HAND SANITIZER- alcohol gel
MediUSA 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.

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 (75%, 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)

Isopropyl Alcohol 75% 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.

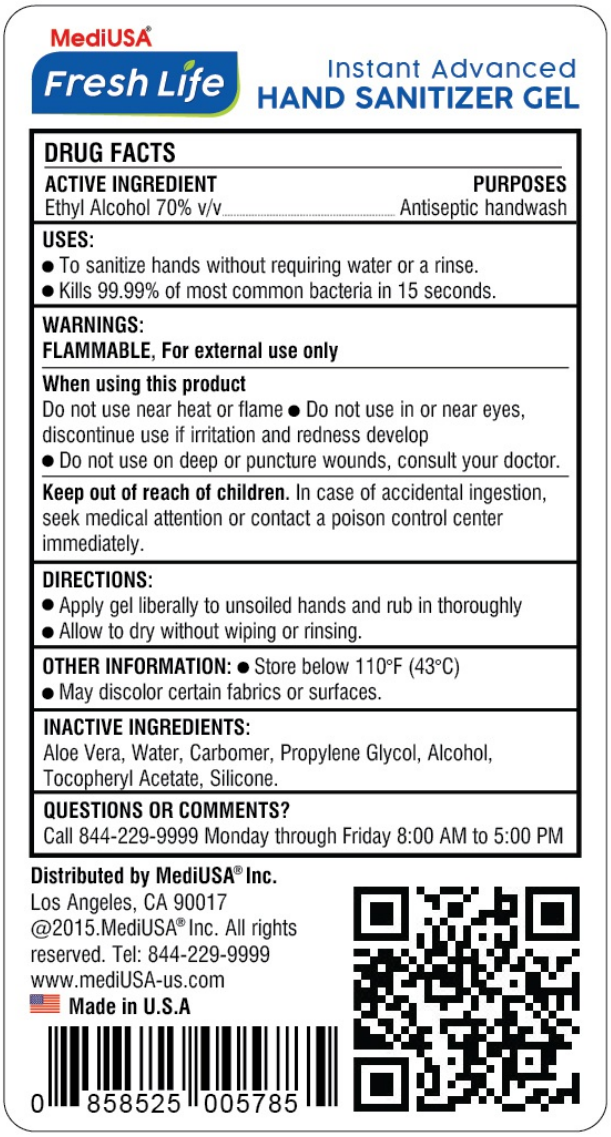
Other information

- 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



MediUSA®

Fresh Life

Instant Advanced

HAND SANITIZER GEL

Kills 99.99% of Germs

REFRESHING & MOISTURIZING ALOE GEL

No water require

4 FL OZ (119mL)

MediUSA

Fresh Life

Instant Advanced
HAND SANITIZER GEL

DRUG FACTS

ACTIVE INGREDIENT	PURPOSES
Ethyl Alcohol 70% v/v	Antiseptic handwash

USES: ● To sanitize hands without requiring water or a rinse
● Kills 99.99% of most common bacteria in 15 seconds.

WARNINGS:
FLAMMABLE, For external use only

When using this product
Do not use near heat or flame ● Do not use in or near eyes, discontinue use if irritation and redness develop ● Do not use on deep or puncture wounds, consult your doctor.

Keep out of reach of children. In case of accidental ingestion, seek medical attention or contact a poison control center immediately.

DIRECTIONS:
● Apply gel liberally to unsoiled hands and rub in thoroughly.
● Allow to dry without wiping or rinsing.

OTHER INFORMATION: ● Store below 110°F (43°C) ● May discolor certain fabrics or surfaces.

INACTIVE INGREDIENTS:
Aloe Vera, Water, Carbomer, Propylene Glycol, Alcohol, Tocopheryl Acetate, Silicone.

QUESTIONS OR COMMENTS?
Call 844-229-9999 Monday through Friday 8:00 AM to 5:00 PM

Distributed by MediUSA® Inc.
Los Angeles, CA 90017
 Tel: 844-229-9999
www.mediUSA-us.com
Made in U.S.A

0 858525 005785

MediUSA®

Fresh Life

Instant Advanced HAND SANITIZER GEL

Kills 99.99% of Germs

REFRESHING & MOISTURIZING ALOE GEL

No water require

2 FL OZ (59mL)

MediUSA

Fresh Life

Instant Advanced
HAND SANITIZER GEL

DRUG FACTS

ACTIVE INGREDIENT	PURPOSES
Ethyl Alcohol 70% v/v	Antiseptic handwash

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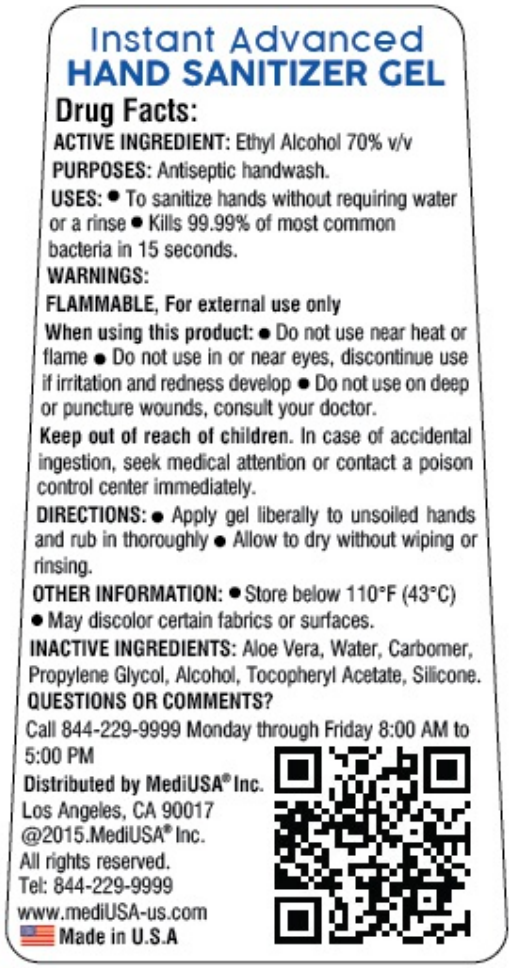

30 ml NDC: 75688-889-00

59 ml NDC: 75688-889-01

119 ml NDC: 75688-889-02

236 ml NDC: 75688-889-03

HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:75688-889
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 70 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
COPPER GLUCONATE (UNII: RV823G6G67)	
DIISOPROPYL SEBACATE (UNII: J8T3X564IH)	
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75688-889-00	30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	04/20/2020	
2	NDC:75688-889-01	59 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	04/20/2020	
3	NDC:75688-889-02	119 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	04/20/2020	
4	NDC:75688-889-03	236 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	04/20/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	03/26/2020	

Labeler - MediUSA Inc. (117500118)

Revised: 4/2020 MediUSA Inc.