

## **ALCOHOL ISOPROPYL- penseur isopropyl alcohol liquid PENSEUR KREATIVA GROUP**

*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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### **MAXIMAX ISOPROPYL ALCOHOL**

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 (70%, 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 70% v/v. Purpose: Antiseptic

### **Purpose**

Antiseptic, Hand Sanitizer

### **Use**

isopropyl alcohol 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**

3875 ml NDC: 81227-002-00

473 ml NDC: 81227-002-03

18925 ml NDC: 81227-002-01

236 ml NDC: 81227-002-02

946 ml NDC: 81227-002-04



# ALCOHOL ISOPROPILICO

## ISOPROPILICO • ISOPROPYL ALCOHOL

**ANTISEPTICO  
ANTISEPTIC**

CONT. NET 128 OZ ( 3785 ML )  
MADE IN DOMINICAN REPUBLIC

# 70%

1 (718) 831 7156  
WWW.PENSEURGROUP.COM

Drug Facts	
ACTIVE INGREDIENTE	PURPOSE
ISOPROPYL ALCOHOL 70%	ANTIMICROBIAL
<b>USES:</b> HAND SANITIZER TO HELP REDUCE BACTERIA THE SKIN	
<b>WARNINGS:</b> FLAMMABLE, KEEP AWAY FROM FIRE OR FLAME	
<b>FOR EXTERNAL USE ONLY:</b>	
<b>WHEN USING THIS PRODUCT,</b> DO NOT USE IN OR NEAR THE EYES. IN CASE OF CONTACT, RINSE EYES THOROUGHLY WITH WATER.	
<b>STOP USE AND ASK A DOCTOR IF,</b> IRRITATION OR RASH APPEARS AND LASTS.	
<b>DIRECTIONS</b> PLACE PRODUCT ON HANDS • RUB UNTIL DRY.	
<b>INACTIVE INGREDIENTS</b> WATER (AQUA) ISOPROPYL ALCOHOL, GLYCERIN, PEROXIDE.	
<b>QUESTIONS?</b> QUESTIONAS? 1 (718) 831-7156 YOU MAY ALSO REPORT SERIOUS SIDE EFFECTS TO THIS PHONE NUMBER MON – FRI 9:AM – 5 AM.	
<b>DISTRIBUTED IN THE UNITED STATES BY:</b>	
<b>PENSEUR KREATIVA GROUP SRL.</b>	
C/ SABANA LARGA NO. 88 ENS. OZAMA RNC: 131-85030-8 TEL.: 1-829-893-9546	



### ALCOHOL ISOPROPYL

penseur isopropyl alcohol liquid

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:81227-002
<b>Route of Administration</b>	TOPICAL		

#### Active Ingredient/Active Moiety

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

#### Inactive Ingredients

Ingredient Name	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
<b>HYDROGEN PEROXIDE</b> (UNII: BBX060AN9V)	0.125 mL in 100 mL
<b>WATER</b> (UNII: 059QF0KO0R)	

## Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81227-002-00	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2021	
2	NDC:81227-002-01	18925 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2021	
3	NDC:81227-002-02	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2021	
4	NDC:81227-002-03	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2021	
5	NDC:81227-002-04	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2021	



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## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

**Labeler** - PENSEUR KREATIVA GROUP (817469188)

**Registrant** - PENSEUR PRODUCTS GROUP (117584143)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
PENSEUR KREATIVA GROUP		817469188	manufacture(81227-002)

Revised: 2/2022

PENSEUR KREATIVA GROUP