

HAND SANITIZER- isopropyl alcohol liquid

Moon Chemical Products

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. 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

100 ml NDC: 76542-002-01

MFD Date:	Lot#:
Active Ingredient: Isopropyl Alcohol 75% 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 thoroughly with water.	
Stop use & ask doctor if: irritation/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 until dry. Supervise children under 6 years old to avoid swallowing.	
Other Information Store between 59-86°F. Avoid freezing and excessive heat above 104°F	
Inactive Ingredients: Glycerine, Hydrogen Peroxide, Purified Water	



Hand Sanitizer
4 oz / 100 mL

8112 SW 8th St, Oklahoma City, OK 73128
(405)787-4110

3875 ml NDC: 76542-002-02

MFD Date:	Lot#:
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Hand Sanitizer

1 gal /3785 mL

8112 SW 8th St, Oklahoma City, OK 73128
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HAND SANITIZER

isopropyl alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76542-002
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:76542-002-01	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2020	
2	NDC:76542-002-02	3785 mL in 1 JUG; Type 0: Not a Combination Product	05/05/2020	

Marketing Information

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

Labeler - Moon Chemical Products (042601120)

Establishment

Name	Address	ID/FEI	Business Operations
Moon Chemical Products		042601120	manufacture(76542-002)

Revised: 5/2020

Moon Chemical Products