

HAND SANITIZER- alcohol gel
Sugarleaf Labs 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.

Hand sanitizer

Active Ingredient(s)

Alcohol 70% 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, fragrance, propylene glycol, triethanolamine, water.

Package Label - Principal Display Panel

NEPTUNE 
WELLNESS SOLUTIONS

HAND SANITIZI GEL

**KILLS HARMFUL GERMS
AND BACTERIA**

Contains 70% Ethyl Alcohol

<i>Drug Facts</i>		<i>Drug Facts (cont)</i>
<i>Active ingredient Purpose</i> Ethyl Alcohol 70% v/vAntiseptic		Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
<i>Uses</i> ■ To help reduce bacteria that potentially can cause disease ■ For use when soap and water are not available		<i>Directions</i> ■ Place enough product on hands to cover all surfaces. Rub hands together until they are completely dry. ■ Supervise children under 6 years of age when using product to avoid swallowing.
<i>Warnings</i> For external use only. Flammable. Keep away from heat or flame.		<i>Other information</i> ■ Store between 15-30 (59-86°F) ■ Avoid freezing and excessive heat above 40°C (104°F)
Do not use ■ In children less than 2 months of age ■ on open skin wounds		<i>Inactive ingredients</i> Carbomer, fragrance, propylene glycol, triethanolamine,
When using this product ■ keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.		<i>Questions?</i> 1-800-3-
Stop use and ask a doctor if irritation or rash occurs. ▶		

33.8 fl. oz. (1.1 qt.) / 1 L

33.8 fl. oz. (1.1 qt.) / 1 L NDC: 74627-003-10

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Made in Mexico



NEPTUNE
WELLNESS SOLUTIONS

HAND SANITIZING GEL

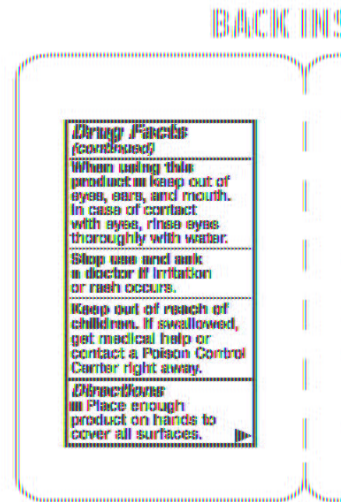
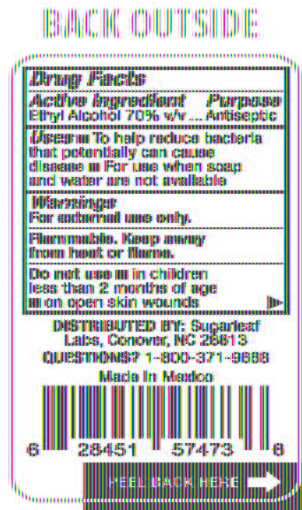
**KILLS HARMFUL
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Contains 70% Ethyl Alcohol

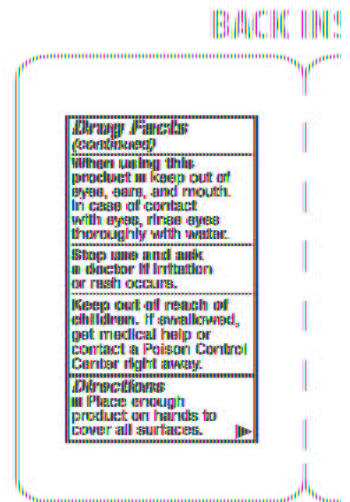
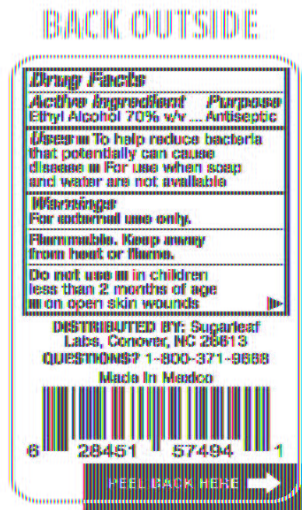
DISTRIBUTED BY: Sugarleaf Labs Contact Us For
QUESTIONS? 1-800-371-9668 **MASD**

16.9 fl.oz. (500ml)

16.9 fl. oz. (500 mL) NDC: 74627-003-05



6.7 fl. oz. (200 mL) NDC: 74627-003-02



4.2 fl. oz. (125 mL) NDC: 74627-003-01



2 fl. oz. (60 mL) NDC: 74627-003-00

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74627-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	1 mL in 100 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	8 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	1 mL in 100 mL
WATER (UNII: 059QF0K00R)	20 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74627-003-10	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/13/2020	
2	NDC:74627-003-00	60 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/07/2020	

3	NDC:74627-003-01	125 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/07/2020	
4	NDC:74627-003-02	200 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/07/2020	
5	NDC:74627-003-05	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/07/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/13/2020	

Labeler - Sugarleaf Labs Inc. (105464061)

Revised: 7/2020

Sugarleaf Labs Inc.