

## **DELEON HAND SANITIZER- hand sanitizer gel**

### **Innovatech Engineering 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.*

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This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

### **Active Ingredient(s)**

Alcohol 65% v/v. Purpose: Antiseptic

### **Purpose**

Antiseptic, Hand Sanitizer

### **Use**

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

### **Warnings**

For external use only. Flammable. Keep away from heat or flame

### **Do not use**

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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

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away.

## Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

## Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

## Inactive ingredients

Carbomer, Triethanolamine, purified water USP

## Package Label - Principal Display Panel

3785 mL NDC:80157-001-01

**DELEÓN**  
COSMETICS

**Hand Sanitizer**  
Gel Antiseptic

65% Ethyl Alcohol

Antiseptic Hand Sanitizer  
For use when soap and water are not available  
Compounded according to WHO, CDC, and FDA guidelines for antimicrobial hand rubs.

- Non-sticky  
- Fast Drying  
- 65% Alcohol

Made in USA

1 gallon (3.8L)

1650 Summit Lake Dr. Ne103  
Tallahassee, FL 32317  
Phone: (850) 219-8246  
Orders: info@innovatech.us

8 56841 00614 1

**DRUG FACTS**  
**Active ingredient**  
Ethyl Alcohol 65% .....  
**Purpose**  
Antiseptic

**Warnings**  
For external use only. **FLAMMABLE**  
Keep away from heat and flame.

**When using this product** • Avoid contact with broken skin. • Avoid contact with eyes. If contact occurs, immediately rinse eyes thoroughly with water.

**Stop use and consult doctor** if irritation, rash or redness develop and persist more than 72 hours.

**Keep out of reach of children** in case of accidental ingestion, seek professional medical assistance or contact a Poison Control Center immediately.

**Directions**  
• Thoroughly wet hands with product and allow to dry without wiping. • For children under 6, use only with adult supervision. • Not recommended for infants.

**Other information** • Storage temperature: 15-30°C (59-86°F) • Do not freeze.

**Inactive ingredients**  
Water, carbomer, Triethanolamine

**Questions or comments?** Tallahassee, FL  
info@innovatech.us DeLeonCosmetics.com

473 mL NDC:80157-001-02

**DELEÓN**  
COSMETICS

**Hand Sanitizer**  
Gel Antiseptic

65% Ethyl Alcohol

Antiseptic Hand Sanitizer  
For use when soap and water are not available  
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**DRUG FACTS**  
**Active ingredient**  
Ethyl Alcohol 65% .....  
**Purpose**  
Antiseptic

**Warnings**  
For external use only. **FLAMMABLE**  
Keep away from heat and flame.

COSMETICS

# Hand Sanitizer

## Clear Gel Antiseptic

65% Ethyl Alcohol



Made in USA

16 fl. oz. (470ml)

Keep away from heat and flame.

**When using this product** • Avoid contact with broken skin. • Avoid contact with eyes. If contact occurs, immediately rinse eyes thoroughly with water.

**Stop use and consult doctor** if irritation, rash or redness develop and persist more than 72 hours.

**Keep out of reach of children** In case of accidental ingestion, seek professional medical assistance or contact a Poison Control Center immediately.

### **Directions**

- Thoroughly wet hands with product and allow to dry without wiping.
- For children under 6, use only with adult supervision.
- Not recommended for infants.

**Other information** • Storage temperature 15-30°C (59-86°F) • Do not freeze

### **Inactive ingredients**

Water, carbomer, Triethanolamine

### **Questions or comments?**

info@innovatech.us

DeLeonCosmetics.com

Tallahassee, FL

DELEÓN  
COSMETICS

## Hand Sanitizer

65% Ethyl Alcohol  
Gel Antiseptic

4 fl. oz. (118 mL)



Made in USA

### DRUG FACTS

#### Active ingredient

Ethyl Alcohol 65% .....Antiseptic

#### Purpose

**Warnings** For external use only.

**FLAMMABLE** Keep away from heat and flame.

**When using this product** • Avoid contact with broken skin. • Avoid contact with eyes. If contact occurs, immediately rinse eyes thoroughly with water.

**Stop use and consult doctor** if irritation, rash or redness develop and persist for more than 72 hours.

**Keep out of reach of children** In case of accidental ingestion, seek professional medical assistance or contact a Poison Control Center immediately.

**Directions** • Thoroughly wet hands with product and allow to dry without wiping. • Children under 6, use only with adult supervision. • Not recommended for infants.

**Other information** • Storage temperature 15-30°C (59-86°F) • Do not freeze

#### Inactive ingredients

Water, carbomer, triethanolamine

#### Questions or comments?

info@innovatech.us

DeLeonCosmetics.com

Tallahassee, FL

## DELEON HAND SANITIZER

hand sanitizer gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80157-001
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	650 mL in 1000 mL

### Inactive Ingredients

Ingredient Name	Strength
CARBOMER 980 (UNII: 4Q93RCW27E)	3 g in 1000 mL
TROLAMINE (UNII: 9O3K93S3TK)	1.1 mL in 1000 mL
WATER (UNII: 059QF0KO0R)	348.9 mL in 1000 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:80157-001	473 mL in 1 BOTTLE, PLASTIC; Type 0; Not a Combination		

<b>1</b>	NDC:80157-001-02	475 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
<b>2</b>	NDC:80157-001-03	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
<b>3</b>	NDC:80157-001-01	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
<b>Marketing Information</b>				
<b>Marketing Category</b>		<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final		part333A	03/30/2020	

**Labeler** - Innovatech Engineering LLC (054312642)

**Registrant** - Innovatech Engineering LLC (054312642)

## Establishment

Name	Address	ID/FEI	Business Operations
Innovatech Engineering LLC		054312642	manufacture(80157-001)

Revised: 9/2020

Innovatech Engineering LLC