

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

*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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The hand sanitizer is manufactured using only the following ingredients in the preparation of the product:

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.

Sterile distilled water or boiled cold water.

Hydrogen Peroxide

Glycerin

Carbomer 1342

Aloe Vera Leaf

FD&C Blue No. 1

FD&C Yellow No. 5

Alpha Tocopherol Acetate

Fragrance

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
- In eyes. In case of contact, rinse eyes thoroughly with water

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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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, Hydrogen Peroxide, Glycerin, Carbomer 1342, Aloe Vera Leaf, FD&C Blue No. 1, FD&C Yellow No. 5, Alpha Tocopherol Acetate, Fragrance.

## Package Label - Principal Display Panel

59 mL NDC: 74988-760-20

DRUG FACTS	Hand Sanitizer				
<table border="1"><thead><tr><th>Active Ingredient</th><th>Purpose</th></tr></thead><tbody><tr><td>Isopropyl alcohol 75%</td><td>Antiseptic</td></tr></tbody></table> <p><b>Use[s]</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.</p> <p><b>Warnings</b> For external use only. Flammable. Keep away from heat or flame</p> <p><b>Do not use</b></p> <ul style="list-style-type: none"><li>• in children less than 2 months of age</li><li>• on open skin wounds</li></ul> <p><b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</p> <p><b>Stop use and ask a doctor</b> if irritation or rash occurs; these may be signs of a serious condition.</p> <p><b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b></p> <ul style="list-style-type: none"><li>• Place enough product on hands to cover all surfaces. Rub hands together until dry.</li><li>• Supervise children under 6 years of age when using this product to avoid swallowing.</li></ul> <p><b>Other information</b></p> <ul style="list-style-type: none"><li>• Store between 15-30C (59-86F)</li><li>• Avoid freezing and excessive heat above 40C (104F)</li></ul> <p><b>Inactive ingredients</b> Water, Hydrogen Peroxide, Glycerin, Carbomer 1342, Aloe Vera Leaf, FD&amp;C Blue No. 1, FD&amp;C Yellow No. 5, Alpha Tocopherol Acetate, Fragrance.</p>	Active Ingredient	Purpose	Isopropyl alcohol 75%	Antiseptic	<p><b>Porrexx</b> High Potency Hand Sanitizer</p> <p>75% Isopropyl Alcohol Formula</p> <p>Made with Plant Extracts and Skin Conditioner</p> <p>KILLS 99.99% OF GERMS*</p> <p>2 oz (59 mL)</p> <p>01 Dispense hand sanitizer on your palms.</p> <p>02 Rub hands together, palm to palm and back of each hand.</p> <p>03 Rub tips of hand with palm of other hand.</p> <p>04 Cover all surfaces until hands feel dry (about 20 sec.)</p> <p>This product is FDA Registered NDC: 74988-760-20</p>
Active Ingredient	Purpose				
Isopropyl alcohol 75%	Antiseptic				

118 mL NDC: 74988-760-40

**DRUG FACTS**

**Active Ingredient**  
Isopropyl alcohol 75%  
**Purpose**  
Antiseptic

**Use[s]**  
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.

**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)  
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**Inactive ingredients** Water, Hydrogen Peroxide, Glycerin, Carbomer 1342, Aloe Vera Leaf, FD&C Blue No. 1, FD&C Yellow No. 5, Alpha Tocopherol Acetate, Fragrance.

Shield your hands from germs and infections. Manufactured and bottled in the USA. FDA registered



# Hand Sanitizer

# Porrrexx

## High Potency Hand Sanitizer



Made with Plant Extracts and Skin Conditioner

KILLS 99.99% OF GERMS\*

4 oz (118 mL)

01



Dispense hand sanitizer on your palms.

02



Rub hands together, palm to palm and back of each hand.

03



Rub tips of hand with palm of other hand.

04



Cover all surfaces until hands feel dry (about 20 sec.)

This product is FDA Registered  
NDC: 74988-760-40

236 mL NDC: 74988-760-80

**DRUG FACTS**

**Active Ingredient**  
Isopropyl alcohol 75%  
**Purpose**  
Antiseptic

**Use[s]**  
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.

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**Directions**  
• Place enough product on hands to cover all surfaces. Rub hands together until dry.  
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• Avoid freezing and excessive heat above 40C (104F)

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# Hand Sanitizer

# Porrrexx

## High Potency Hand Sanitizer



Made with Plant Extracts and Skin Conditioner

KILLS 99.99% OF GERMS\*

8 oz (236 mL)

01



Dispense hand sanitizer on your palms.

02



Rub hands together, palm to palm and back of each hand.

03



Rub tips of hand with palm of other hand.

04



Cover all surfaces until hands feel dry (about 20 sec.)

This product is FDA Registered  
NDC: 74988-760-80

473 mL NDC: 74988-760-16

**DRUG FACTS**

**Active Ingredient**  
Isopropyl alcohol 75% **Purpose**  
Antiseptic

**Use[s]**  
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.

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**Directions**  
• Place enough product on hands to cover all surfaces. Rub hands together until dry.  
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**Other information**  
• Store between 15-30C (59-86F)  
• Avoid freezing and excessive heat above 40C (104F)

**Inactive ingredients** Water, Hydrogen Peroxide, Glycerin, Carbomer 1342, Aloe Vera Leaf, FD&C Blue No. 1, FD&C Yellow No. 5, Alpha Tocopherol Acetate, Fragrance.

