

HAND SANITIZER- isopropyl 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.

Isopropyl Alcohol Antiseptic 75% Topical Solution Hand Sanitizer

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. 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)

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.

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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

1249 L (330 gal) NDC: 74208-175-05



Flotek Chemistry
1004 S. Plainsman Rd
Marlow, OK 73055
Phone (580) 658-6608
Emergency telephone 1-405-282-8510

Isopropyl Alcohol Antiseptic 75% Topical Solution Hand Sanitizer Non-Sterile Solution

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



Signal Word: DANGER

Hazard Statements:

- H319 Causes serious eye irritation.
- H336 May cause drowsiness or dizziness
- H225 Highly flammable liquid and vapor

Precautionary Statements:

- 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

Manufactured under FDA
Policy during CoVid-19
Health Emergency.
Formulation per WHO &
FDA guidance on alcohol-
based hand sanitizer.

Drug Facts	
Active Ingredient[s]	Purpose
Isopropyl alcohol 75% v/v.....	Antiseptic
Use[s] Health Care personnel hand rub to help reduce bacteria that potentially can cause disease.	
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Net Contents: 330 gal

Lot:

208.2 L (55 gal) NDC: 74208-175-04



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For external use only. Flammable. Keep away from heat or flame	
Do not use	
<ul style="list-style-type: none"> <li style="width: 50%;">• in children less than 2 months of age <li style="width: 50%;">• on open skin wounds 	
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Net Contents: 55 gal

Lot:

18.9 L (5 gal) NDC: 74208-175-03



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<i>Inactive ingredients</i> glycerin, hydrogen peroxide, purified water USP	

Net Contents: 5 gal

Lot:

15.1 L (4 x 1 gal) NDC: 74208-175-02



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Net Contents: 4 x 1 gal bottles

Lot:

3.8 L (1 gal) NDC: 74208-175-01

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Lot:

Net Contents: 1 Gal

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<i>Active Ingredient[s]</i>	<i>Purpose</i>
Isopropyl alcohol 75% v/v.....	Antiseptic
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HAND SANITIZER

isopropyl alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74208-175
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
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74208-175-01	3785 mL in 1 JUG; Type 0: Not a Combination Product	04/01/2020	
2	NDC:74208-175-02	15141 mL in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	04/01/2020	
3	NDC:74208-175-03	18927 mL in 1 CONTAINER; Type 0: Not a Combination Product	04/01/2020	
4	NDC:74208-175-04	208197 mL in 1 DRUM; Type 0: Not a Combination Product	04/01/2020	
5	NDC:74208-175-05	1249186 mL in 1 CONTAINER; 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	04/01/2020	

Labeler - Flotek Chemistry, LLC (116701044)

Registrant - Flotek Industries, Inc (159997535)

Establishment

Name	Address	ID/FEI	Business Operations
Flotek Chemistry, LLC		116701044	manufacture(74208-175)