

ISOPROPYL ALCOHOL ANTISEPTIC 75% TOPICAL HAND SANITIZER NON-STERILE SOLUTION- isopropyl alcohol gel
Enviro Science Technology 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.

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.

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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

473 ml NDC: 77845-514-16

**Isopropyl Alcohol Antiseptic 75%
Topical Solution**

**Hand Sanitizer
Non-sterile Solution**

NDC 77845-514-16

NET CONTENTS:
■ 16 fl oz (473 mL) □ 1 Gal (3785 mL)



Made in the U.S.A.

Mfg By: EST Inc.
15785 S. Keeler Terrace
Olathe, Kansas 66062



PLEASE RECYCLE





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 <ul style="list-style-type: none">• in children less than 2 months of age• on open skin wounds	
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Directions <ul style="list-style-type: none">• 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.	
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3785 ml NDC: 77845-514-10

**Isopropyl Alcohol Antiseptic 75%
Topical Solution**

**Hand Sanitizer
Non-sterile Solution**

NDC 77845-514-10

NET CONTENTS:
☐ 16 fl oz (473 mL) ☒ 1 Gal (3785 mL)

 Mfg By: EST Inc.
15785 S. Keeler Terrace
Olathe, Kansas 66062

Made in the U.S.A.

 PLEASE RECYCLE





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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Directions

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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 glycerin, hydrogen peroxide, purified water USP

18.93 liter NDC: 7845-514-50

**Isopropyl Alcohol Antiseptic 75%
Topical Solution**

**Hand Sanitizer
Non-sterile Solution**

NDC 77845-514-50

NET CONTENTS:
☐ 16 fl oz (473 mL) ☒ 1 Gal (3785 mL)
☒ 5 Gal (18.93 L)

 Mfg By: EST Inc.
15785 S. Keeler Terrace
Olathe, Kansas 66062

Made in the U.S.A.

 PLEASE RECYCLE





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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ISOPROPYL ALCOHOL ANTISEPTIC 75% TOPICAL HAND SANITIZER NON-STERILE SOLUTION

isopropyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77845-514
Route of Administration	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)			1.45 mL in 100 mL	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)			0.125 mL in 100 mL	
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77845-514-10	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2020	
2	NDC:77845-514-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2020	
3	NDC:77845-514-50	18927 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	05/11/2020	

Labeler - Enviro Science Technology Inc (604179080)

Registrant - Enviro Science Technology Inc (604179080)

Establishment			
Name	Address	ID/FEI	Business Operations
Enviro Science Technology Inc		604179080	manufacture(77845-514)

Revised: 5/2020

Enviro Science Technology Inc