HAND SANITIZER- isopropyl alcohol liquid Imperial Western Products, 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.

Hand Sanitizer Non-Sterile Solution Isopropyl Alcohol Antiseptic 75% Hand Gel

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

208,000 ml NDC: 77344-002-09



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HAND SANITIZER*

NON-STERILE SOLUTION



Isopropyl Alcohol Antiseptic 75% Hand Gel 🔹

208 L 55 gal

· ENFORCE

Drug Feets	
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Other information	
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Enforce Products is a Division of Imperial Western Products Inc. Questions? Comments? Contract us of (300) 975-6677 or (760) 398-0615. Manufactured by Imperial Western Products-Inc. Osachella, CA 92295

18,900 ml NDC: 77344-002-07



HAND

SANITIZER

NON-STERILE SOLUTION



Isopropyl Alcohol Antiseptic 75% Hand Gel •

18.92 L 5 gal

* ENFORCE PRODUCTS

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hopropyl atomici 75% s/s	Purpose Interptic
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3784 ml NDC: 77344-002-05



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HAND SANITIZER*

NON-STERILE SOLUTION



3.78 L 1 gal

PRODUCTS

Drug Feets	
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Enfonse Products is a Division of Imperial Western Products Inc. Questions? Comments? Contact us at (300) 975-6677 or (760) 398-0615 Manuschused by Imperial Western Products-Inc. Coachello, CA 90296 Mode in the USA

946 ml NDC: 77344-002-02



HAND SANITIZER*

NON-STERILE SOLUTION



Isopropyl Alcohol Antiseptic 75% Hand Gel

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946 mL 32 oz

ENFORCE.

Purpose topropyl alcohol 75% v/v	Drug Facts	
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 Store between 15-30C (59-86F) 		e when using this product to
	Other information	
 Avoid freezing and excessive heat above 40C (104F) 	 Store between 15-30C (59-86F) 	
	· Avoid freezing and excessive heat abo	ove 40C (104F)

Enforce Products is a Division of Imperial Western Products Inc.
Questions? Comments?
Contact us at (800) 975-6677 or (760) 398-0815
Manufactured by Imperial Western Products Inc.
Coachella, CA 92236
Made in the USA

473 ml NDC: 77344-002-01





NON-STERILE SOLUTION



• Isopropyl Alcohol Antiseptic 75% Hand Gel •

473 mL 16 oz

PRODUCTS

Drug Facts

Purpose Antiseptic

Use[s]
Hand sanitizer to help reduce bacteria that potror use when soap and water are not available.

in children less than 2 months of age

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

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Other information

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Inactive ingredients glycerin, hydrogen peroxide, purified water USP

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Questions? Comments?

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Manufactured by Imperial Western Products Inc. Coachella, CA 92236

Made in the USA

250 ml NDC: 77344-002-25



HAND SANITIZER*

NON-STERILE SOLUTION



Isopropyl Alcohol Antiseptic 75% Hand Gel 🔹

250 mL

ENFORCE PRODUCTS

Drug Facts

Isopropyl alcohol 75% v/v.

Purpose

Icohol 75% v/v.....

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 us

- · 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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Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Enforce Products is a Division of Imperial Western Products Inc.

Questions? Comments?

Contact us at (800) 975-6677 or (760) 398-0815

Manufactured by Imperial Western Products Inc. Coachella, CA 92236

Made in the USA

HAND SANITIZER

isopropyl alcohol liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:77344-002

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII: ND2M416302)	ISOPROPYL ALCOHOL	750 mL in 1000 mL

Inactive Ingredients		
Ingredient Name	Strength	
CARBOMER 940 (UNII: 4Q93RCW27E)	5 mL in 1000 mL	
TRIETHANOLAMINE 2-CYCLOHEXYL-4,6-DINITROPHENOLATE (UNII: N2TK31JIAH)	7 mL in 1000 mL	
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 1000 mL	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	1.25 mL in 1000 mL	
WATER (UNII: 059QF0KO0R)		

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77344- 002-01	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2020	
2	NDC:77344- 002-02	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2020	
3	NDC:77344- 002-05	3784 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2020	
4	NDC:77344- 002-07	18900 mL in 1 PAIL; Type 0: Not a Combination Product	05/18/2020	
5	NDC:77344- 002-09	208000 mL in 1 DRUM; Type 0: Not a Combination Product	05/18/2020	
6	NDC:77344- 002-25	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/18/2020	

Labeler - Imperial Western Products, Inc. (046592515)

Establishment				
Name	Address	ID/FEI	Business Operations	
Imperial Western Products, Inc.		046592515	manufacture(77344-002)	

Revised: 1/2022 Imperial Western Products, Inc.