

## **PANTERO HAND SANITIZER- isopropyl alcohol liquid**

**Pantero, 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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### **Pantero, Inc. Hand Sanitizer (75% Isopropanol)**

#### **Active Ingredient**

Isopropyl alcohol 75% v/v

#### **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.**

On children less than 2 months of age

On open skin wounds

#### **Instruction for use**

When using this product, keep out of eyes, ears and mouth.

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

#### **Stop use**

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**

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.

## Storage and handling

Store between 59-86F (15-30C).

Avoid freezing and excessive heat above 104F (40C).

## Inactive ingredients

Glycerine, hydrogen peroxide, purified water USP

## Package Label

• HAND SANITIZER • HAND SANITIZER • HAND SANITIZER • HAND SANITIZER • HAND SANITIZER • HAND SANITIZER •

**PANTERO**

**HAND SANITIZER**

NO GMOs • NO PARABENS  
NO SYNTHETIC FRAGRANCES

28 FL OZ (828mL)  
NDC 74153-222-28

Drug Facts	
<b>Active Ingredient</b> Isopropyl Alcohol 75% w/v	<b>Purpose</b> Antiseptic, Hand Sanitizer
<b>Use</b> Hand sanitizer to help reduce bacteria that can potentially cause disease. For use when soap and water are not available.	
<b>Warnings</b> For external use only. Flammable. Keep away from heat or flame.	
<b>Do not use:</b> <ul style="list-style-type: none"><li>■ In children less than 2 months of age</li><li>■ On open skin wounds</li></ul>	
<b>When using this product</b> keep out of eyes, ears and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition. <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> <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 six years of age when using this product to avoid swallowing.</li></ul>	
<b>Storage and Handling</b> <ul style="list-style-type: none"><li>■ Store between 15-30°C (59-86°F)</li><li>■ Avoid freezing and excessive heat above 40°C (104°F)</li></ul>	
<b>Inactive Ingredients</b> Glycerin, hydrogen peroxide, purified water USP	
<b>Questions or Comments?</b> Call 833.PANTERO; (1-833-728-8376), M-F	

Distributed by:  
PANTERO INC.  
TROY, MI 48063  
WWW.PANTERO.COM

MADE IN USA

PLASTIC BOTTLE

Pantero\_HandSanitizer\_28ozISO75\_10x4.75-NDC-74153.222.28.indd 1

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# HAND SANITIZER

NO GMOs • NO PARABENS  
NO SYNTHETIC FRAGRANCES

4 FL OZ (118mL)  
NDC 74153-222-04

<b>Drug Facts</b>	
<b>Active Ingredient</b>	<b>Purpose</b>
Isopropyl Alcohol 75% v/v. . . . .	Antiseptic, Hand Sanitizer
<b>Use</b> Hand sanitizer to help reduce bacteria that can potentially cause disease. For use when soap and water are not available.	
<b>Warnings</b>	
For external use only. Flammable. Keep away from heat or flame.	
<b>Do not use:</b>	
<ul style="list-style-type: none"> <li>■ In children less than 2 months of age</li> <li>■ On open skin wounds</li> </ul>	
<b>When using this product</b> keep out of eyes, ears and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
<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 six years of age when using this product to avoid swallowing.</li> </ul>	
<b>Storage and Handling</b>	
<ul style="list-style-type: none"> <li>■ Store between 15-30°C (59-86°F)</li> <li>■ Avoid freezing and excessive heat above 40°C (104°F)</li> </ul>	
<b>Inactive Ingredients</b>	
Glycerin, hydrogen peroxide, purified water USP	
<b>Questions or Comments?</b>	
Call 833.PANTERO; (1-833-726-8376), M-F	

