

HAND SANITIZER GEL WITH FRAGRANCE- isopropyl 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. 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. Triethanolamine.
- e. Propylene glycol.
- f. Acrylic copolymer or carbomer.
- g. Fragrance.
- h. Sterile distilled water or boiled cold water.

The formulation meets the required efficacy for the protection of human health from germs and viruses when used in the absence of water and soap.

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, triethanolamine, propylene glycol, acrylic copolymer and/or carbomer, fragrance, purified water USP

Package Label - Principal Display Panel

118 mL NDC:74664-007-01



Drug Facts	Purpose
Active ingredient(s) 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	
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, Triethanolamine, Propylene glycol, Glycerin, Hydrogen Peroxide, Acrylic copolymer and/or Carbomer, Fragrance	

236 mL NDC: 74664-007-02



Alcohol Antiseptic 75%
Fragrant Topical Gel

Hand Sanitizer
Non-Sterile Solution

Manufactured by:
TriChem Industries
2600 N Cresson Hwy
Cresson, TX 75035

8 oz (236 mL)

Drug Facts	
Active ingredient(s) Isopropyl Alcohol 75% v/v.....Antiseptic	Purpose
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, Triethanolamine, Propylene glycol, Glycerin, Hydrogen Peroxide, Acrylic copolymer and/or Carbomer, Fragrance	

473 mL NDC: 74664-007-03



Alcohol Antiseptic 75%
Fragrant Topical Gel

Hand Sanitizer
Non-Sterile Solution

Manufactured by:
 TriChem Industries
 2600 N Cresson Hwy
 Cresson, TX 75035

16 oz (473 mL)

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 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, Triethanolamine, Propylene glycol, Glycerin, Hydrogen Peroxide, Acrylic copolymer and/or Carbomer, Fragrance	

18900 mL NDC: 74664-007-04



Alcohol Antiseptic 75%
Fragrant Topical Gel

Hand Sanitizer
Non-Sterile Solution

Manufactured by:
 TriChem Industries
 2600 N Cresson Hwy
 Cresson, TX 75035

5 gal (18,900 mL)

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 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, Triethanolamine, Propylene glycol, Glycerin, Hydrogen Peroxide, Acrylic copolymer and/or Carbomer, Fragrance	

20800 mL NDC: 74664-007-05



Alcohol Antiseptic 75%
Fragrant Topical Gel

Hand Sanitizer
Non-Sterile Solution

Manufactured by:
 TriChem Industries
 2600 N Cresson Hwy
 Cresson, TX 75035

55 gal drum (20800 mL)

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 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, Triethanolamine, Propylene glycol, Glycerin, Hydrogen Peroxide, Acrylic copolymer and/or Carbomer, Fragrance	

1041000 mL NDC: 74664-007-06



Alcohol Antiseptic 75%
Fragrant Topical Gel

Hand Sanitizer
Non-Sterile Solution

Manufactured by:
 TriChem Industries
 2600 N Cresson Hwy
 Cresson, TX 75035

275 gal tote (1041000 mL)

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 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, Triethanolamine, Propylene glycol, Glycerin, Hydrogen Peroxide, Acrylic copolymer and/or Carbomer, Fragrance	

12491000 mL NDC: 74664-007-07



Alcohol Antiseptic 75%
Fragrant Topical Gel

Hand Sanitizer
Non-Sterile Solution

Manufactured by:
 TriChem Industries
 2600 N Cresson Hwy
 Cresson, TX 75035

330 gal tote (1249000 mL)

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 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, Triethanolamine, Propylene glycol, Glycerin, Hydrogen Peroxide, Acrylic copolymer and/or Carbomer, Fragrance	

24605000 mL NDC: 74664-007-08



Alcohol Antiseptic 75%
Fragrant Topical Gel

Hand Sanitizer
Non-Sterile Solution

Manufactured by:
TriChem Industries
2600 N Cresson Hwy
Cresson, TX 75035

6500 gal tanker (24605000 mL)

Drug Facts	
Active ingredient(s) Isopropyl Alcohol 75% v/v.....Antiseptic	Purpose
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, Triethanolamine, Propylene glycol, Glycerin, Hydrogen Peroxide, Acrylic copolymer and/or Carbomer, Fragrance	

HAND SANITIZER GEL WITH FRAGRANCE

isopropyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74664-007
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
ACRYLIC ACID/SODIUM ACRYLATE COPOLYMER (1:1; 600 MP.A.S AT 0.2 %) (UNII: M4PPW69Y4H)	
TROLAMINE (UNII: 9O3K93S3TK)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

ALOE (UNII: V5VD430YW9)	
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.367 mL in 100 mL
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74664-007-01	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/18/2020	
2	NDC:74664-007-02	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/18/2020	
3	NDC:74664-007-03	18900 mL in 1 PAIL; Type 0: Not a Combination Product	09/18/2020	
4	NDC:74664-007-05	1041000 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	09/18/2020	
5	NDC:74664-007-06	1249000 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	09/18/2020	
6	NDC:74664-007-07	24605000 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	09/18/2020	
7	NDC:74664-007-04	20800 mL in 1 DRUM; Type 0: Not a Combination Product	09/18/2020	
8	NDC:74664-007-08	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/18/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/18/2020	

Labeler - Tri-Chem Industries (798244414)

Registrant - Tri-Chem Industries (798244414)

Establishment

Name	Address	ID/FEI	Business Operations
Tri-Chem Industries		798244414	manufacture(74664-007) , label(74664-007) , pack(74664-007) , repack(74664-007) , relabel(74664-007)

Revised: 9/2020

Tri-Chem Industries