

## **HAND SANITIZER- alcohol gel**

### **Tri-Chem Industries**

*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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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. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (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. Aminomethyl propanol (1.5% v/v)
- d. 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)**

Alcohol 80% v/v. Purpose: Antiseptic

### **Purpose**

Antiseptic, Hand Sanitizer Gel

### **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, aminomethyl propanol, purified water USP

**Package Label - Principal Display Panel**

18.93 L NDC: 74664-002-10



<b>Drug Facts</b>	
<b>Active ingredient(s)</b> Alcohol 70% v/v.....	<b>Purpose</b> 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> <b>For external use only. Flammable. Keep away from heat or flame.</b> <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>	
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<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 59 - 86°F (15 - 30°C)</li> <li>Avoid freezing and excessive heat above 104°F (40°C)</li> </ul>	
<b>Inactive ingredients</b> Water, Hypromellose, Glycerin, Hydrogen Peroxide, Acrylic copolymer, Triethanolamine, Fragrance	

208.20 L NDC: 74664-002-20



<b>Drug Facts</b>	
<b>Active ingredient(s)</b> Alcohol 70% v/v.....	<b>Purpose</b> 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> <b>For external use only. Flammable. Keep away from heat or flame.</b> <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>	
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<b>Other information</b> <ul style="list-style-type: none"> <li>Store between 59 - 86°F (15 - 30°C)</li> <li>Avoid freezing and excessive heat above 104°F (40°C)</li> </ul>	
<b>Inactive ingredients</b> Water, Hypromellose, Glycerin, Hydrogen Peroxide, Acrylic copolymer, Triethanolamine, Fragrance	

1041 L NDC: 74664-002-30



<b>Drug Facts</b>	
<b>Active ingredient(s)</b> Alcohol 70% v/v.....	<b>Purpose</b> 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> <b>For external use only. Flammable. Keep away from heat or flame.</b> <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 eye, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. <b>Stop use and ask 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 59 - 86°F (15 - 30°C)</li> <li>Avoid freezing and excessive heat above 104°F (40°C)</li> </ul>	
<b>Inactive ingredients</b> Water, Hypromellose, Glycerin, Hydrogen Peroxide, Acrylic copolymer, Triethanolamine, Fragrance	

1249.2 L NDC: 74664-002-40



<b>Drug Facts</b>	
<b>Active ingredient(s)</b> Alcohol 70% v/v.....	<b>Purpose</b> 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> <b>For external use only. Flammable. Keep away from heat or flame.</b> <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 eye, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. <b>Stop use and ask 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 59 - 86°F (15 - 30°C)</li> <li>Avoid freezing and excessive heat above 104°F (40°C)</li> </ul>	
<b>Inactive ingredients</b> Water, Hypromellose, Glycerin, Hydrogen Peroxide, Acrylic copolymer, Triethanolamine, Fragrance	

24605.2 L NDC: 74664-002-50



<b>Drug Facts</b>	
<b>Active ingredient(s)</b> Alcohol 70% v/v.....	<b>Purpose</b> 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> <b>For external use only. Flammable. Keep away from heat or flame.</b> <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 eye, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. <b>Stop use and ask 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 59 - 86°F (15 - 30°C)</li> <li>Avoid freezing and excessive heat above 104°F (40°C)</li> </ul>	
<b>Inactive ingredients</b> Water, Hypromellose, Glycerin, Hydrogen Peroxide, Acrylic copolymer, Triethanolamine, Fragrance	

118 mL NDC: 74664-002-60



<b>Drug Facts</b>	
<b>Active ingredient(s)</b> Alcohol 70% v/v.....	<b>Purpose</b> 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> <b>For external use only. Flammable. Keep away from heat or flame.</b> <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>	
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<b>Other information</b> <ul style="list-style-type: none"> <li>Store between 59 - 86°F (15 - 30°C)</li> <li>Avoid freezing and excessive heat above 104°F (40°C)</li> </ul>	
<b>Inactive ingredients</b> Water, Hypromellose, Glycerin, Hydrogen Peroxide, Acrylic copolymer, Triethanolamine, Fragrance	

236 mL NDC: 74664-002-70





<b>Drug Facts</b>	
<b>Active ingredient(s)</b> Alcohol 70% v/v.....	<b>Purpose</b> 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> <b>For external use only. Flammable. Keep away from heat or flame.</b> <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 eye, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. <b>Stop use and ask 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 59 - 86°F (15 - 30°C)</li> <li>Avoid freezing and excessive heat above 104°F (40°C)</li> </ul>	
<b>Inactive ingredients</b> Water, Hypromellose, Glycerin, Hydrogen Peroxide, Acrylic copolymer, Triethanolamine, Fragrance	

473 mL NDC: 74664-002-80



<b>Drug Facts</b>	
<b>Active ingredient(s)</b> Alcohol 70% v/v.....	<b>Purpose</b> 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> <b>For external use only. Flammable. Keep away from heat or flame.</b> <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 eye, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. <b>Stop use and ask 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>	
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<b>Inactive ingredients</b> Water, Hypromellose, Glycerin, Hydrogen Peroxide, Acrylic copolymer, Triethanolamine, Fragrance	

## HAND SANITIZER

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:74664-002
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ALCOHOL</b> (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
<b>HYDROGEN PEROXIDE</b> (UNII: BBX060AN9V)	0.125 mL in 100 mL
<b>WATER</b> (UNII: 059QF0KO0R)	

**TROLAMINE** (UNII: 9O3K93S3TK)

**ACRYLIC ACID/SODIUM ACRYLATE COPOLYMER (1:1; 600 MPa.S AT 0.2%)** (UNII: M4PPW69Y4H)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74664-002-10	18927 mL in 1 PAIL; Type 0: Not a Combination Product	04/01/2020	
2	NDC:74664-002-20	208198 mL in 1 DRUM; Type 0: Not a Combination Product	04/01/2020	
3	NDC:74664-002-30	1249000000 mL in 1 TANK; Type 0: Not a Combination Product	04/01/2020	
4	NDC:74664-002-40	1041000000 mL in 1 TANK; Type 0: Not a Combination Product	04/01/2020	
5	NDC:74664-002-50	246050000000 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	04/01/2020	

### Marketing Information

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

**Labeler** - Tri-Chem Industries (798244414)

**Registrant** - Tri-Chem Industries (798244414)

### Establishment

Name	Address	ID/FEI	Business Operations
Tri-Chem Industries		798244414	manufacture(74664-002)

Revised: 11/2021

Tri-Chem Industries