

ALCOHOL- alcohol liquid

Ignacio Reyes Gonzalez

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.

This is a Isorpopyl Alcohol 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 Isopropyl Alcohol 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 (USP or Food Chemical Codex (FCC) grade) (96%, volume/volume (v/v)) in an liquid solution denatured

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)

Alcohol 96% v/v. Purpose: First aid Antiseptic

Purpose

First Aid Antiseptic

Use

First aid to help prevent the risk of infection in minor cuts, scrapes and burns.

Warnings

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

Do not use

- do not use with electricautery procedures

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.

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 small amount of this product 1 to 3 times daily.
- May be covered with a sterile bandaged, let dry first.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive Ingredient

Purified Water

Package Label - Principal Display Panel

Isopropyl Alcohol Rubbing

96% USP

Drug Facts	
Active ingredient.	Purpose
Alcohol Isopropyl 96% v/v.....	First Aid Antiseptic
Use[s]	
First Aid to help prevent the risk of infection in minor cuts, scrapes and burns	
Warnings	
For external use only, do not consume. Flammable, keep away from fire or flame.	
Do not use	
<ul style="list-style-type: none"> • With electrocautery procedures. • Use only on a well ventilated area. 	
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.	
Directions	
<ul style="list-style-type: none"> • Place enough product on the area to cover all surfaces. • Supervise children under 6 years of age when using this product to avoid swallowing. 	
Other information	
<ul style="list-style-type: none"> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) 	

Questions? Call 52-33-2580-6280

Septiklin

Independencia #416, El Rosario, Tlaquepaque, Jalisco, Mexico, 45500
Made in México

NET CONTENTS

473.17 mL

(16 fl. Oz.)

743 mL NDC: 77196-004-01

ALCOHOL			
alcohol liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77196-004
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	

ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	100 mL in 100 mL	
Inactive Ingredients				
Ingredient Name			Strength	
WATER (UNII: 059QF0K00R)			10 mL in 100 mL	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77196-004-01	473.17 mL in 1 BOTTLE, PLASTIC; 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 - Ignacio Reyes Gonzalez (951577216)

Establishment

Name	Address	ID/FEI	Business Operations
Ignacio Reyes Gonzalez		951577216	manufacture(77196-004)

Revised: 6/2020

Ignacio Reyes Gonzalez