

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

Alcohol 65%

Purpose

Antiseptic

Use

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

Warnings

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

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

- Spray on hands and rub together 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 Propylene Glycol, PEG-40 Hydrogenated Castor Oil, Fragrance, Water

Package Label

F30265-1694 sanitizer pen



WATERLESS ANTI-BACTERIAL HAND CLEANSER

ethyl alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49852-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	65 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49852-001-08	8 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	01/07/2010	

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

Establishment

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

Revised: 12/2009

Tri-Coastal Design Company Inc.