

INSTANT HAND SANITIZER- alcohol gel

Provision Medical

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 66.5%

Purpose

Antiseptic

Use

For handwashing to decrease bacteria on skin without soap and water.

Warnings

For external use only

Flammable, keep away from fire or flame.

Keep out of reach of children.

Do not use in eyes, if this happens, rinse thoroughly with water.

Stop use, ask a doctor if irritation develops and persists for 72 hours. If ingested, get medical help or contact a Poison Control Center right away.

Directions

- wet hands & wrists thoroughly with product and allow to dry without wiping

Inactive ingredients

aloe vera, carbomer, D&C green #5, D&C yellow #10, fragrance, purified water, triethanolamine

Principal Display Panel - 0.9g Packet Label

Provision Medical PRODUCTS

INSTANT

HAND

SANITIZER

0.9 g (1/32 oz.)

Manufactured for

Provision Medical Products

Palm Desert, CA 92211

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PRODUCTS

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HAND
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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69 103-3554
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
alcohol (UNII: 3K9958V90M) (alcohol - UNII:3K9958V90M)	alcohol	665 mL in 1 g

Inactive Ingredients

Ingredient Name	Strength
aloe (UNII: V5VD430YW9)	

carbomer interpolymmer type a (allyl sucrose crosslinked) (UNII: 59TL3WG5CO)	
d&c green no. 5 (UNII: 8J6RDU8L9X)	
d&c yellow no. 10 (UNII: 35SW5USQ3G)	
water (UNII: 059QF0KO0R)	
trolamine (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69103-3554-1	0.9 g in 1 PACKET; Type 0: Not a Combination Product	03/16/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	03/16/2015	

Labeler - Provision Medical (036936831)

Registrant - Safetec of America, Inc. (874965262)

Establishment

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	MANUFACTURE(69103-3554)

Revised: 3/2015

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