#### HAND SANITIZER - 70% ALCOHOL- is opropyl alcohol gel NxGen Brands, 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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#### Leafywell - Hand Sanitizer

#### **Product Description**

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. Isopropyl Alcohol (70%, 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. Carbomer (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)

Isopropyl 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. 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.

#### 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

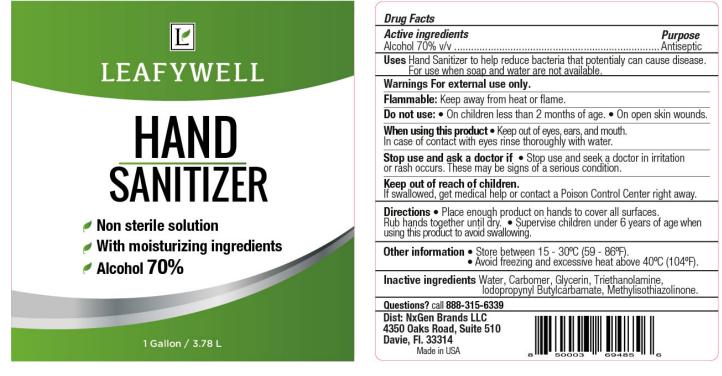
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

#### **Inactive ingredients**

glycerin, hydrogen peroxide, purified water USP

### Package Label - Principal Display Panel

3.78 L NDC: 76867-999-07



HAND SANITIZER - 70% ALCOHOL							
isopropyl alcohol gel							
Product Information							
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76867-999				
Route of Administration	TOPICAL						

	Ingredient Name		<b>Basis of Strengtl</b>	1 Strength	
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)			ISOPROPYL ALCOHOL	75 mL in 100 mL	
Inactive Ingred	ients				
	Strength				
GLYCERIN (UNII: PDC6A3C0OX)			1.45 mL in 100 mL		
HYDROGEN PEROXIDE (UNII: BBX060AN9V)			0.125 mL in 100 mL		
WATER (UNII: 059Q)	FOKOOB)				
(orth, 055Q					
(orun 000Q)					
Packaging	Package Description	Mar	keting Start	Marketing End Date	
Packaging # Item Code		<b>Mar</b> 0 5/0 1/2	Date	0	
Packaging # Item Code	Package Description 3.78 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination		Date	0	
Packaging # Item Code 1 NDC:76867-999-	Package Description 3.78 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination		Date	0	
Packaging # Item Code 1 NDC:76867-999-	Package Description 3.78 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		Date	0	
Packaging # Item Code 1 NDC:76867-999- 07	Package Description 3.78 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product formation	0 5/0 1/2	<b>Date</b> 020	0	

# Labeler - NxGen Brands, LLC (095702886)

# Registrant - NxGen Brands, LLC (095702886)

## Establishment

Name	Address	<b>ID/FEI</b>	Business Operations
NxGen Brands, LLC		095702886	manufacture(76867-999), pack(76867-999), label(76867-999)

Revised: 5/2020

NxGen Brands, LLC