

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

### **Plough Center, UTHSC**

*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**

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**

200 ml NDC: 74236-075-01

Package Quantity: Single Unit

<b>Drug Facts</b>	
<b>Active Ingredient[s]</b>	<b>Purpose</b>
Isopropyl Alcohol 75% v/v	Antiseptic
<b>Uses[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>	
<b>When using this product</b>	
<ul style="list-style-type: none"> <li>■ Keep out of eyes, ears, and mouth</li> <li>■ In case of contact with eyes, rinse thoroughly with water</li> </ul>	
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 15-30°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	

**UTHSC**  
**PLOUGH CENTER**  
 FOR STERILE DRUG DELIVERY SOLUTIONS

## Hand Sanitizer

Non-sterile Solution  
 Isopropyl Alcohol Antiseptic 75%  
 Topical Application

**200 mL**

Manufactured by  
 The University of Tennessee Health Science Center  
 Plough Center for Sterile Drug Delivery  
[uthsc.edu/plough-center](http://uthsc.edu/plough-center) • Memphis, TN

200 ml NDC: 74236-075-12

Package Quantity: Case of 12 units

**Drug Facts**

Active Ingredient[s]	Purpose
Isopropyl Alcohol 75% v/v	Antiseptic

**Uses[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 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 15-30°C (59-86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

**Inactive Ingredients**

Glycerin, hydrogen peroxide, purified water USP



**PLOUGH CENTER**  
FOR STERILE DRUG DELIVERY SOLUTIONS

## Hand Sanitizer

Non-sterile Solution  
Isopropyl Alcohol Antiseptic 75%  
Topical Application

**200 mL**

Manufactured by  
The University of Tennessee Health Science Center  
Plough Center for Sterile Drug Delivery  
uthsc.edu/plough-center • Memphis, TN

## HAND SANITIZER

isopropyl alcohol liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74236-075
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: 059QF0K00R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74236-075-12	200 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:74236-075-01	200 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	

### Marketing Information

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

**Labeler** - Plough Center, UTHSC (116984054)

**Registrant** - Plough Center, UTHSC (116984054)

### Establishment

Name	Address	ID/FEI	Business Operations
University of Tennessee		116984054	manufacture(74236-075)

Revised: 3/2020

Plough Center, UTHSC