

## **FALCON HAND SANITIZER- alcohol solution**

### **Falcon Distributors**

*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 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

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**

glycerin, hydrogen peroxide, purified water USP

**Package Label - Principal Display Panel**

4oz (118 mL) NDC: 75545-700-01



8oz (236 mL) NDC: 75545-700-02



# FALCON HAND SANITIZER

ISO PROPYL ALCOHOL ANTISEPTIC 75%  
TOPICAL SOLUTION  
NON-STERILE SOLUTION  
NDC: 75545-700-02

FALCON DISTRIBUTORS  
(719) 524-1251  
One Lord of the Rings, CO 80920  
www.falcondistributors.com

NET WEIGHT: 9OZ. (256.6 mL)

### DRUG FACTS

ACTIVE INGREDIENT(S)	PURPOSE
Isopropyl alcohol 75% w/v	Antiseptic

**USES:**  
Hand sanitizer to help reduce bacteria that potentially 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 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 seek doctor if irritation or rash occurs. There 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.

**CONTRAINDICATIONS:**  
• 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 15-30°C (59-86°F)  
• For directions and dosage see label box # 400 (101F)

**INACTIVE INGREDIENTS:** glycerin, hydrogen peroxide, purified water USP



# FALCON HAND SANITIZER

ISO PROPYL ALCOHOL ANTISEPTIC 75%  
TOPICAL SOLUTION  
NON-STERILE SOLUTION  
NDC: 75545-700-02

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• Store between 15-30°C (59-86°F)  
• For directions and dosage see label box # 400 (101F)

**INACTIVE INGREDIENTS:** glycerin, hydrogen peroxide, purified water USP

16oz (473 mL) NDC: 75545-700-03



# FALCON HAND SANITIZER

ISOPROPYL ALCOHOL ANTISEPTIC 75% TOPICAL SOLUTION  
NON-STERILE SOLUTION  
NDC: 75545-700-03

FALCON DISTRIBUTORS  
(719) 550-1551  
Colorado Springs, CO 80920  
www.FalconDistributors.com

NET WEIGHT 16 OZ. (473.2 mL)

### DRUG FACTS

ACTIVE INGREDIENT(S)	FORM
Isopropyl Alcohol 70% v/v	Aerosol
<b>USE(S)</b>	
Is an antiseptic hand sanitizer that kills germs on your hands. It is not for use on cuts or abrasions. It is not for use on the face.	
<b>WARNINGS</b>	
<ul style="list-style-type: none"> <li>Flammable</li> <li>Do not use near heat or open flame</li> <li>Do not use near children</li> <li>Do not use near food</li> <li>Do not use if you have a known allergy to any of the ingredients</li> <li>Do not use if you have a known allergy to any of the ingredients</li> <li>Do not use if you have a known allergy to any of the ingredients</li> </ul>	
<b>DESCRIPTION</b>	
<ul style="list-style-type: none"> <li>Isopropyl Alcohol 70% v/v</li> <li>Isopropyl Alcohol 70% v/v</li> <li>Isopropyl Alcohol 70% v/v</li> </ul>	
<b>HOW SUPPLIED</b>	
<ul style="list-style-type: none"> <li>16 oz. (473.2 mL) aerosol can</li> <li>16 oz. (473.2 mL) aerosol can</li> </ul>	
<b>MARKETING INFORMATION</b>	
<ul style="list-style-type: none"> <li>Product Name: Falcon Hand Sanitizer</li> <li>Product Name: Falcon Hand Sanitizer</li> </ul>	



# FALCON HAND SANITIZER

ISOPROPYL ALCOHOL ANTISEPTIC 75% TOPICAL SOLUTION  
NON-STERILE SOLUTION  
NDC: 75545-700-03

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NET WEIGHT 16 OZ. (473.2 mL)

