

HAND SANITIZER- alcohol gel
GMA Supplies 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.

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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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 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

GMA SUPPLIES HAND SANITIZER GALLON CONTAINER LABEL

HAND SANITIZER
with
GLYCERIN

Leaves Hands Feeling Soft

Kills Bacteria & Cares for your Skin

GMA SUPPLIES
Protect what you love

GMA SUPPLIES, HAND SANITIZER, cleanses & cares for your hands killing harmful bacteria, while moisturizing and softening your skin with glycerin. It helps to prevent contagious diseases, often transmitted by contact with contaminated surfaces.

Drug Facts	Drug Facts (continued)
Active ingredient Ethyl alcohol 70% v/vAntiseptic	These may be signs of a serious condition.
Purpose Antiseptic, Hand Sanitizer	Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away at 1-800-222-1222.
Uses Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	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.
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.	Other information -Store between 15-30°C (59-86°F) -Avoid freezing and excessive heat above 40°C (104°F)
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.	Inactive ingredients water (aqua), carbomer, triethanolamine, glycerin.
	Questions? +1 (786) 683-1238

MANUFACTURED BY MYSTIC INTL S.A. DE C.V.

Batch N° (See container) Expires: 3 years from manufacturing date

NET CONTENT
1.056 GALLON / 4 L

8 60005 94582 5

12.95 (CM)

9.0

GEL ANTIBACTERIAL GMA SUPPLIES ETIQUETA PARA ENVASE DE GALON

4 L NDC: 80869-420-04

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80869-420
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.3 mL in 100 mL
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80869-420-04	4000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

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

Labeler - GMA Supplies LLC (117706246)

Establishment

Name	Address	ID/FEI	Business Operations
GMA Supplies LLC		117706246	manufacture(80869-420)

Revised: 12/2020

GMA Supplies LLC