

## **HAND SANITIZER- isopropyl alcohol liquid**

**Mg12, LP**

*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.*

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### **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

**DIRECTIONS**  
Apply topically to your hands. Rub in and allow to dry without wiping. Apply when desired. Some mild irritation or burning may occur on dry or cracked skin, this is normal and will pass after a few minutes. Shake well.

**For topical use only. Do not ingest. Avoid direct contact with eyes and other sensitive areas. If you are pregnant or have a medical condition, consult a physician before use.**

**100% Antiseptic**

**Mg<sup>12</sup>**  
THE POWER OF MAGNESIUM

**Magnificent**  
*Antibacterial*  
**Hand Sanitizer**

*Fresh Scent-Lemon*  
*Soothes & Moisturizes Skin w/ Aloe Vera*

**Kills Harmful Germs & Bacteria**

63% Alcohol per 4 fl oz (118 mL)

**Ultra-Pure & Effective**

**INGREDIENTS**  
Isopropyl Alcohol 70%,  
Aloe Vera Gel,  
Magnesium Chloride,  
Vegetable Glycerin,  
Lemon Essential Oil.

**877.331.4252 Mg12.com**  
8604 Ellisboro Road  
Stokesdale, NC 27357  
3rd John 1:2

**120 ml**

NDC: 78735-0007-04

## HAND SANITIZER

isopropyl alcohol liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78735-0007
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
LEMON OIL (UNII: I9GRO824LL)	0.125 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	

## Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78735-0007-4	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

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# Magnificent

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Fresh Scent-Lemon

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## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

**Labeler** - Mg12, LP (032170536)

**Establishment**

Name	Address	ID/FEI	Business Operations
Mg12, LP		032170536	manufacture(78735-0007)

Revised: 10/2020

Mg12, LP