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# Hand Sanitizer

# Porrexx

High Potency Hand Sanitizer



Made with Plant Extracts and Skin Conditioner

KILLS 99.99% OF GERMS\*

473 mL (16 oz)

01



Dispense hand sanitizer on your palms.

02



Rub hands together, palm to palm and back of each hand.

03



Rub tips of hand with palm of other hand.

04



Cover all surfaces until hands feel dry (about 20 sec.)

This product is FDA Registered  
NDC: 74988-760-16

3.79 L NDC: 74988-760-37

**DRUG FACTS**

**Active Ingredient[s]**  
Isopropyl alcohol 75% **Purpose**  
Antiseptic

**Use[s]**  
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

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**Inactive ingredients** Water, Hydrogen Peroxide, Glycerin, Carbomer 1342, Aloe Vera Leaf, FD&C Blue No. 1, FD&C Yellow No. 5, Alpha Tocopherol Acetate, Fragrance.

Shield your hands from germs and infections. Manufactured and bottle in the USA. FDA registered



# Hand Sanitizer

# Porrexx

High Potency Hand Sanitizer

Made with Plant Extracts and Skin Conditioner

KILLS 99.99% OF GERMS\*

3.79 L (1 Gal)



Dispense hand sanitizer on your palms.



Rub hands together, palm to palm and back of each hand.



Rub tips of hand with palm of other hand.



Cover all surfaces until hands feel dry (about 20 sec.)

This product is FDA Registered  
NDC: 74988-760-37

208 L NDC: 74988-760-55

**DRUG FACTS**

**Active Ingredient**  
Isopropyl alcohol 75% .....Antiseptic

**Purpose**

**Use[s]**  
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.

**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, Hydrogen Peroxide, Glycerin, Carbomer 1342, Aloe Vera Leaf, FD&C Blue No. 1, FD&C Yellow No. 5, Alpha Tocopherol Acetate, Fragrance.



# Hand Sanitizer



High Potency Hand Sanitizer



Made with Plant Extracts and Skin Conditioner

KILLS 99.99% OF GERMS\*

208 L (55 Gal)

This product is FDA Registered  
NDC: 74988-760-55

Shield your hands from germs and infections. Manufactured and bottle in the USA. FDA registered

## 1041 L NDC: 74988-760-41

**DRUG FACTS**

**Active Ingredient(s)**  
Isopropyl Alcohol 75% .....Antiseptic

**Purpose**

**Use(s)**  
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.

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- 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, Hydrogen Peroxide, Glycerin, Carbomer 1342, Aloe Vera Leaf, FD&C Blue No. 1, FD&C Yellow No. 5, Alpha Tocopherol Acetate, Fragrance.

Hand Sanitizer

High Potency Hand Sanitizer

Made with Plant Extracts and Skin Conditioner

KILLS 99.99% OF GERMS\*

1041 L (275 Gal)

This product is FDA Registered  
NDC: 74988-760-41

Shield your hands from germs and infections. Manufactured and bottle in the USA. FDA registered



## 25741 L NDC: 74988-760-74

**DRUG FACTS**

**Active Ingredient(s)**  
Isopropyl Alcohol 75% .....Antiseptic

**Purpose**

**Use(s)**  
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.

**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, Hydrogen Peroxide, Glycerin, Carbomer 1342, Aloe Vera Leaf, FD&C Blue No. 1, FD&C Yellow No. 5, Alpha Tocopherol Acetate, Fragrance.

Hand Sanitizer

High Potency Hand Sanitizer

Made with Plant Extracts and Skin Conditioner

KILLS 99.99% OF GERMS\*

25741 L (6800 Gal)

This product is FDA Registered  
NDC: 74988-760-74

Shield your hands from germs and infections. Manufactured and bottle in the USA. FDA registered



# HAND SANITIZER

isopropyl alcohol gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:74988-760
<b>Route of Administration</b>	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)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0K00R)	
CARBOMER 1342 (UNII: 809Y72KV36)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74988-760-20	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/20/2020	
2	NDC:74988-760-80	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/20/2020	
3	NDC:74988-760-40	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/20/2020	
4	NDC:74988-760-37	3790 mL in 1 JUG; Type 0: Not a Combination Product	05/20/2020	
5	NDC:74988-760-55	208000 mL in 1 DRUM; Type 0: Not a Combination Product	05/20/2020	
6	NDC:74988-760-41	1041000 mL in 1 TANK; Type 0: Not a Combination Product	05/20/2020	
7	NDC:74988-760-74	25741000 mL in 1 CONTAINER; Type 0: Not a Combination Product	05/20/2020	
8	NDC:74988-760-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/20/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/20/2020	

**Labeler** - SanitizeNow Inc. (117475870)**Establishment**

Name	Address	ID/FEI	Business Operations
SanitizeNow Inc.		117475870	manufacture(74988-760)

