# ISOPROPYL RUBBING ALCOHOL 70%- alcohol liquid Artesanales P.R. LLC

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The hand sanitizer is manufactured using grade ingredients:

Isopropyl Alcohol (USP or Food Chemical Codex) (99% (v/v) in an aqueous solution water

the firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Isopropyl Alcohol 99% v/v. Purpose: Antiseptic

Antiseptic, Hand Sanitizer

Hand Sanitizer to help reduce bacteria that can potentially cause a disease. For use when soap and water are not available

in children less than 2 onths of age

on open skin wounds

For external use only. Flammable. Keep away from heat or flame

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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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.

store between 15-30C (59-86F)

avoid freezing and excessive heat above 40C (104F)

water

# ISOPROPYL RUBBING

#### Drug Facts

Active ingredient Isopropyl alcohol 70% .....First aid antiseptic

Purpose

Use helps prevent the risk of infection in: • minor cuts • scrapes • burns

#### Warnings For external use only

Flammable • keep away from fire or flame, heat, spark, electrical

Ask a doctor before use for deep wounds, animal bites or serious burns

When using this product • do not get into eyes • do not apply over large areas of body • do not use longer than 1 week

Stop use and ask a doctor if conditions persists or gets worse

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

Directions · clean the affected area · Apply 1 to 3 times daily

Other information · does not contain, nor is intended as a substitute for grain or ethyl alcohol • will produce serious gastric disturbances if taken internally

Inactive ingredient Di water



Manufactured: Artesanales PR, LLC PO BOX 56068, Bayamon, PR 00960 Tel (787)979-9962 e-mail: artesanalespr@gmail.com



#### **ISOPROPYL RUBBING ALCOHOL 70%**

alcohol liquid

#### **Product Information**

**Product Type** 

HUMAN OTC DRUG

Item Code (Source)

NDC:78824-625

**Route of Administration** 

TOPICAL

#### **Active Ingredient/Active Moiety**

**Ingredient Name** 

**Basis of** Strength

Strength

ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL -

**ISOPROPYL** ALCOHOL

70 mL in 99 mL

UNII:ND2M416302)

**Inactive Ingredients** 

**Ingredient Name** 

Strength

WATER (UNII: 059QF0KO0R)

Packaging								
#	tem Code	Item Code Package Description		Marketing End Date				
1	NDC:78824- 625-01	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/03/2020					
2	NDC:78824- 625-02	3785 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 Drug	505G(a)(3)	03/03/2020					

## Labeler - Artesanales P.R. LLC (117238442)

## **Registrant -** Artesanales P.R. LLC (117238442)

Establishment								
Name	Address	ID/FEI	Business Operations					
Artesanales P.R. LLC		117238442	manufacture(78824-625)					

Revised: 1/2024 Artesanales P.R. LLC