

FOREVER HAND SANITIZER HAND SANITIZER- alcohol gel

Aloe Vera of America, 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 for an OTC drug listing SPL for Forever Hand Sanitizer

Active Ingredients

Active ingredient	Purpose
Ethyl Alcohol 62%...	Antimicrobial

Inactive Ingredients

Water (Aqua), Aloe Barbadensis Leaf Juice (Stabilized* Aloe Vera Gel), Honey, Isopropyl Alcohol, Fragrance (Parfum), Glycerin, Tetrahydroxypropyl, Ethylenediamine, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Tocopheryl Acetate, Isopropyl Myristate.

Purpose Section

Uses

- hand sanitizer to decrease bacteria on the skin
- recommended for repeated use

Warnings

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For external use only.

Flammable. Keep away from fire or flame.

Indications & Usage

- do not use in or near the eyes. If contact occurs, rinse thoroughly with water.
- avoid contact with broken skin.

Stop use and ask a doctor if

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- rash or irritation develops and lasts.

Keep out of reach of children

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Dosage & Administration Directions

Directions

- wet hands thoroughly with product
- briskly rub hands together until dry
- children under 6 years of age should be supervised when using this product

Other information

- store at 20°C to 25°C (68°F to 77°F) when possible. Do not store above 40°C (104° F).
- may discolor certain fabrics

Package Label Principal Display Panel

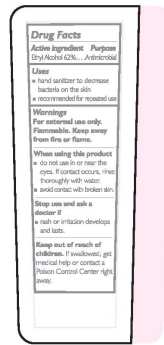
FOREVER HAND SANITIZER LABEL ART

colors

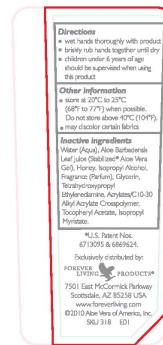
Light Green: PMS 376
Dark Green: PMS 371
Gray: PMS Cool Gray 9



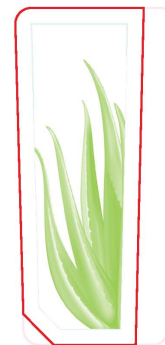
Top Panel
1/16" from die edges



Back
1/8" from die edges



Base
1/16" from die edges



Back of Base
(adhesive print)
1/8" from die edges

Label

FOREVER HAND SANITIZER HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11697-318
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Alcohol (UNII: 3K9958V90M) (Alcohol - UNII:3K9958V90M)	Alcohol	36.58 mL in 59 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Aloe Vera Leaf (UNII: ZY81Z83H0X)	
Honey (UNII: Y9H1V576FH)	
Isopropyl Alcohol (UNII: ND2M416302)	
LAVANDULA ANGUSTIFOLIA FLOWERING TOP (UNII: 9YT4B71U8P)	
Cymbopogon Citratus Leaf (UNII: 06JMS448M5)	
Glycerin (UNII: PDC6A3C0OX)	
EDETOL (UNII: Q4R969U9FR)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
Isopropyl Myristate (UNII: 0RE8K4LNJS)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11697-318-02	59 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	08/16/2010	

Labeler - Aloe Vera of America, Inc. (049049463)

Revised: 9/2010

Aloe Vera of America, Inc.