

**HAND SANITIZER- isopropyl alcohol gel**  
**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.*

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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 70% v/v. Purpose: Antiseptic

**Purpose**

Antiseptic

**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

Water, Glycerin, acrylates/c10-30 alkyl acrylate cross polymer, aminomethyl propanol, isopropyl alcohol, isopropyl myristate, caprylyl glycol, phenoxyethanol, benzophenone-4, tocopheryl acetate

## Package Label - Principal Display Panel

59 ml NDC: 79878-002-00

ACTIVE INGREDIENTE	PURPOSE
ISOPROPYL ALCOHOL 70%	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 CROSSPOLYMER, 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 STATES BY:** PENSEUR PRODUCTS GROUP LLC, ADDRESS: 1750 N BAYSHORE DR, APT 3508 MIAMI FL, ZIP/POSTAL CODE: 33132-3213.

7 01575 38196 8

118 ml NDC: 79878-002-01



**NEW**

# HAND ANTIBACTERIAL SANITIZER

DESINFECTANTE DE MANOS

**CONT. NET 4 OZ ( 118 ML )**

MADE IN DOMINICAN REPUBLIC

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



7 01575 38197 5



### 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.

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**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 CROSSPOLYMER, AMINOMETRIL PROPANOL, FRAGRANCE (PERFUM).

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237 ml NDC: 79878-002-02



NEW

# HAND ANTIBACTERIAL SANITIZER

DESINFECTANTE DE MANOS

CONT. NET 8 OZ ( 237 ML )

MADE IN DOMINICAN REPUBLIC

(718) 831 7156  
WWW.PENSEURGROUP.COM



<b>Drug Facts</b>	
<b>ACTIVE INGREDIENTE</b> ISOPROPYL ALCOHOL 70% .....	<b>PURPOSE</b> ANTIMICROBIAL
<b>USES:</b> HAND SANITIZER TO HELP REDUCE BACTERIA THESKIN	
<b>WARNINGS:</b> FLAMMABLE, KEEP AWAY FROM FIRE ORFLAME	
<b>FOR EXTERNAL USE ONLY:</b>	
<b>WHEN USING THIS PRODUCT.</b> DO NOT USEIN IN OR NEAR THE EYES. IN CASE OF CONTACT. RINSE EYES THROUGHLY WINTH WATER.	
<b>STOP USE AND ASK A DOCTOR IF.</b> IRRITATION OR RASH APPEARS AND LASTS.	
<b>KEEP OUT OF REACH OF CHILDREN.</b> IF SWALLOWED GET MEDICLA HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.	
<b>DIRECTIONS</b> PLACE PRODUCT ON HANDS • RUB UNTIL DRY.	
<b>INACTIVE INGREDIENTS</b> WATER (AQUA) ISOPROPYL ALCOHOL, CAPRYL GLYCOL, GLYCERIN ISOPROPYL MYRISTATE, TOCOPHERYL ACETATE, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, AMINOMETRYL PROPANOL, FRAGRANCE (PERFUM).	
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296 ml NDC: 79878-002-03



NEW

# HAND ANTIBACTERIAL SANITIZER

DESINFECTANTE DE MANOS

CONT. NET 10 OZ ( 296 ML )

MADE IN DOMINICAN REPUBLIC

1 (718) 831 7156  
WWW.PENSEURGROUP.COM

<b>Drug Facts</b>	
<b>ACTIVE INGREDIENTE</b> ISOPROPYL ALCOHOL 70% .....	<b>PURPOSE</b> ANTIMICROBIAL
<b>USES:</b> HAND SANITIZER TO HELP REDUCE BACTERIA THESKIN	
<b>WARNINGS:</b> FLAMMABLE, KEEP AWAY FROM FIRE ORFLAME	
<b>FOR EXTERNAL USE ONLY:</b>	
<b>WHEN USING THIS PRODUCT.</b> DO NOT USEIN IN OR NEAR THE EYES. IN CASE OF CONTACT. RINSE EYES THROUGHLY WINTH WATER.	
<b>STOP USE AND ASK A DOCTOR IF.</b> IRRITATION OR RASH APPEARS AND LASTS.	
<b>KEEP OUT OF REACH OF CHILDREN.</b> IF SWALLOWED GET MEDICLA HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.	
<b>DIRECTIONS</b> PLACE PRODUCT ON HANDS • RUB UNTIL DRY.	
<b>INACTIVE INGREDIENTS</b> WATER (AQUA) ISOPROPYL ALCOHOL, CAPRYL GLYCOL, GLYCERIN ISOPROPYL MYRISTATE, TOCOPHERYL ACETATE, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, AMINOMETRYL PROPANOL, FRAGRANCE (PERFUM).	
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<b>DISTRIBUTED IN THE UNITED STATES BY:</b> PENSEUR PRODUCTS GROUP LLC, ADDRESS: 1750 N BAYSHORE DR, APT 3508 MIAMI FL, ZIP/POSTAL CODE: 33132-3213-.	



