

ANTISEPTIC HAND SANITIZER- ethyl alcohol gel
Innovation Specialties 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.

ANTISEPTIC HAND SANITIZER

Drug Facts

Active ingredient

Ethyl alcohol 62%

Purpose

Antiseptic

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

Use

For handwashing to decrease bacteria on the skin.

Warnings

Flammable, keep away from fire or flame. For external use only.

Do not use in the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation and redness develop and persist for more than 72 hours.

Directions

Wet hands thoroughly with product, briskly rub hands together until dry. Supervise children in the use of this product.

Inactive ingredients

Carbomer, Fragrance, Glycerin, Propylene Glycol, Tocopheryl Acetate, Triethanolamine, Water.

Store at room temperature 15⁰ to 30⁰C (59⁰ to 86⁰F)

Questions?

HOTLINE # 1-855-755-5346

Made in China for Innovation Line Culver City, CA 90230

Packaging

HAND SANITIZER

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NPN# 80062390

Lot # **49279** Exp: **08-17 1FL OZ (30ML)**

Made in China For Innovation Line Culver City, CA 90230
Product # 5258

ANTISEPTIC HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76138-113(NDC:70412-110)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76138-113-03	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/02/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	01/02/2016	

Labeler - Innovation Specialties Inc (030837314)

Establishment

Name	Address	ID/FEI	Business Operations
Innovation Specialties Inc		030837314	relabel(76138-113) , repack(76138-113)