

HAND SANITIZER- isopropyl alcohol gel
Alimentos Delicias del Norte, S.A. de C.V.

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.

Delicias Hand Sanitizer

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.

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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

Alimentos Delicias del Norte, S.A. de C.V. Hand Sanitizer Gel Antibacterial	
Drug Facts	
Active Ingredient Purpose Ethyl Alcohol 70% by volume	Antiseptic Handwash
Uses • For handwashing to decrease bacteria on the skin	
Warnings • For external use only • Flammable, keep away from fire or flame, heat, sparks and sources of static discharge	
Do not use • In eyes	
When using this product • If in eyes, rinse promptly and thoroughly with water • Discontinue use if irritation and redness develop	
Step use and ask a doctor if • Eye or skin irritation or redness occurs for more than 72 hours • Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions • Apply liberal amount into hand • Spread by rubbing hands together • Rub to fingers with attention to area around nails and between fingers	
Other information • For additional information, Safety Data Sheet (SDS) • For emergency medical information in USA, call 1-800-391-1504	
Inactive ingredients Deionized water, Carbomer, Glycerin, Propylene glycol, Aloe barbadensis extract, Fragancia eucalipto, spermin, Triethanolamine	
Questions? call (210) 264-7448	
Distributed by: USA Import Products & Distribution, LLC 21079 Stone Oak Parkway Ste. 1105-403 San Antonio, Tx. 78258 USA (210) 264-7448	
© 2020 USA Import Products & Distribution, LLC. 450 ml (15.2 US fl oz) 27-0320489 / 81-484-2126	

450 ml NDC: 74368-002-01

Alimentos Delicias del Norte, S.A. de C.V.
Hand Sanitizer
Gel Antibacterial

Drug Facts

<i>Active Ingredient</i>	<i>Purpose</i>
Isopropyl Alcohol 70% by volume	Antiseptic Handwash

Uses

- For handwashing to decrease bacteria on the skin

Warnings

- For external use only
- Flammable, keep away from fire or flame, heat, sparks and sources of static discharge

Do not use

- In eyes

When using this product

- If in eyes, rinse promptly and thoroughly with water
- Discontinue use if irritation and redness develop

Stop use and ask a doctor if

- Eye or skin irritation or redness occurs for more than 72 hours

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberal amount into hand
- Spread by rubbing hands together
- Rub to dryness with attention to area around nails and between fingers

Other information

- For additional information, Safety Data Sheet (SDS)
- For emergency medical information in USA, call 1-800-391-1504

Inactive ingredients

Carbomero, Water, Ethyl Alcohol, Hydrogen Peroxide

Questions? call (210) 264-7448

Distributed by: USA Import Products & Distribution, LLC.
20079 Stone Oak Parkway Ste. 1105-493
San Antonio, Tx. 78258 USA (210) 264-7448

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3.78 lts (128 US fl oz)

27-0320498 / 81-484-2126

isopropyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74368-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	450 mL in 450 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER 940 (UNII: 4Q93RCW27E)	
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74368-002-01	450 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/13/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/13/2020	

Labeler - Alimentos Delicias del Norte, S.A. de C.V. (814842126)

Establishment

Name	Address	ID/FEI	Business Operations
Alimentos Delicias del Norte, S.A. de C.V.		814842126	manufacture(74368-002)

Revised: 5/2020

Alimentos Delicias del Norte, S.A. de C.V.