

HAND SANITIZER- isopropyl alcohol gel

Biowellness 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.

Hand Sanitizer Aloe Vera and vitamin E

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 70% v/v. Purpose: Antiseptic

Chlorhexidine Gluconate 0.25g

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

250ml NDC: 79122-001-84


[biowellness.life](https://www.biowellness.life)
www.biowellness.life
www.biowellness.life

Manufactured by
 Dewars Cosmetique Ltda
 Made in Colombia

IMPORTED BY

Biowellness.
 Biowellness LLC
 Miami, FL 33015, USA
 Phone: +1 (786) 786 2828
www.biowellness.us
 LOT NUMBER:


Hand Sanitizer
 ADVANCED MOISTURIZING
 ALOE VERA AND VITAMIN E

KILLS 99.99% OF GERMS

70% ALCOHOL

Drug Facts

Active Ingredient.....	Purpose
Ethyl Alcohol 70%.....	Antiseptic
Inactive Ingredients:	
• Water (Aqua), Glycerin, Carbomer, Triethanolamine, Tocopheryl acetate, Aloe Barbadensis, Leaf extract.	
Warnings: Flammable. Keep away from fire or flame.	
For external use only. When using this product avoid contact with eyes. Keep out of reach of children. If swallowed get medical help promptly.	
Stop use and ask a doctor: If any irritation appears, these may be signs of a serious condition.	
Uses:	
• To help decrease bacteria on the skin. • Recommended for repeated use.	
Directions:	
• Place a small amount of the product in one hand and rub hands together even between fingers until dry. • Supervise children under 6 year of age when using this product to avoid swallowing.	
Other Information:	
Store in a cool place below 110°F (43° C). Avoid freezing. May discolor certain fabrics of surfaces.	

8.45 oz (250 ml)

HAND SANITIZER
isopropyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79122-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	0.25 g in 100 mL
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CASTOR OIL (UNII: D5340Y2I9G)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
ALOE ARBORESCENS LEAF (UNII: 09TD8L5SQV)	
CARBOBENZOXYCARBONYL-PHENYLALANYL-ALANINYLDIAZOMETHANE (UNII: FQ11Y48OCY)	
WATER (UNII: 059QF0K00R)	
2-PHENYLPROPANAL PROPYLENE GLYCOL ACETAL (UNII: 1ZRR9A405A)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79122-001-84	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/25/2020	
2	NDC:79122-001-45	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/25/2020	
3	NDC:79122-001-55	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/25/2020	



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/25/2020	

Labeler - Biowellness LLC (117554321)

Registrant - Biowellness LLC (117554321)

Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 7/2020

Biowellness LLC