HAND SANITIZER- alcohol liquid Flotek Chemistry, LLC

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.

Health Care personnel hand rub to help reduce bacteria that potentially can cause disease.

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

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

18927 mL (5 gal) NDC: 74208-280-04

NDC 74208-280-04

Drug Facts	
Active Ingredient[s] Isopropyl alcohol 75% v/v	Purpose Antiseptic
Use[s] Health Care personnel hand rub to potentially can cause disease.	to help reduce bacteria that
Warnings For external use only. Flammable. Keep aw	ray from heat or flame
Do not use • in children less than 2 months of age • o	on open skin wounds
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Other information	
 Store between 15-30C (59-86F) Avoid above 40C (104F) 	freezing and excessive heat
Inactive ingredients glycerin, hydroger	a paravida purified water LICP

Signal Word: DANGER **Hazard Statements:** H319 Causes serious eye irritation.

Precautionary Statements:



H225 Highly flammable liquid and vapor

P370 + P378 in case of fire: Use dry sodium carbonate to extinguish P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking

Emergency telephone 1-405-282-8510

DOT Proper Shipping Name: UN1219, Isopropanol Solutions, 3, PG II



Hand Sanitizer

Alcohol Antiseptic 80% Topical Solution Non-Sterile Solution Item# FHS62106

Meets FDA, WHO, and CDC Guidelines

Net Contents: 5 gal

Lot:



Flotek Chemistry, LLC 1004 S. Plainsman Rd Marlow, OK 73055 Phone (580) 658-6608

3785.4 mL (1 gal) NDC: 74208-280-03

Drug Facts Active Ingredient[s]

Purpose

.Antiseptic

Use[s] Health Care personnel hand rub to help reduce bacteria that potentially can cause disease.

Warnings

Isopropyl alcohol 75% v/v ...

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

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

Other information • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Questions? To report adverse reactions, contact 580-658-6608.

Signal Word: DANGER Hazard Statements: H319 Causes serious eye irritation. sodium carbonate to extinguish H225 Highly flammable liquid and

Precautionary Statements: P370 + P378 In case of fire: Use dry P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking





Hand Sanitizer

Alcohol Antiseptic 80% Topical Solution Non-Sterile Solution Item# FHS62090

Meets FDA, WHO, and CDC Guidelines

Lot:

Net Contents: 1 Gal



Flotek Chemistry, LLC 1004 S. Plainsman Rd Marlow, OK 73055 Phone (580) 658-6608

1892.7 mL (0.5 gal) NDC: 74208-280-02

NDC 74208-280-02

Drug Facts Active Ingredient[s] Purpose

Isopropyl alcohol 75% v/v

Health Care personnel hand rub to help reduce bacteria that potentially can cause disease.

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

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.

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

Other information • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients glycerin, hydrogen peroxide, purified water USP Questions? To report adverse reactions, contact 580-658-6608.

Signal Word: DANGER Hazard Statements:

H319 Causes serious eye irritation. sodium carbonate to extinquish H225 Highly flammable liquid and vapor

Precautionary Statements: P370 + P378 In case of fire: Use dry P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking



Hand Sanitizer

Alcohol Antiseptic 80% Topical Solution

> Non-Sterile Solution Item# FHS62083

Meets FDA, WHO, and CDC Guidelines

Net Contents: 0.5 Gal



Flotek Chemistry, LLC 1004 S. Plainsman Rd Marlow, OK 73055 Phone (580) 658-6608

NDC 74208-280-	-01
Drug Facts	<u> </u>
Active Ingredient[s] Isopropyl alcohol 75% v/v	Purpose Antiseptic
Use[s] Health Care personnel hand rub to h potentially can cause disease.	elp reduce bacteria that
Warnings For external use only. Flammable. Keep away fr	om heat or flame
Do not use • in children less than 2 month wounds	ns of age • on open skin
When using this product keep out of eyes, ears, contact with eyes, rinse eyes thoroughly with w	
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Keep out of reach of children. If swallowed, get Poison Control Center right away.	t medical help or contact a
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 Supervise children under 6 years of age when swallowing. 	using this product to avoid
Other information • Store between 15 freezing and excessive heat above 40C (104F)	i-30C (59-86F) • Avoid
Inactive ingredients glycerin, hydrogen pe	eroxide, purified water USP
Questions? To report adverse reactions, contact	580-658-6608

Signal Word: DANGER Hazard Statements: H319 Causes serious eye irritation. sodium carbonate to extinguish H225 Highly flammable liquid and

Precautionary Statements: P370 + P378 In case of fire: Use dry P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking





Hand Sanitizer

Alcohol Antiseptic 80% Topical Solution Non-Sterile Solution Item# FHS62076

Meets FDA, WHO, and CDC Guidelines

Lot:

Net Contents: 1 Liter



Flotek Chemistry, LLC 1004 S. Plainsman Rd Marlow, OK 73055 Phone (580) 658-6608

HAND SANITIZER

alcohol liquid

Product Information

Product Type Item Code (Source) NDC:74208-280 HUMAN OTC DRUG

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) ALCOHOL 80 mL in 100 mL

Inactive Ingredients Ingredient Name Strength GLYCERIN (UNII: PDC6A3C0OX) 1.45 mL in 100 mL HYDROGEN PERO XIDE (UNII: BBX060AN9V) 0.125 mL in 100 mL

WATER (UNII: 059QF0KO0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74208-280- 01	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2020	
2	NDC:74208-280- 02	1892.7 mL in 1 CONTAINER; Type 0: Not a Combination Product	05/11/2020	
3	NDC:74208-280- 03	3785.4 mL in 1 JUG; Type 0: Not a Combination Product	05/11/2020	
4	NDC:74208-280- 04	18927 mL in 1 CONTAINER; Type 0: Not a Combination Product	05/11/2020	

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not final	part333A	05/11/2020				

Labeler - Flotek Chemistry, LLC (116701044)

Registrant - Flotek Industries, Inc (159997535)

Establishment					
Name	Address	ID/FEI	Business Operations		
Flotek Chemistry, LLC		116701044	manufacture(74208-280)		

Revised: 5/2020 Flotek Chemistry, LLC