### DRUG FACTS

ACTIVE INGREDIENT(S)	FORM
Isopropyl Alcohol 70% v/v	Aerosol
<b>USE(S)</b>	
Is an antiseptic hand sanitizer that kills germs on your hands. It is not for use on cuts or abrasions. It is not for use on the face.	
<b>WARNINGS</b>	
<ul style="list-style-type: none"> <li>Flammable</li> <li>Do not use near heat or open flame</li> <li>Do not use near children</li> <li>Do not use near food</li> <li>Do not use if you have a known allergy to any of the ingredients</li> <li>Do not use if you have a known allergy to any of the ingredients</li> <li>Do not use if you have a known allergy to any of the ingredients</li> </ul>	
<b>DESCRIPTION</b>	
<ul style="list-style-type: none"> <li>Isopropyl Alcohol 70% v/v</li> <li>Isopropyl Alcohol 70% v/v</li> <li>Isopropyl Alcohol 70% v/v</li> </ul>	
<b>HOW SUPPLIED</b>	
<ul style="list-style-type: none"> <li>16 oz. (473.2 mL) aerosol can</li> <li>16 oz. (473.2 mL) aerosol can</li> </ul>	
<b>MARKETING INFORMATION</b>	
<ul style="list-style-type: none"> <li>Product Name: Falcon Hand Sanitizer</li> <li>Product Name: Falcon Hand Sanitizer</li> </ul>	

23oz (680 mL) NDC: 75545-700-04



# FALCON HAND SANITIZER REFILL

ISOPROPYL ALCOHOL ANTISEPTIC 75% TOPICAL SOLUTION  
NON-STERILE SOLUTION  
NDC: 75545-700-04

ACTIVE INGREDIENT(S)	FORM
Isopropyl Alcohol 70% v/v	Aerosol
<b>USE(S)</b>	
Is an antiseptic hand sanitizer that kills germs on your hands. It is not for use on cuts or abrasions. It is not for use on the face.	
<b>WARNINGS</b>	
<ul style="list-style-type: none"> <li>Flammable</li> <li>Do not use near heat or open flame</li> <li>Do not use near children</li> <li>Do not use near food</li> <li>Do not use if you have a known allergy to any of the ingredients</li> <li>Do not use if you have a known allergy to any of the ingredients</li> <li>Do not use if you have a known allergy to any of the ingredients</li> </ul>	
<b>DESCRIPTION</b>	
<ul style="list-style-type: none"> <li>Isopropyl Alcohol 70% v/v</li> <li>Isopropyl Alcohol 70% v/v</li> <li>Isopropyl Alcohol 70% v/v</li> </ul>	
<b>HOW SUPPLIED</b>	
<ul style="list-style-type: none"> <li>23 oz. (680 mL) aerosol can</li> <li>23 oz. (680 mL) aerosol can</li> </ul>	
<b>MARKETING INFORMATION</b>	
<ul style="list-style-type: none"> <li>Product Name: Falcon Hand Sanitizer Refill</li> <li>Product Name: Falcon Hand Sanitizer Refill</li> </ul>	

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NET WEIGHT: 23 OZ. (680.2 mL)



# FALCON HAND SANITIZER REFILL

ISOPROPYL ALCOHOL ANTISEPTIC 75% TOPICAL SOLUTION  
NON-STERILE SOLUTION  
NDC: 75545-700-04

<b>ACTIVE INGREDIENT(S)</b>	<b>DATE &amp; PLACE</b>	<b>LOT/EXP</b>
Isopropyl alcohol 70% v/v		Antibiotic
<b>USE(S)</b>	Hand sanitizer helps reduce bacteria that potentially cause disease. For use when soap and water are not available.	
<b>WARNINGS</b>	For use only on hands. Flammable. Keep away from heat or flame. Do not use: - In adults or children sensitive to eyes - on open skin wounds	
<b>PRECAUTIONS</b>	Please avoid steps about disposal of eyes, as it may result in case of contact with eyes, always thoroughly rinse eyes with water and seek medical attention if necessary. 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>DESCRIPTION</b>	- Phenoxymethylpenicillin sodium salt of sodium calcium hydroxide solution - Caproic acid sodium salt. Hygienic eye skin and mucous membrane antiseptic.	
<b>OTHER INFORMATION</b>	- Store between 15-30C (59-86F) - Avoid freezing and excessive heat above 40C (104F)	
<b>ACTIVE INGREDIENT(S)</b>	glycerin, hydroxyethylcellulose, purified water USP	

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NET WEIGHT: 23 OZ. (690.2 mL)

