

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

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

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
- in the case of eye contact, rinse eyes thoroughly with water

Other information

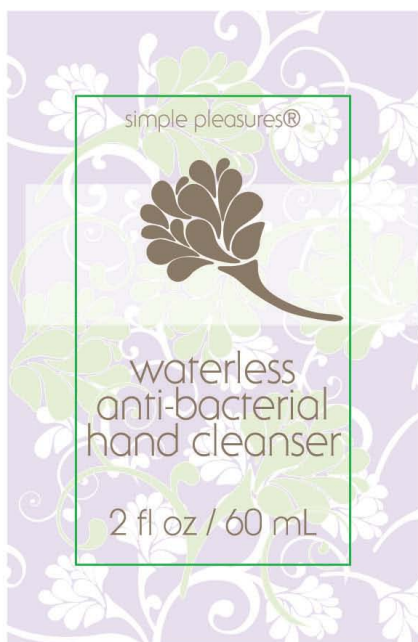
- store below 105F
- may discolor some fabrics

Inactive Ingredients

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

Package Label

Package Label



OUTSIDE

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INSIDE

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GLUE

FOLD

WATERLESS ANTI-BACTERIAL HAND CLEANSER

ethyl alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49852-161
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	62 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
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FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49852-161-60	60 mL in 1 BOTTLE, PLASTIC		
2	NDC:49852-161-45	45 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	12/11/2009	

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.