

HAND SANITIZER- isopropyl alcohol gel
SR MARKETING INTERNATIONAL INC

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.

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



Hand Sanitizer

GEL ANTIBACTERIAL

Aloe vera & Vitamin E

ALCOHOL 70%

300 mL



Drug Facts

Active ingredient (v/v).....**Purpose**
Ethyl Alcohol 70.0 %.....Antiseptic skin cleanser

Uses
• Antiseptic (skin) cleanser • Medicated (skin) cleanser • Antibacterial (skin) cleanser
• Kills harmful bacteria/germs • Effective in destroying (harmful) bacteria to provide antiseptic cleansing • For personal hand hygiene to help prevent the spread of bacteria

Warnings
For external use only.
When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water.
Stop use and ask/consult a doctor/ physician/ health care practitioner/ health care provider/ health care professional if irritation develops.
Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away.

Directions
Adults and children over 2 years: • For occasional and personal domestic use.
• Supervise children when they use this product. • Rub thoroughly into hands for at least 30 seconds. Allow to dry.

Inactive ingredients
Aqua/Water(Eau, Alcohol, Glycerin, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Triethanolamine, Parfum (Fragrance), Aloe Barbadosis Leaf Extract, Avena Sativa Kernel Extract, PEG-40 Hydrogenated Castor Oil, Tocopherol Acetate.



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SR MARKETING INTERNATIONAL,
Miami, FL


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300 ml NDC: 74799-001-30

HAND SANITIZER			
isopropyl alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74799-001
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)		ISOPROPYL ALCOHOL	70 mL in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1 mL in 100 mL
CLOPYRALID TRIETHANOLAMINE (UNII: O7T195VRMB)	0.25 mL in 100 mL
ALOE (UNII: V5VD430YW9)	0.01 mL in 100 mL
WATER (UNII: 059QF0K00R)	
ACRYLATES/VINYL ISODECANOATE CROSSPOLYMER (10000 MPAS NEUTRALIZED AT 0.5%) (UNII: 2N8MDB79NA)	0.25 mL in 100 mL
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	0.1 mL in 100 mL

Product Characteristics			
Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74799-001-30	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2020	



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

Labeler - SR MARKET ING INT ERNAT IONAL INC (008087072)

Registrant - SR MARKET ING INT ERNAT IONAL INC (008087072)

Establishment

Name	Address	ID/FEI	Business Operations
AMENI GROUP SAS		885162108	manufacture(74799-001)

Revised: 6/2020

SR MARKETING INTERNATIONAL INC