

WATERLESS 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 63%

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

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

Other information

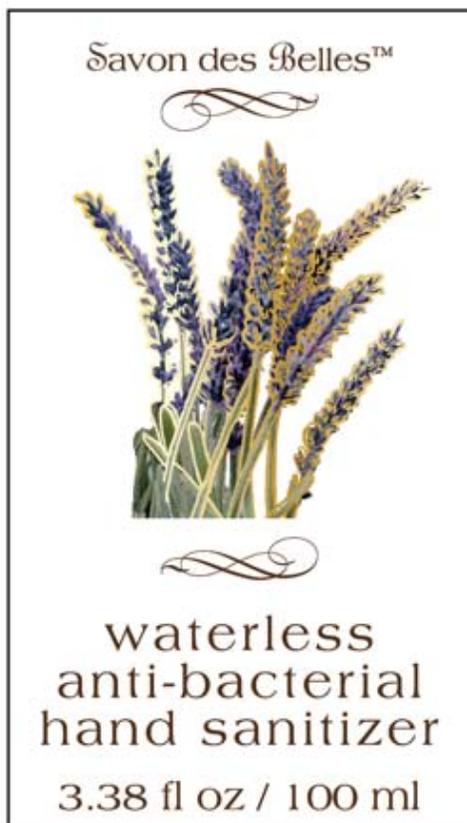
- Store below 105F
- May discolor some fabrics

Inactive Ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, DC Red 33, FDC Blue 1, Fragrance, Propylene Glycol, Triethanolamine, Water

Package Label

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WATERLESS ANTI BACTERIAL HAND SANITIZER

ethyl alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49852-034
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	63 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49852-034-03	100 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333	08/01/2010	

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

Name	Address	ID/FEI	Business Operations
Landy International		545291775	manufacture

Revised: 7/2010

Tri-Coastal Design Company Inc.