HAND SANITIZER - 80% 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.

Leafywell - Hand Sanitizer 80%

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 (80%, 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 80% 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

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel



NDC: 76867-989-001



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NDC: 76867-989-003



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4300 Quike Road, Surie 540

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NDC: 76867-989-004 NDC: 76867-989-007



Drug Facts Active ingredients Alcohol 80% v/v Purpose Antiseptic Uses Hand Sanitizer to help reduce bacteria that potentialy can cause disear For use when soap and water are not available. Warnings For external use only. Flammable: Keep away from heat or flame. Do not use: • On 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 thoroughly with water. Stop use and ask a doctor if. • Stop use and seek a doctor in 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 - 30°C (59 - 86°F). • Avoid freezing and excessive heat above 40°C (104°F). Inactive ingredients Water, Carbomer, Glycarin, Triethanolamine, lodopropynyl Butylcarbamate, Methylisothiazolinone. Questions? call 888-315-6339 Dist: NxGen Brands LLC 4350 Oaks Road, Suite 510 Davie, FL 33314 Made in USA

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:76867-989 Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 mL in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL	
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL	
WATER (UNII: 059QF0KO0R)		

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76867-989- 03	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2020	
2	NDC:76867-989- 01	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2020	
3	NDC:76867-989- 04	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/08/2020	
4	NDC:76867-989- 02	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2020	
5	NDC:76867-989- 05	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/08/2020	
6	NDC:76867-989- 06	2000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2020	
7	NDC:76867-989- 07	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	05/08/2020		

Labeler - NxGen Brands, LLC (095702886)

Registrant - NxGen Brands, LLC (095702886)

Establishment			
Name	Address	ID/FEI	Business Operations

NxGen Brands, LLC	095702886	manufacture(76867-989), pack(76867-989), label(76867-989)

Revised: 5/2020 NxGen Brands, LLC