

HAND SANITIZER- isopropyl alcohol liquid
Penseur Products Group LLC

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.

Active Ingredient(s)

Isopropyl Alcohol 70% v/v. Purpose: Antiseptic

Purpose

ANTIMICROBIAL

Use

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

Warnings

For external use only.

If taken internally, serious gastric disturbances will result.

Flammable. Keep away from fire or flame

Use only in a well ventilated area, fumes may be toxic.

Do not use

deep or puncture wounds, animal bites, or serious burns.

When using this product do not get into eyes.

Do not apply over large areas of the body.

do not use longer than one week unless directed by a doctor.

Stop use and ask a doctor if condition persists or gets worse.

Keep out of reach of children. In case of ingestion, get medical help or contact a Poison Control Center right away (1-800-222-1222) or (911).

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 affected area
- apply small amounts of this product on the area 1-3 times daily.
- if bandaged, let dry first
- may be covered with a sterile bandage.

Other information

- Store at room temperature
- does not contain, nor is intended as a substitute for grain or ethyl alcohol.

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

236 ml NDC: 79878-005-00

Drug Facts

ACTIVE INGREDIENTE	PURPOSE
ISOPROPYL ALCOHOL 70%	ANTIMICROBIAL

USES: FIRST AID TO HELP PREVENT THE RISK OF INFECTION IN MINOR CUTS, SCRAPES, AND BURNS.

WARNINGS

For external use only.

- IF TAKEN INTERNALLY, SERIOUS GASTRIC DISTURBANCES WILL RESULT

Flammable, keep away from fire or flame.

- use only in a well-ventilated are; fumes may be toxic

Ask a doctor before use if you have deep or puncture wounds, animal bites, or serious burns.

When using this product

- do not get into eyes
- do not apply over large areas of the body
- do not use longer than one week unless directed by a doctor

Stop use and ask a doctor if condition persists or gets worse.

Keep out of reach of children. in case of ingestion, get medical help or contact a poison control center right away (1-800-222-1222). o (911)

Directions

- clean affected area
- apply small amount of this product on the area 1-3 times daily
- if bandaged, let dry first
- may be covered with a sterile bandage

Other information

- store at room temperature
- do es not contain, nor is intended as a substitute for grain or ethyl alcohol

Inactive ingredient purified water glycerin, hydrogen peroxide usp

QUESTIONS? 1 (718) 831 7156 YOU MAY ALSO REPORT SERIOUS SIDE AFFECTS TO THIS PHONE NUMBER MON-FRI 9: AM - 5:PM

DISTRIBUTED IN THE UNITED STATES BY: PENSEUR PRODUCTS GROUP LLC ADDRESS: 1750 N BAYSHORE DR, APT 3508 MIAMI FL ZIP/ POSTAL CODE: 33132-3213-

7 01575 38203 3

24H 1 (718) 831 7156
WWW.PENSEURGROUP.COM

946 ml NDC: 79878-005-01

PENSEUR GROUP

Liquid **NEW HAND SANITIZER**
ISOPROPILICO - ISOPROPYL ALCOHOL

ANTISEPTICO ANTISEPTIC

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

70%

Drug Facts

ACTIVE INGREDIENTE	PURPOSE
ISOPROPYL ALCOHOL 70%	ANTIMICROBIAL

USES: FIRST AID TO HELP PREVENT THE RISK OF INFECTION IN MINOR CUTS, SCRAPES, AND BURNS.

WARNINGS
For external use only.
• IF TAKEN INTERNALLY, SERIOUS GASTRIC DISTURBANCES WILL RESULT
Flammable, keep away from fire or flame.
• **use only in a well-ventilated are; fumes may be toxic**

Ask a doctor before use if you have deep or puncture wounds, animal bites, or serious burns.

When using this product • do not get into eyes
• do not apply over large areas of the body
• do not use longer than one week unless directed by a doctor

Stop use and ask a doctor if condition persists or gets worse.

Keep out of reach of children. in case of ingestion, get medical help or contact a poison control center right away (1-800-222-1222), o (911)

Directions • clean affected area • apply small amount of this product on the area 1-3 times daily • if bandaged, let dry first • may be covered with a sterile bandage

Other information • store at room temperature
• do es not contain, nor is intended as a substitute for grain or ethyl alcohol

Inactive ingredient purified water glycerin, hydrogen peroxide usp

QUESTIONS? 1 (718) 831 7156 YOU MAY ALSO REPORT SERIOUS SIDE AFFECTS TO THIS PHONE NUMBER MON-FRI 9: AM - 5:PM

DISTRIBUTED IN THE UNITED STATES BY: PENSEUR PRODUCTS GROUP LLC ADDRESS: 1750 N BAYSHORE DR, APT 3508 MIAMI FL ZIP/ POSTAL CODE: 33132-3213-

7 01575 38200 2

1 (718) 831 7156
WWW.PENSEURGROUP.COM

3785 ml NDC: 79878-005-02

PENSEUR GROUP

Liquid **NEW HAND SANITIZER**
ISOPROPILICO - ISOPROPYL ALCOHOL

ANTISEPTICO ANTISEPTIC

CONT. NET 126 OZ (3785 ML)
MADE IN DOMINICAN REPUBLIC

70%

Drug Facts

ACTIVE INGREDIENTE	PURPOSE
ISOPROPYL ALCOHOL 70%	ANTIMICROBIAL

USES: FIRST AID TO HELP PREVENT THE RISK OF INFECTION IN MINOR CUTS, SCRAPES, AND BURNS.

WARNINGS
For external use only.
• IF TAKEN INTERNALLY, SERIOUS GASTRIC DISTURBANCES WILL RESULT
Flammable, keep away from fire or flame.
• **use only in a well-ventilated are; fumes may be toxic**

Ask a doctor before use if you have deep or puncture wounds, animal bites, or serious burns.

When using this product • do not get into eyes
• do not apply over large areas of the body
• do not use longer than one week unless directed by a doctor

Stop use and ask a doctor if condition persists or gets worse.

Keep out of reach of children. in case of ingestion, get medical help or contact a poison control center right away (1-800-222-1222), o (911)

Directions • clean affected area • apply small amount of this product on the area 1-3 times daily • if bandaged, let dry first • may be covered with a sterile bandage

Other information • store at room temperature
• do es not contain, nor is intended as a substitute for grain or ethyl alcohol

Inactive ingredient purified water glycerin, hydrogen peroxide usp

QUESTIONS? 1 (718) 831 7156 YOU MAY ALSO REPORT SERIOUS SIDE AFFECTS TO THIS PHONE NUMBER MON-FRI 9: AM - 5:PM

DISTRIBUTED IN THE UNITED STATES BY: PENSEUR PRODUCTS GROUP LLC ADDRESS: 1750 N BAYSHORE DR, APT 3508 MIAMI FL ZIP/ POSTAL CODE: 33132-3213-

7 01575 38192 0

1 (718) 831 7156
WWW.PENSEURGROUP.COM

HAND SANITIZER

isopropyl alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79878-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79878-005-00	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/24/2020	
2	NDC:79878-005-01	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/24/2020	
3	NDC:79878-005-02	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/24/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/24/2020	

Labeler - Penseur Products Group LLC (117584143)**Registrant** - Penseur Products Group LLC (117584143)**Establishment**

Name	Address	ID/FEI	Business Operations
PENSEUR PRODUCTS GROUP LLC		117584143	manufacture(79878-005)