

ISOPROPYL ALCOHOL- isopropyl alcohol liquid
PENSEUR PRODUCTS LLC 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.

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.

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 - Principal Display Panel

236.58 ml NDC: 79878-001-00

KILLS 99.99% OF GERMS

PENSEUR GROUP

ALCOHOL ISOPROPILICO
ISOPROPYL ALCOHOL

75%
CONT. NET 8 OZ (237ML)
MADE IN DOMINICAN REPUBLIC

ANTISEPTICO / ANTISEPTIC

Drug Facts	
Active ingredient (s) Isopropyl Alcohol 75% v/v	Purpose Antiseptic
Use (s) hand 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	

FABRICADO EN LA REPUBLICA DOMINICANA POR PENSEUR IREATIVA GROUP S.R.L. DIRECCION: CALLE 19 ESQUINA BONHAIRE ALMA ROSA SEGUNDA, TEL. 1 (809) 699 2384. DISTRIBUIDO EN ESTADOS UNIDOS POR PENSEUR PRODUCTS GROUP LLC, ADDRESS 1750 N BAYSHORE MIAMI FLORIDA DUNS NUMBER 11-758-414 • MAIL: PENSEURGROUP@GMAIL.COM WWW.PENSEURGROUP.COM

7 01575 38192 0

3785.41 ml NDC: 79878-001-03

KILLS 99.99% OF GERMS



ALCOHOL ISOPROPILICO ISOPROPYL ALCOHOL

ANTISEPTICO / ANTISEPTIC

75%

CONT. NET 1 GAL (3785ML)
MADE IN DOMINICAN REPUBLIC

Drug Facts	
Active ingredient (s) Isopropyl Alcohol 75% v/v	Purpose Antiseptic
Use (s) hand 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	



FABRICADO EN LA REPUBLICA DOMINICANA POR PENSEUR IREATIVA GROUP S.R.L. DIRECCION: CALLE 19 ESQUINA BONAIRE ALMA ROSA SEGUNDA, TEL. 1 (809) 699 2394. DISTRIBUIDO EN ESTADOS UNIDOS POR PENSEUR PRODUCTS GROUP LLC, ADDRESS 1750 N BAYSHORE MIAMI FLORIDA DUNS NUMBER 11-758-414 • MAIL: PENSEURGROUP@GMAIL.COM WWW.PENSEURGROUP.COM

473.17 ml NDC: 79878-001-01

KILLS 99.99% OF GERMS



ALCOHOL ISOPROPILICO ISOPROPYL ALCOHOL

ANTISEPTICO / ANTISEPTIC

75%

CONT. NET 16 OZ (473ML)
MADE IN DOMINICAN REPUBLIC

Drug Facts	
Active ingredient (s) Isopropyl Alcohol 75% v/v	Purpose Antiseptic
Use (s) hand 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	



FABRICADO EN LA REPUBLICA DOMINICANA POR PENSEUR IREATIVA GROUP S.R.L. DIRECCION: CALLE 19 ESQUINA BONAIRE ALMA ROSA SEGUNDA, TEL. 1 (809) 699 2394. DISTRIBUIDO EN ESTADOS UNIDOS POR PENSEUR PRODUCTS GROUP LLC, ADDRESS 1750 N BAYSHORE MIAMI FLORIDA DUNS NUMBER 11-758-414 • MAIL: PENSEURGROUP@GMAIL.COM WWW.PENSEURGROUP.COM

946.35 ml NDC: 79878-001-02

KILLS 99.99% OF GERMS



ALCOHOL ISOPROPILICO ISOPROPYL ALCOHOL

ANTISEPTICO / ANTISEPTIC

75%

CONT. NET 32 OZ (946ML)
MADE IN DOMINICAN REPUBLIC

Drug Facts

Active Ingredient (s) Isopropyl Alcohol 75% v/v	Purpose Antiseptic
Use (s) hand 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.	
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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	



FABRICADO EN LA REPUBLICA DOMINICANA POR PENSEUR IREATIVA GROUP S.L. DIRECCIÓN: CALLE 19 ESQUINA BOHAIRE ALMA
 POZA SEGUNDA, TEL. 1 (809) 699 2394. DISTRIBUIDO EN ESTADOS UNIDOS POR PENSEUR PRODUCTS GROUP LLC, ADDRESS 1750 N
 BAYSHORE MIAMI FLORIDA DUNS NUMBER 11-738-414 • MAIL: PENSEURGROUP@GMAIL.COM WWW.PENSEURGROUP.COM



ISOPROPYL ALCOHOL

isopropyl alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79878-001
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: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79878-001-00	236.588 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2020	

2	NDC:79878-001-01	473.176 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2020	
3	NDC:79878-001-02	946.353 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2020	
4	NDC:79878-001-03	3785.41 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/10/2020	

Labeler - PENSEUR PRODUCTS LLC GROUP (117584143)

Establishment

Name	Address	ID/FEI	Business Operations
PENSEUR PRODUCTS LLC GROUP		117584143	manufacture(79878-001)

Revised: 7/2020

PENSEUR PRODUCTS LLC GROUP