# MG12, MAGNIFICENT HAND SANITIZER (UNSCENTED)- is opropyl 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

120 ml NDC: 78735-833-04



# MG12, MAGNIFICENT HAND SANITIZER (UNSCENTED) isopropyl alcohol liquid Product Information Product Type HUMAN OTC DRUG Item Code (Source) Route of Administration TOPICAL

#### **Active Ingredient/Active Moiety**

#### **Ingredient Name**

**Basis of Strength** 

Strength

 ${\tt ISOPROPYL}$  ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII: ND2M416302)

ISOPROPYL ALCOHOL 75 mL in 100 mL

#### **Inactive Ingredients**

indetive ingredients		
Ingredient Name	Strength	
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL	
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL	
WATER (UNII: 059QF0KO0R)		

#### **Product Characteristics**

Froduct Characteristics			
Color	Score		
Shape	Size		
Flavor	Imprint Code		
Contains			

#### **Packaging**

#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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1 NDC:78735-0000-4 120 mL in 1 BOTTLE; Type 0: Not a Combination Product 10/25/2020

#### **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.





# Magnificent

Antibacterial

Ultra-Pure & Effective

## **Hand Sanitizer**

Soothes & Moisturizes Skin w/ Aloe Vera

Kills Harmful Germs & Bacteria

63% Alcohol per 4 fl oz (118 mL)

#### **INGREDIENTS**

70% Isopropyl Alcohol, Aloe Vera Gel (1x-CG), Magnesium Chloride, Vegetable Glycerin.





#### **Marketing Information**

OTC monograph not final	part333A	03/30/2020	

### **Labeler** - Mg 12, LP (032170536)

Establishment			
Name	Address	ID/FEI	Business Operations
Mg12, LP		032170536	manufacture(78735-0000)

Revised: 10/2020 Mg12, LP