

ANTI BACTERIAL HAND SANITIZER - 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

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

Avoid the eyes and mucous membranes.
In case of contact; rinse area thoroughly with water

Keep out of reach of children

If swallowed contact a doctor or Poison Control Center immediately.

Directions

Rub dime sized amount between hands until dry

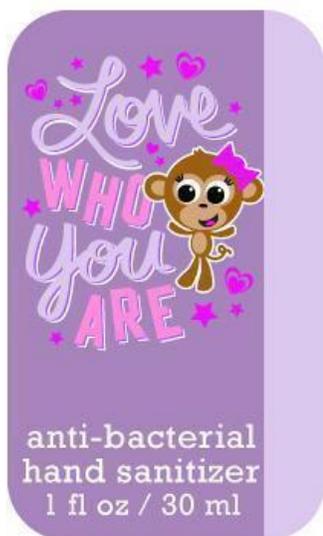
Other Information

Store below 105F
May discolor some fabrics

Inactive ingredients

Benzophenone-4, Carbomer, Fragrance, FDC Blue 1, DC Red 33, Glycerin, PEG-40 Hydrogenated Castor Oil, Propylene Glycol, Tocopherol and Jojoba Oil, Triethanolamine, Water (Aqua)

Package Label



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PEEL

Drug Facts
Active Ingredient
 Ethyl Alcohol 62%
Purpose Antiseptic

Use
 For decreasing bacteria on the skin

Warnings

- For external use only
- Flammable, keep away from fire & flame

Drug Facts (continued)

Does not contain grain alcohol; Do not drink. If taken internally will produce serious gastric disturbances

Avoid the eyes and mucous membranes. In case of contact, rinse area thoroughly with water

Keep out of reach of children
 If swallowed contact a doctor or Poison Control Center immediately

Directions
 Rub dime sized amount between hands until dry

Drug Facts (continued)

Store below 105°F
 May discolor some fabrics

Inactive Ingredients
 Benzophenone-4, Carbomer, Fragrance (Parfum), FD&C Blue 1, D&C Red 33, Glycerin, PEG-40 Hydrogenated Castor Oil, Propylene Glycol, Tocopherol & Jojoba Oil, Triethanolamine, Water (Aqua)

1 fl oz / 30 ml

12M

ANTI BACTERIAL HAND SANITIZER			
ethyl alcohol liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49852-160
Route of Administration	TOPICAL		
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
SULISOBENZONE (UNII: 1W6L629B4K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TOCOPHEROL (UNII: R0ZB2556P8)	
JOJOBA OIL (UNII: 724GKU717M)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49852-160-30	30 mL in 1 BOTTLE, PLASTIC		
2	NDC:49852-160-40	40 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	11/15/2011	

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

Name	Address	ID/FEI	Business Operations
Guangzhou St Eva Fine Chemical Co Ltd		528039793	manufacture(49852-160)

Revised: 7/2014

Tri-Coastal Design Company Inc.