

INSTANT HAND SANITIZER- alcohol gel
APEX Sanitation, LLC

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 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 – Pouch

NDC 57685-7110-0

APEX

ANTISEPTIC

Instant Hand

Sanitizer

Fresh Scent
with Aloe Vera

0.0570 fl.oz. (1.68 mL)

MFD for **APEX SANITATION, LLC.**

Detroit, MI 48228 800-281-1878

www.ApexAntiseptic.com

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INSTANT HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57685-7110
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
alcohol (UNII: 3K9958V90M) (alcohol - UNII:3K9958V90M)	alcohol	540.26 g in 1 L

Inactive Ingredients

Ingredient Name	Strength
aloe (UNII: V5VD430 YW9)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
d&c green no. 5 (UNII: 8J6 RDU8L9X)	
d&c yellow no. 10 (UNII: 35SW5USQ3G)	
water (UNII: 059QF0K00R)	
trolamine (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57685-7110-0	0.00168 L in 1 POUCH		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	03/27/2013	

Labeler - APEX Sanitation, LLC (078776562)**Registrant** - Safetec of America, Inc. (874965262)**Establishment**

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	MANUFACTURE(57685-7110)

Revised: 3/2013

APEX Sanitation, LLC