

HAND SANITIZER GEL- 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.

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. 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. 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

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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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

118 mL NDC: 74664-004-01



Drug Facts	
Active ingredient(s) Alcohol 70% v/v	Purpose 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	
When using this product keep out of eye, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. Stop use and ask 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 <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.	
Other information <ul style="list-style-type: none">• Store between 59 - 86°F (15 - 30°C)• Avoid freezing and excessive heat above 104°F (40°C)	
Inactive ingredients Water, Hypromellose, Silicone Dioxide, Glycerin, Hydrogen Peroxide	

236 mL NDC: 74664-004-02



Drug Facts	
Active ingredient(s)	Purpose
Alcohol 70% 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	
When using this product keep out of eye, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. Stop use and ask 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	
<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.	
Other information	
<ul style="list-style-type: none">• Store between 59 - 86°F (15 - 30°C)• Avoid freezing and excessive heat above 104°F (40°C)	
Inactive ingredients Water, Hypromellose, Silicone Dioxide, Glycerin, Hydrogen Peroxide	

473 mL NDC: 74664-004-03



Drug Facts	
Active ingredient(s)	Purpose
Alcohol 70% 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 	
When using this product keep out of eye, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. Stop use and ask 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 <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. 	
Other information <ul style="list-style-type: none"> • Store between 59 - 86°F (15 - 30°C) • Avoid freezing and excessive heat above 104°F (40°C) 	
Inactive ingredients Water, Hypromellose, Silicone Dioxide, Glycerin, Hydrogen Peroxide	

18.93 L NDC: 74664-004-04



Drug Facts	
Active ingredient(s)	Purpose
Alcohol 70% v/v	Antiseptic
Use(s) Hand sanitizer to help reduce bacteria that potentially can cause disease. For us 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 	
When using this product keep out of eye, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. Stop use and ask 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 <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. 	
Other information <ul style="list-style-type: none"> • Store between 59 - 86°F (15 - 30°C) • Avoid freezing and excessive heat above 104°F (40°C) 	
Inactive ingredients Water, Hypromellose, Silicone Dioxide, Glycerin, Hydrogen Peroxide	

208 L NDC: 74664-004-05



Drug Facts	
Active ingredient(s)	Purpose
Alcohol 70% 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 	
When using this product keep out of eye, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. Stop use and ask 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 <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. 	
Other information <ul style="list-style-type: none"> Store between 59 - 86°F (15 - 30°C) Avoid freezing and excessive heat above 104°F (40°C) 	
Inactive ingredients Water, Hypromellose, Silicone Dioxide, Glycerin, Hydrogen Peroxide	

1040 L NDC: 74664-004-06



Drug Facts	
Active ingredient(s)	Purpose
Alcohol 70% v/v	Antiseptic
Use(s) Hand sanitizer to help reduce bacteria that potentially can cause disease. For us 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 	
When using this product keep out of eye, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. Stop use and ask 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 <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. 	
Other information <ul style="list-style-type: none"> • Store between 59 - 86°F (15 - 30°C) • Avoid freezing and excessive heat above 104°F (40°C) 	
Inactive ingredients Water, Hypromellose, Silicone Dioxide, Glycerin, Hydrogen Peroxide	

1249 L NDC: 74664-004-07



Drug Facts	
Active ingredient(s)	Purpose
Alcohol 70% 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 	
When using this product	
keep out of eye, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
Stop use and ask 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	
<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. 	
Other information	
<ul style="list-style-type: none"> Store between 59 - 86°F (15 - 30°C) Avoid freezing and excessive heat above 104°F (40°C) 	
Inactive ingredients	
Water, Hypromellose, Silicone Dioxide, Glycerin, Hydrogen Peroxide	

24605 L NDC: 74664-004-08



Drug Facts	
Active ingredient(s)	Purpose
Alcohol 70% 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 	
When using this product keep out of eye, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
Stop use and ask 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	
<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. 	
Other information	
<ul style="list-style-type: none"> Store between 59 - 86°F (15 - 30°C) Avoid freezing and excessive heat above 104°F (40°C) 	
Inactive ingredients Water, Hypromellose, Silicone Dioxide, Glycerin, Hydrogen Peroxide	

HAND SANITIZER GEL

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74664-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	0.3 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.75 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)			1.5 mL in 100 mL	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74664-004-02	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/24/2020	
2	NDC:74664-004-01	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/24/2020	
3	NDC:74664-004-03	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/24/2020	
4	NDC:74664-004-04	18930 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/24/2020	
5	NDC:74664-004-05	208000 mL in 1 DRUM; Type 0: Not a Combination Product	06/24/2020	
6	NDC:74664-004-06	1040000 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	06/24/2020	
7	NDC:74664-004-07	1249000 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	06/24/2020	
8	NDC:74664-004-08	24605000 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	06/24/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	06/24/2020	

Labeler - Tri-Chem Industries (798244414)

Registrant - Tri-Chem Industries (798244414)

Establishment

Name	Address	ID/FEI	Business Operations
Tri-Chem Industries		798244414	manufacture(74664-004) , relabel(74664-004) , repack(74664-004)

Revised: 6/2020

Tri-Chem Industries