

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

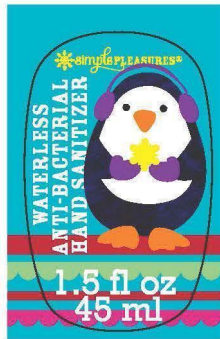
Other information

- Store below 105F
- May discolor some fabrics

Inactive Ingredients

Water (Aqua), Carbomer, Glycerin, Propylene Glycol, Triethanolamine, Aloe Barbadensis Leaf Gel, Tocopheryl Acetate, Fragrance (Parfum), FDC Blue 1, FDC Yellow5

Package Label



WATERLESS ANTI-BACTERIAL HAND CLEANSER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49852-182
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: ZY81Z83H0X)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49852-182-45	45 mL in 1 BOTTLE, PLASTIC		
2	NDC:49852-182-60	60 mL in 1 TUBE		
3	NDC:49852-182-80	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(49852-182)

Revised: 7/2014

Tri-Coastal Design Company Inc.