# GERMS OUT- is opropyl 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

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 infestion 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 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 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 ml NDC: 79878-003-00



3785 ml NDC: 79878-003-01



473 ml NDC: 79878-003-02



946 ml NDC: 79878-003-03



## **GERMS OUT**

isopropyl alcohol liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79878-003	
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)			
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)			
WATER (UNII: 059QF0KO0R)			

	Packaging				
ı	#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
		NDC:79878-003- 00	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/24/2020	

2 NDC:79878-003-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/24/2020		
3 NDC:79878-003-02	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/24/2020		
4 NDC:79878-003-03	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/24/2020		
Marketing Information				
	111441011			
Marketing Categor		Marketing Start Date	Marketing End Date	
Marketing Categor OTC monograph not fin	y Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	

# 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(79878-003)	

Revised: 9/2020 PENSEUR PRODUCTS GROUP LLC