

CARE HAND- isopropyl alcohol gel
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.

PENSEUR HAND SANITIZER

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. Carbopomer (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

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.

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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

3785 NDC: 81227-101-01



KILLS 99.99 OF GERMS

CARE ANTIBACTERIAL DESINFECTANTE DE MANOS HAND



MAXIMUM STRENGTH,
ENRICHED WITH VITAMINE E.

CONT. 128 OZ
(3785ML)

1 (718) 831 7156
WWW.PENSEURGROUP.COM

CONTAINS MOUSTURIZER LEAVES HANDS SOFT

MADE IN DOMINICAN REPUBLIC



Drug Facts

ACTIVE INGREDIENTE ISOPROPYL ALCOHOL 70% **PURPOSE** ANTIMICROBIAL

USES: HAND SANITIZER TO HELP REDUCE BACTERIA THE SKIN

WARNINGS: FLAMMABLE, KEEP AWAY FROM FIRE OR FLAME

FOR EXTERNAL USE ONLY:

WHEN USING THIS PRODUCT. DO NOT USE IN OR NEAR THE EYES. IN CASE OF CONTACT, RINSE EYES THOROUGHLY WITH WATER.

STOP USE AND ASK A DOCTOR IF. IRRITATION OR RASH APPEARS AND LASTS.

KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

DIRECTIONS

PLACE PRODUCT ON HANDS • RUB UNTIL DRY.

INACTIVE INGREDIENTS

WATER (AQUA) ISOPROPYL ALCOHOL, CAPRYL GLYCOL, GLYCERIN ISOPROPYL MYRISTATE, TOCOPHERYL ACETATE, ACRYLATES/C10-30 ALKYL ACRYLATE COPOLYMER, AMINOMETRYL PROPANOL, FRAGRANCE (PERFUM).

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

**DISTRIBUTED IN THE UNITED STATE,
PR AND DOMINICAN REPUBLIC BY:**
PENSEUR KREATIVA GROUP SRL.

C/ SABANA LARGA NO. 88 ENS. OZAMA
RNC: 131-85030-8 TEL.: 1-829-893-9546

CARE HAND

isopropyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81227-000
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)	1.45 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	28.425 mL in 100 mL

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81227-000-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2021	
2	NDC:81227-000-02	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2021	
3	NDC:81227-000-03	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2021	
4	NDC:81227-000-04	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2021	
5	NDC:81227-000-05	296 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2021	
6	NDC:81227-000-06	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2021	
7	NDC:81227-000-07	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2021	
8	NDC:81227-000-08	1892.71 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2021	
9	NDC:81227-000-09	2 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product	01/01/2021	



GO
GERMS OUT
HAND SANITIZER

Drug Facts

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THE SKIN

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PLACE PRODUCT ON HANDS * RUB UNTIL DRY

INACTIVE INGREDIENTS
AWATER (AQUA) ISOPROPYL ALCOHOL, GLYSERIN,
CARBOPOL.

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

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

DISTRIBUTED BY: TRENDS NOW
SAN JUAN PR 00908 PHONE NUMBRE (787) 299 0543

DISTRIBUIDO POR TRENDS NOW

EXPIRATION DATE : 08/2023 • LOT. 10000 08112023

CONT. NET 1 GALON (128 OZ)



7 24373 73108 7



Empty & Recycle Cap
PLASTIC BOTTLE
PENSEUR GROUP
PET

MADE IN DOMINICAN REPUBLIC.

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	12/15/2020	

Labeler - PENSEUR KREATIVA GROUP (817469188)

Registrant - PENSEUR KREATIVA GROUP (817469188)

Establishment

Name	Address	ID/FEI	Business Operations
PENSEUR KREATIVA GROUP		817469188	manufacture(81227-000)

Revised: 2/2022

PENSEUR KREATIVA GROUP