

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

*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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### **75 % Isopropyl Alcohol-Based Hand Sanitizer**

#### **75 % v/v Isopropyl Alcohol-Based 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.

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

#### **Inactive ingredients**

glycerin, hydrogen peroxide, purified water USP

#### **Package Label - Principal Display Panel**



# Topical Solution

## Antiseptic Hand Rub Non-sterile Solution



237 mL (8 fl. oz)

Batch #:

2103 E. Rockhurst Street, Springfield, MO 65802  
[www.RhomarWater.com](http://www.RhomarWater.com) | [TalkToUs@RhomarWater](mailto:TalkToUs@RhomarWater)

### Drug Facts

#### Active ingredient[s]

Isopropyl alcohol 75 % v/v .....

#### Purpose

Antiseptic

#### Use[s]

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 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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**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 & excessive heat above 40 °C(104 °F).

**Inactive ingredients:** Glycerin, hydrogen peroxide, purified water USP.



**RHOMAR WATER**  
Heat Transfer Fluids • Hydronic System Solutions

**Isopropyl Alcohol Antiseptic 75 % Topical Solution**  
**Antiseptic Hand Rub, Non-sterile Solution**



**473 mL (16 fl. oz)**  
**Batch #:**

**Drug Facts**

Active ingredient[s]	Purpose
Isopropyl alcohol 75 % v/v .....	Antiseptic

**Use[s]:** 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 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 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.

2103 E. Rockhurst Street, Springfield, MO 65802 | 417-862-2600 | 800-543-5975 | www.RhomarWater.com | TalkToUs@RhomarWater.com



**RHOMAR WATER**  
Heat Transfer Fluids • Hydronic System Solutions

**Isopropyl Alcohol Antiseptic 75 % Topical Solution**

**Antiseptic Hand Rub, Non-sterile Solution**



**3,785 mL (128 fl. oz)**  
**Batch #:**

Drug Facts	
Active ingredient[s]	Purpose
Isopropyl alcohol 75 % v/v .....	Antiseptic
<b>Use[s]:</b> Hand sanitizer to help reduce bacteria that 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 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.	

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**HAND SANITIZER**

isopropyl alcohol liquid

**Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75503-472
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**Route of Administration**

TOPICAL

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75.15 mL in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	4.17 mL in 100 mL
WATER (UNII: 059QF0K00R)	19.23 mL in 100 mL

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75503-472-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/16/2020	
2	NDC:75503-472-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/16/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/16/2020	

**Labeler** - Rhomar Water (799881776)**Registrant** - Rhomar Water (799881776)**Establishment**

Name	Address	ID/FEI	Business Operations
Rhomar Water		799881776	manufacture(75503-472)

Revised: 4/2020

Rhomar Water