blue 1, Fragrance, Glycerin, Jojobs Oil, PEG-40, Hydrogenated Castor Oil, Propylene Glycol, Tocopherol,Triethanolamine, Water Manufactured for and Distributed by ©2010 Tri-Coastal Design Wharton, NJ 07885 www.tricoastaldesign.com All rights reserved. Made in China

WATERLESS ANTI-BACTERIAL HAND CLEANSER

ethyl alcohol liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49852-163	
Route of Administration	TOPICAL			

16 fl oz / 473 ml

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
GLYCERIN (UNII: PDC6A3C0OX)			
JOJOBA OIL (UNII: 724GKU717M)			
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)			
TROLAMINE (UNII: 9O3K93S3TK)			
WATER (UNII: 059QF0KO0R)			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:49852-163-16	473 mL in 1 BOTTLE, PUMP		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333	09/01/2010	

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

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

Revised: 8/2010 Tri-Coastal Design Company Inc.