HAND SANITIZER - 80% ALCOHOL- isopropyl 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

NDC: 76867-989-002

NDC: 76867-989-003

Drug Facts

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Inactive ingredients Water, Carbomer, Glycerin, Triethanolamine, Iodopropynyl Butylcarbamate, Methylisothiazolinone.

Questions? call 888-315-6339

Dist: NxGen Brands LLC
4350 Oaks Road, Suite 510
Davie, FL 33314

Made in USA

NDC: 76867-989-004

Drug Facts

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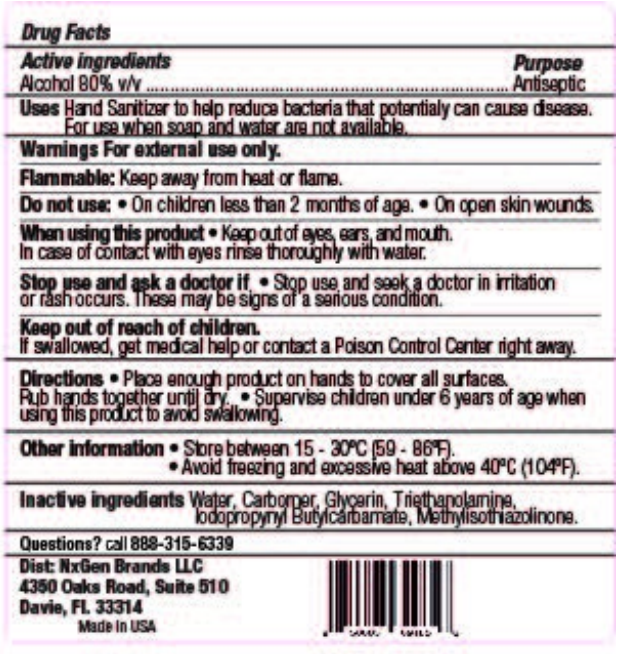
NDC: 76867-989-007



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HAND SANITIZER - 80% ALCOHOL

isopropyl alcohol gel

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
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

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