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# HAND SANITIZER

NO GMOs • NO PARABENS  
NO SYNTHETIC FRAGRANCES

2 FL OZ (59mL)  
NDC 74153-222-02

<b>Drug Facts</b>	
<b>Active Ingredient</b>	<b>Purpose</b>
Isopropyl Alcohol 75% v/v	Antiseptic, Hand Sanitizer
<b>Use</b> Hand sanitizer to help reduce bacteria that can potentially cause disease. For use when soap and water are not available.	
<b>Warnings</b>	
For external use only. Flammable. Keep away from heat or flame.	
<b>Do not use:</b>	
<ul style="list-style-type: none"> <li>■ In children less than 2 months of age</li> <li>■ On open skin wounds</li> </ul>	
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.	
<b>Directions</b>	
<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 six years of age when using this product to avoid swallowing.</li> </ul>	
<b>Storage and Handling</b>	
<ul style="list-style-type: none"> <li>■ Store between 15-30°C (59-86°F)</li> <li>■ Avoid freezing and excessive heat above 40°C (104°F)</li> </ul>	
<b>Inactive Ingredients</b>	
Glycerin, hydrogen peroxide, purified water USP	
<b>Questions or Comments?</b>	
Call 833.PANTERO; (1-833-726-8376), M-F	

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# HAND SANITIZER

NO GMOs • NO PARABENS  
NO SYNTHETIC FRAGRANCES

8 FL OZ (237mL)  
NDC 74153-222-08

<b>Drug Facts</b>	
<b>Active Ingredient</b>	<b>Purpose</b>
Isopropyl Alcohol 75% v/v. . . . .	Antiseptic, Hand Sanitizer
<b>Use</b> Hand sanitizer to help reduce bacteria that can potentially cause disease. For use when soap and water are not available.	
<b>Warnings</b>	
For external use only. Flammable. Keep away from heat or flame.	
<b>Do not use:</b>	
<ul style="list-style-type: none"> <li>■ In children less than 2 months of age</li> <li>■ On open skin wounds</li> </ul>	
<b>When using this product</b> keep out of eyes, ears and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
<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 six years of age when using this product to avoid swallowing.</li> </ul>	
<b>Storage and Handling</b>	
<ul style="list-style-type: none"> <li>■ Store between 15-30°C (59-86°F)</li> <li>■ Avoid freezing and excessive heat above 40°C (104°F)</li> </ul>	
<b>Inactive Ingredients</b>	
Glycerin, hydrogen peroxide, purified water USP	
<b>Questions or Comments?</b>	
Call 833.PANTERO; (1-833-726-8376), M-F	

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# HAND SANITIZER

NO GMOs • NO PARABENS  
NO SYNTHETIC FRAGRANCES

12 FL OZ (355mL)  
NDC 74153-222-12

<b>Drug Facts</b>	
<b>Active Ingredient</b> Isopropyl Alcohol 75% v/v. . . . .	<b>Purpose</b> Antiseptic, Hand Sanitizer
<b>Use</b> Hand sanitizer to help reduce bacteria that can potentially cause disease. For use when soap and water are not available.	
<b>Warnings</b> For external use only. Flammable. Keep away from heat or flame.	
<b>Do not use:</b> ■ In children less than 2 months of age ■ On open skin wounds	
<b>When using this product</b> keep out of eyes, ears and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<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 enough product on hands to cover all surfaces. Rub hands together until dry. ■ Supervise children under six years of age when using this product to avoid swallowing.	
<b>Storage and Handling</b> ■ Store between 15-30°C (59-86°F) ■ Avoid freezing and excessive heat above 40°C (104°F)	
<b>Inactive Ingredients</b> Glycerin, hydrogen peroxide, purified water USP	
<b>Questions or Comments?</b> Call 833.PANTERO; (1-833-726-8376), M-F	

