

HAND SANITIZER- berish antibacterial liquid
Soluciones Cosméticas SA de CV

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.

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

Drug Facts

Active Ingredient	Purpose
Ethyl alcohol 70%.....	Antiseptic

Uses

- Recommended for aseptic hand cleansing. This product does not replace the use of soap & water.
- This product does not replace the use of soap & water. Recommended for repeated use.

Warnings

For external use only.

When using this product:

Avoid contact with eyes. In case of accidental contact, flush eyes thoroughly with water for 15 minutes. Avoid contact with broken skin or if you have allergies to any ingredients.

Stop use and consult a doctor if skin irritation occurs.

Keep out of reach of children. If swallowed get medical help at a Poison Control Center immediately.

FLAMMABLE: Keep out of heat.

Directions:

- Place a small amount of product in your hand.
- Rub hands together briskly for at least 30 seconds until dry.
- Children under 6 years of age should use adult supervision

Inactive ingredients

Water, Propylene Glycol, Carbomer, Sodium Hidroxide.

Questions? 52-55-5685-62-16



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Elaborated by: Soluciones Cosmeticas, S.A. de C.V. Año de Juarez No. 110. Col. Granjas San Antonio. Iztapalapa, Mexico City. Zip Code 09070

Distributed by: Private D Capital Group Corp 16901 Collins Avenue, Suite 2003 Sunny Isles Beach, FL Zip Code 33160

Made in Mexico

*With a correct hand washing technique



500 ml NDC: 75165-001-01

HAND SANITIZER

berish antibacterial liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75165-006
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	700 L in 1000 L	
Inactive Ingredients				
Ingredient Name		Strength		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		20 L in 1000 L		
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)		0.1 L in 1000 L		
CARBOMER 940 (UNII: 4Q93RCW27E)		7 L in 1000 L		
WATER (UNII: 059QF0KO0R)		270 L in 1000 L		
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75165-006-01	1000 L in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	03/30/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	03/30/2020		

Labeler - Soluciones Cosmeticas SA de CV (814818001)

Registrant - Soluciones Cosmeticas SA de CV (814818001)

Establishment

Name	Address	ID/FEI	Business Operations
Soluciones Cosmeticas, SA de CV		814818001	manufacture(75165-006)

Revised: 4/2020

Soluciones Cosmeticas SA de CV