WATERLESS ANTI-BACTERIAL HAND CLEANSER - 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 and mucous membranes
- In the case of eyes or mucous membrane contact; rinse area thoroughly with water Use only as directed

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 dime 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

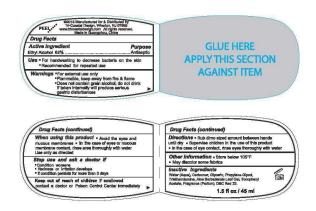
- Store below 105F
- May discolor some fabrics

Inactive Ingredients

Water (Aqua), Carbomer, Glycerin, Propylene Glycol, Triethanolamine, Aloe Barbadensis Leaf Gel, Tocopheryl Acetate, Fragrance (Parfum), DC Red 33

Package Label





WATERLESS ANTI-BACTERIAL HAND CLEANSER

alcohol liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49852-181	
Route of Administration	TOPICAL			

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

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
GLYCERIN (UNII: PDC6A3C0OX)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
TROLAMINE (UNII: 9O3K93S3TK)			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			
ALPHA-TO COPHEROL ACETATE (UNII: 9E8X80D2L0)			
D&C RED NO.33 (UNII: 9DBA0SBB0L)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49852-181-45	45 mL in 1 BOTTLE, PLASTIC		
2	NDC:49852-181-60	60 mL in 1 TUBE		
3	NDC:49852-181-80	237 mL in 1 BOTTLE, PUMP		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	07/15/2013		

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

Establishment				
Name	Address	ID/FEI	Business Operations	
Ningbo Pulisi Daily Chemical Products Co.,Ltd.		529047265	manufacture (49852-181)	

Revised: 7/2014 Tri-Coastal Design Company Inc.