473 ml NDC: 79878-002-04



**NEW**

**PENSEUR GROUP**

**HAND ANTIBACTERIAL SANITIZER**  
DESINFECTANTE DE MANOS

CONT. NET 16 OZ ( 473 ML )

MADE IN DOMINICAN REPUBLIC

1 (718) 831 7156  
WWW.PENSEURGROUP.COM

Drug Facts	
<b>ACTIVE INGREDIENTE</b> ISOPROPYL ALCOHOL 70% .....	<b>PURPOSE</b> 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>KEEP OUT OF REACH OF CHILDREN.</b> IF SWALLOWED GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.	
<b>DIRECTIONS</b> PLACE PRODUCT ON HANDS • RUB UNTIL DRY.	
<b>INACTIVE INGREDIENTS</b> WATER (AQUA) ISOPROPYL ALCOHOL, CAPRYL GLYCOL, GLYCERIN ISOPROPYL MYRISTATE, TOCOPHERYL ACETATE, ACRYLATES/C10-30 ALKYL ACRYLATE COPOLYMER, AMINOMETRIL PROPANOL, FRAGRANCE (PERFUM).	
<b>QUESTIONS?</b> 1 (718) 831 7156 YOU MAY ALSO REPORT SERIOUS SIDE EFFECTS TO THIS PHONE NUMBER MON - FRI 9: AM - 5:PM.	
<b>DISTRIBUTED IN THE UNITED STATES BY:</b> PENSEUR PRODUCTS GROUP LLC, ADDRESS: 1750 N BAYSHORE DR, APT 3508 MIAMI FL, ZIP/POSTAL CODE: 33132-3213.	

7 01575 38193 7

946 ml NDC: 79878-002-05

**NEW**

**PENSEUR GROUP**

**HAND ANTIBACTERIAL SANITIZER**  
DESINFECTANTE DE MANOS

CONT. NET 32 OZ ( 946 ML )

MADE IN DOMINICAN REPUBLIC

1 (718) 831 7156  
WWW.PENSEURGROUP.COM

Drug Facts	
<b>ACTIVE INGREDIENTE</b> ISOPROPYL ALCOHOL 70% .....	<b>PURPOSE</b> 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.	
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<b>DIRECTIONS</b> PLACE PRODUCT ON HANDS • RUB UNTIL DRY.	
<b>INACTIVE INGREDIENTS</b> WATER (AQUA) ISOPROPYL ALCOHOL, CAPRYL GLYCOL, GLYCERIN ISOPROPYL MYRISTATE, TOCOPHERYL ACETATE, ACRYLATES/C10-30 ALKYL ACRYLATE COPOLYMER, AMINOMETRIL PROPANOL, FRAGRANCE (PERFUM).	
<b>QUESTIONS?</b> 1 (718) 831 7156 YOU MAY ALSO REPORT SERIOUS SIDE EFFECTS TO THIS PHONE NUMBER MON - FRI 9: AM - 5:PM.	
<b>DISTRIBUTED IN THE UNITED STATES BY:</b> PENSEUR PRODUCTS GROUP LLC, ADDRESS: 1750 N BAYSHORE DR, APT 3508 MIAMI FL, ZIP/POSTAL CODE: 33132-3213.	

7 01575 38195 1

1893 ml NDC: 79878-002-06



NEW

# HAND ANTIBACTERIAL SANITIZER

DESINFECTANTE DE MANOS

CONT. NET 64 OZ ( 1893 ML )

MADE IN DOMINICAN REPUBLIC

1 (718) 831 7156  
WWW.PENSEURGROUP.COM

### Drug Facts

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

**USES:** HAND SANITIZER TO HELP REDUCE BACTERIA THESKIN

**WARNINGS:** FLAMMABLE, KEEP AWAY FROM FIRE ORFLAME

**FOR EXTERNAL USE ONLY:**

**WHEN USING THIS PRODUCT.** DO NOT USEN IN OR NEAR THE EYES. IN CASE OF CONTACT. RINSE EYES THROUGHLY WINTH WATER.

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

**KEEP OUT OF REACH OF CHILDREN.** IF SWALLOWED GET MEDICLA 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 CROSSPOLYMER, AMINOMETRYL PROPANOL, FRAGRANCE (PERFUM).

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

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3785 ml NDC: 79878-002-07



NEW

# HAND ANTIBACTERIAL SANITIZER

DESINFECTANTE DE MANOS

CONT. NET 1 GALLON ( 3785 ML )

MADE IN DOMINICAN REPUBLIC

1 (718) 831 7156  
WWW.PENSEURGROUP.COM

### Drug Facts

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

**USES:** HAND SANITIZER TO HELP REDUCE BACTERIA THESKIN

**WARNINGS:** FLAMMABLE, KEEP AWAY FROM FIRE ORFLAME

**FOR EXTERNAL USE ONLY:**

**WHEN USING THIS PRODUCT.** DO NOT USEN IN OR NEAR THE EYES. IN CASE OF CONTACT. RINSE EYES THROUGHLY WINTH WATER.

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

**KEEP OUT OF REACH OF CHILDREN.** IF SWALLOWED GET MEDICLA 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 CROSSPOLYMER, AMINOMETRYL PROPANOL, FRAGRANCE (PERFUM).

**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-.



## HAND SANITIZER

isopropyl alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:79878-002
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
WATER (UNII: 059QF0K00R)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
SULISOBENZONE (UNII: 1W6L629B4K)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79878-002-00	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2020	
2	NDC:79878-002-01	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2020	
3	NDC:79878-002-02	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2020	
4	NDC:79878-002-03	296 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2020	
5	NDC:79878-002-04	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2020	
6	NDC:79878-002-05	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2020	
7	NDC:79878-002-06	1893 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2020	
8	NDC:79878-002-07	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2020	

**Marketing Information**

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

**Labeler** - PENSEUR PRODUCTS LLC GROUP (117584143)**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
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Revised: 7/2020

PENSEUR PRODUCTS LLC GROUP