32oz (946 mL) NDC: 75545-700-05



# FALCON HAND SANITIZER

ISOPROPYL ALCOHOL ANTISEPTIC 75% TOPICAL SOLUTION  
NON-STERILE SOLUTION  
NDC: 75545-700-05

**FALCON DISTRIBUTORS**  
(719) 550-1551  
Colorado Springs, CO 80920  
www.FalconDistributors.com

FOR 24 HOUR EMERGENCY INFORMATION  
CALL CHEMTREC: (800) 424-9300

NET WEIGHT 32 OZ (946.5 mL)

DRUG FACTS	
ACTIVE INGREDIENT(S)	PURPOSE
Isopropyl alcohol 75% v/v.....	Antiseptic
<b>USE(S)</b>	
Hand sanitizer to help reduce bacteria that potentially can 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 6 years of age when using this product to avoid swallowing.</li> </ul>	
<b>OTHER INFORMATION</b>	
<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>	
<b>INACTIVE INGREDIENTS</b> glycerin, hydrogen peroxide, purified water USP	





# FALCON HAND SANITIZER

ISOPROPYL ALCOHOL ANTISEPTIC 75% TOPICAL SOLUTION

NON-STERILE SOLUTION

NDC: 75545-700-05

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FOR 24 HOUR EMERGENCY INFORMATION  
CALL CHEMTREC: (800) 424-9300

NET WEIGHT 32 OZ (946.5 mL)

## DRUG FACTS

ACTIVE INGREDIENT[S]	PURPOSE
Isopropyl alcohol 75% v/v.....	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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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** glycerin, hydrogen peroxide, purified water USP

128oz (3785 mL) NDC: 75545-700-06



# FALCON HAND SANITIZER

ISOPROPYL ALCOHOL ANTISEPTIC 75% TOPICAL SOLUTION

NON-STERILE SOLUTION

NDC: 75545-700-06

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Colorado Springs, CO 80920  
www.FalconDistributors.com

FOR 24 HOUR EMERGENCY INFORMATION  
CALL CHEMTREC: (800) 424-9300

NET WEIGHT 1 GALLON (128 OZ.)

## DRUG FACTS

ACTIVE INGREDIENT[S]	PURPOSE
Isopropyl alcohol 75% v/v.....	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)
- Avoid freezing and excessive heat above 40C (104F)

**INACTIVE INGREDIENTS** glycerin, hydrogen peroxide, purified water USP



# FALCON HAND SANITIZER

ISOPROPYL ALCOHOL ANTISEPTIC 75% TOPICAL SOLUTION

NON-STERILE SOLUTION

NDC: 75545-700-06

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FOR 24 HOUR EMERGENCY INFORMATION  
CALL CHEMTREC: (800) 424-9300

NET WEIGHT 1 GALLON (128 OZ.)

## DRUG FACTS

ACTIVE INGREDIENT[S]	PURPOSE
Isopropyl alcohol 75% v/v	Antiseptic

### USE[S]

Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

### WARNINGS

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### Do not use

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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** glycerin, hydrogen peroxide, purified water USP

## FALCON HAND SANITIZER

alcohol solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:75545-700
<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 L in 100 L

### Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 L in 100 L
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 L in 100 L
WATER (UNII: 059QF0K00R)	18.425 L in 100 L

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75545-700-01	.118 L in 1 BOTTLE; Type 0: Not a Combination Product	04/21/2020	
2	NDC:75545-700-02	.236 L in 1 BOTTLE; Type 0: Not a Combination Product	04/21/2020	
3	NDC:75545-700-03	.473 L in 1 BOTTLE; Type 0: Not a Combination Product	04/21/2020	
4	NDC:75545-700-04	.680 L in 1 BOTTLE; Type 0: Not a Combination Product	04/21/2020	

5	NDC:75545-700-05	.946 L in 1 BOTTLE; Type 0: Not a Combination Product	04/21/2020	
6	NDC:75545-700-06	3.785 L in 1 BOTTLE; Type 0: Not a Combination Product	04/21/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/21/2020	

**Labeler** - Falcon Distributors (161361548)

## Establishment

Name	Address	ID/FEI	Business Operations
Falcon Distributors		161361548	manufacture(75545-700)

Revised: 4/2020

Falcon Distributors