

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.

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



Drug Facts	
Active ingredient(s) Alcohol 80% 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 glycerin, hydrogen peroxide, aminomethyl propanol, purified water USP	

10208.20 L NDC: 74664-002-20



Alcohol Antiseptic 80%
Topical Gel

Hand Sanitizer
Non-Sterile Solution

Manufactured by:
TriChem Industries
2600 N Cresson Hwy
Cresson, TX 76035

275 gal tote

Drug Facts	Purpose
Active ingredient(s) Alcohol 80% 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 glycerin, hydrogen peroxide, aminomethyl propanol, purified water USP	



Alcohol Antiseptic 80%
Topical Gel

Hand Sanitizer
Non-Sterile Solution

Manufactured by:
TriChem Industries
2600 N Cresson Hwy
Cresson, TX 76035

330 gal tote

Drug Facts	Purpose
Active ingredient(s) Alcohol 80% 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 glycerin, hydrogen peroxide, aminomethyl propanol, purified water USP	



Alcohol Antiseptic 80%
Topical Gel

Hand Sanitizer
Non-Sterile Solution

Manufactured by:
TriChem Industries
2600 N Cresson Hwy
Cresson, TX 76035

6500 gal bulk

Drug Facts	Purpose
Active ingredient(s) Alcohol 80% 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 glycerin, hydrogen peroxide, aminomethyl propanol, purified water USP	



Drug Facts	
Active ingredient(s) Alcohol 80% v/v.....	Purpose 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 glycerin, hydrogen peroxide, aminomethyl propanol, purified water USP	

1041 L NDC: 74664-002-30
 1249.2 L NDC: 74664-002-40
 24605.2 L NDC: 74664-002-50

HAND SANITIZER			
alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74664-002
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	70 mL in 100 mL
Inactive Ingredients			
	Ingredient Name		Strength

AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
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: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)