PURITY HAND SANITIZER- alcohol gel Soluciones Cosmeticas 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.

Purity Hand Sanitizer 70% Alcohol + Jojoba + Vit C

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

Water, Carbomer, C12-C15 Alkyl Lactate, Propylene Glycol, Fragrance, Aminomethyl Propanol, Simmondsia Chinensis Seed Oil, Sodium Ascorbyl Phosphate, Limonene.

Package Label - Principal Display Panel

500 mL NDC: 75165-008-01



Drug Facts

Active ingredient

Purpose

Ethyl alcohol 70% v/v

Antisentic

Use (s) Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when water is 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 throughly 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 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 15-30°C (59-86°F) Avoid freezing and excessive heat above 40°C (104°F) May discolor certain fabrics or surfaces

Inactive ingredients: Water, Carbomer, C12-15 Alkyl Lactate, Propylene Glycol, Fragrance, Aminomethy Propanol, Simmondsia Chinensis Seed Oil, Sodium Ascorbyl Phosphate, Limonene.

QUESTIONS: 800-517-2247





DISTRIBUTED BY: HUMAN CHOICE, LLC 210 GRIZZAFFI STREET, MORGAN CITY LA 70380

MADE IN MEXICO

PURITY HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75165-008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL	

Inactive Ingredients				
Ingredient Name	Strength			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.3 mL in 100 mL			
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.1 mL in 100 mL			
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)	0.5 mL in 100 mL			
C12-15 ALKYL LACTATE (UNII: GC844VRD7E)	0.5 mL in 100 mL			
WATER (UNII: 059QF0KO0R)	28.344 mL in 100 mL			
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	0.2 mL in 100 mL			
LIMO NENE, (+)- (UNII: GFD7C86Q1W)	0.001 mL in 100 mL			
JOJOBA OIL (UNII: 724GKU717M)	0.03 mL in 100 mL			
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	0.025 mL in 100 mL			

l	Packaging				
l	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 N	NDC:75165-008-01	500 mL in 1 BOTTLE; 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(75165-008)	

Revised: 6/2020 Soluciones Cosmeticas SA de CV