#### HAND SANITIZER- is opropyl 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.

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#### **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.

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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.

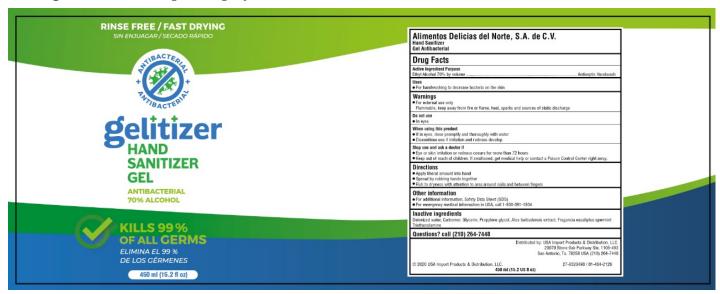
#### Other information

- 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



450 ml NDC: 74368-002-01

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

# Hand Sanitizer Gel Antibacterial

## **Drug Facts**

Active Ingredient

Purpose

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.

3.78 Its (128 US fl oz)

#### **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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27-0320498 / 81-484-2126

HAND SANITIZER

### 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: ZY8 1Z8 3H0 X)	
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	
GLYCERIN (UNII: PDC6 A3C0 O X)	

#### **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**

9			
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.		8 148 42 126	manufacture(74368-002)	