

ISOPROPYL ALCOHOL HAND SANITIZER- isopropyl alcohol solution
Iron Lab, 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.

Isopropyl Alcohol Hand Sanitizer

Active Ingredient(s)

Isopropyl Alcohol 75% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Rub

Use

Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

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.

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

Isopropylhandsanitizer 500 ml NDC: 74375-200-01

BY
P'ure.
ISOPROPYL ALCOHOL
ANTISEPTIC 75%
TOPICAL SOLUTION

Antiseptic Hand Rub

Non-sterile Solution

Net Contents:
16.9 fl oz (500 ml)

Drug Facts	
<i>Active Ingredient[s]</i>	<i>Purpose</i>
Isopropyl alcohol 75% v/v.....	Antiseptic
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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.	
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Inactive ingredients glycerin, hydrogen peroxide, purified water USP.	

TAMPER EVIDENT: For your protection, this product has a plastic seal around the neck. Do not use if seal is damaged or missing at time of purchase.

Manufactured by: Iron Lab S.A. de C.V.
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PRODUCT OF MEXICO

Batch & Expiration printed on container

7 502268 987480

ISOPROPYL ALCOHOL HAND SANITIZER

isopropyl alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74375-200
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C00X)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74375-200-01	500 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	08/10/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/10/2021	

Labeler - Iron Lab, S.A. de C.V. (951575800)

Establishment

Name	Address	ID/FEI	Business Operations
Iron Lab, S.A. de C.V.		951575800	manufacture(74375-200)

Revised: 8/2021

Iron Lab, S.A. de C.V.