

## **5406 HAND SANITIZER- ethyl alcohol gel**

### **Innovation Specialties**

*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.*

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## **5406 hand sanitizer**

### ***Drug Facts***

***Active ingredient:*** Ethyl alcohol 62%.

***Purpose:*** Antiseptic

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 persists for more than 72 hours.

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

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.

***Questions?*** HOTLINE # 1-855-755 5346 NPN# 80062390

Store at room temperature 15° to 30°C (59° to 86°F).

Made in China For Innovation Line Los Angeles,  
CA 90066 Product # 5406

### **Packaging**

# HAND SANITIZER

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Lot # 64252 Exp: 10-2019 1FL OZ (30ML)

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## 5406 HAND SANITIZER

ethyl alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76138-116(NDC:70412-110)
<b>Route of Administration</b>	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
<b>CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE</b> (UNII: 0A5MM307FC)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76138-116-03	30 mL in 1 CONTAINER; Type 0: Not a Combination Product	07/11/2018	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/11/2018	

**Labeler** - Innovation Specialties (030837314)

## Establishment

Name	Address	ID/FEI	Business Operations
Innovation Specialties		030837314	relabel(76138-116) , repack(76138-116)

Revised: 12/2022

Innovation Specialties