

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.

1000 ML

Active Ingredient(s)

Alcohol 70% 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

purified water USP, propylene Glycol, Carbomer, Aminomethyl Propanol

Package Label - Principal Display Panel

BERSIH.

**Antiseptic Alcohol 70%
Topical Solution**

**Hand Sanitizer
Non-sterile Solution**

Product Volume 1,000 lts.



Drug Facts	
Active ingredient[s]	Purpose
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Distributed by: Astrum, LLC 123 W Elizabeth St
Brownsville, TX 78520
Tax ID: 32059835150
Made in Mexico

1000 L NDC: 75165-600-01

HAND SANITIZER

berish antibacterial liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75165-600
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)	2 L in 1000 L
CARBOMER 940 (UNII: 4Q93RCW27E)	8 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:75165-600-01	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(75165-600)