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.

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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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

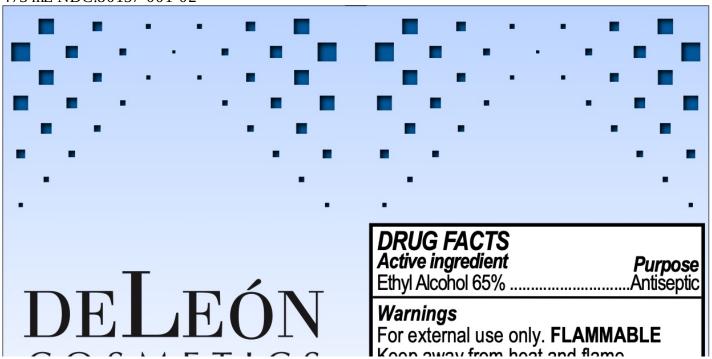
Carbomer, Triethanolamine, purified water USP

Package Label - Principal Display Panel

3785 mL NDC:80157-001-01



473 mL NDC:80157-001-02



COSMETICS

Hand Sanitizer

Clear Gel Antiseptic

65% Ethyl Alcohol



16 fl. oz. (470ml)

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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

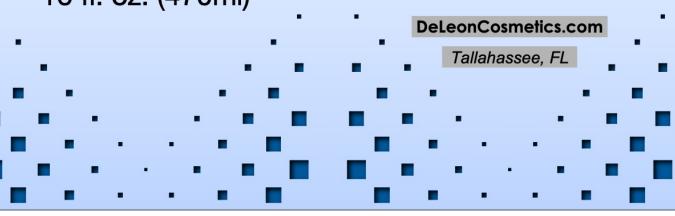
- Thoroughly wet hands with product and allow to dry without wiping. For children under 6, use only with adult supervision.
- Not recommended for infants.

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

Inactive ingredients

Water, carbomer, Triethanolamine

Questions or comments? info@innovatech.us



118 mL NDC: 80517-001-03



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

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Inactive ingredients

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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: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII: 3K9958 V90M)

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	

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	# Item Code	Package Description	Marketing Start Date	Marketing End Date				
1	NDC-901E7 001	472 mL in 1 DOTTLE DLASTIC, Type O. Not a Combination						

	NDC:8015/-001-	4/3 IIL III 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
_		118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
	NDC:80157-001- 01	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
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