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**HAND SANITIZER**

NO GMOs • NO PARABENS  
NO SYNTHETIC FRAGRANCES

16 FL OZ (473mL)  
NDC 74153-222-16

<b>Drug Facts</b>	
<b>Active Ingredient</b> Isopropyl Alcohol 75% v/v	<b>Purpose</b> Antiseptic, Hand Sanitizer
<b>Use</b> Hand sanitizer to help reduce bacteria that can potentially cause disease. For use when soap and water are not available.	
<b>Warnings</b> For external use only. Flammable. Keep away from heat or flame.	
<b>Do not use:</b> ■ In children less than 2 months of age ■ On open skin wounds	
<b>When using this product</b> keep out of eyes, ears and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<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 enough product on hands to cover all surfaces. Rub hands together until dry. ■ Supervise children under six years of age when using this product to avoid swallowing.	
<b>Storage and Handling</b> ■ Store between 15-30°C (59-86°F) ■ Avoid freezing and excessive heat above 40°C (104°F)	
<b>Inactive Ingredients</b> Glycerin, hydrogen peroxide, purified water USP	
<b>Questions or Comments?</b> Call 833.PANTERO; (1-833-726-8376), M-F	

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**HAND SANITIZER**

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NO SYNTHETIC FRAGRANCES

18 FL OZ (532mL)  
NDC 74153-222-18

<b>Drug Facts</b>	
<b>Active Ingredient</b> Isopropyl Alcohol 75% v/v	<b>Purpose</b> Antiseptic, Hand Sanitizer
<b>Use</b> Hand sanitizer to help reduce bacteria that can potentially cause disease. For use when soap and water are not available.	
<b>Warnings</b> For external use only. Flammable. Keep away from heat or flame.	
<b>Do not use:</b> ■ In children less than 2 months of age ■ On open skin wounds	
<b>When using this product</b> keep out of eyes, ears and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<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 enough product on hands to cover all surfaces. Rub hands together until dry. ■ Supervise children under six years of age when using this product to avoid swallowing.	
<b>Storage and Handling</b> ■ Store between 15-30°C (59-86°F) ■ Avoid freezing and excessive heat above 40°C (104°F)	
<b>Inactive Ingredients</b> Glycerin, hydrogen peroxide, purified water USP	
<b>Questions or Comments?</b> Call 833.PANTERO; (1-833-726-8376), M-F	

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Drug Facts	
Active Ingredient	Purpose
Isopropyl Alcohol 75% w/v	Antiseptic, Hand Sanitizer
<b>Use</b> Hand sanitizer to help reduce bacteria that can potentially cause disease. For use when soap and water are not available.	
<b>Warnings</b> For external use only. Flammable. Keep away from heat or flame.	
<b>Do not use:</b> <ul style="list-style-type: none"> <li>■ In children less than 2 months of age</li> <li>■ On open skin wounds</li> </ul>	
<b>When using this product</b> keep out of eyes, ears and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> <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 six years of age when using this product to avoid swallowing.</li> </ul>	
<b>Storage and Handling</b> <ul style="list-style-type: none"> <li>■ Store between 15-30°C (59-86°F)</li> <li>■ Avoid freezing and excessive heat above 40°C (104°F)</li> </ul>	
<b>Inactive Ingredients</b> Glycerin, hydrogen peroxide, purified water USP	
<b>Questions or Comments?</b> Call 833.PANTERO; (1-833-726-8376), M-F	

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## PANTERO HAND SANITIZER

isopropyl alcohol liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:74153-222(NDC:74171-100)
<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: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74153-222-32	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:74153-222-18	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
3	NDC:74153-222-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
	NDC:74153-222-	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination		



4	NDC:74153-222-02	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
5	NDC:74153-222-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
6	NDC:74153-222-04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
7	NDC:74153-222-12	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
8	NDC:74153-222-28	828 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/17/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

**Labeler** - Pantero, Inc. (116669041)

**Registrant** - Joy Frestedt (018853696)

## Establishment

Name	Address	ID/FEI	Business Operations
Ques Industries Inc		107110678	manufacture(74153-222)

## Establishment

Name	Address	ID/FEI	Business Operations
Pantero, Inc.		116669041	relabel(74153-222) , repack(74153-222)

Revised: 4/2020

Pantero, Inc.