

FIORI GALLON HAND SANITIZER- hand sanitizer gel

International Merchandise Group

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.

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.

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.

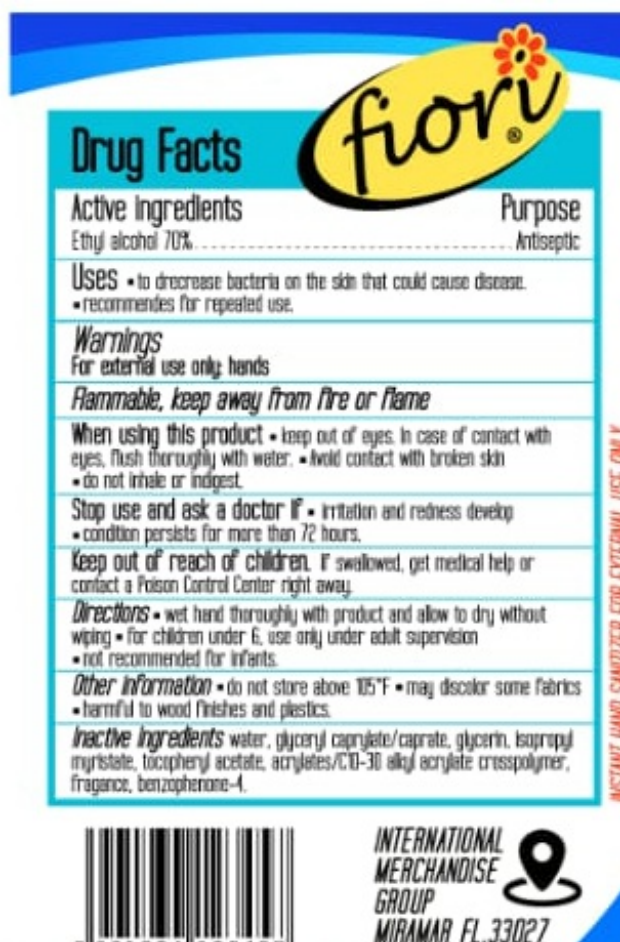
Other information

- 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



The image shows the principal display panel of a Fiori hand sanitizer package. At the top, there is a blue and yellow wave graphic with the 'fiori' logo in a yellow oval. Below this is a 'Drug Facts' panel with a blue header. The panel is divided into several sections: 'Active Ingredients' (Ethyl alcohol 70%), 'Purpose' (Antiseptic), 'Uses' (to decrease bacteria on the skin that could cause disease), 'Warnings' (For external use only; hands), 'Flammable, keep away from fire or flame', 'When using this product' (keep out of eyes, flush with water, avoid contact with broken skin), 'Stop use and ask a doctor if' (irritation and redness develop), 'Keep out of reach of children', 'Directions' (wet hand thoroughly with product and allow to dry without wiping), 'Other information' (do not store above 105°F, may discolor some fabrics), and 'Inactive ingredients' (water, glyceryl caprylate/caprate, glycerin, isopropyl myristate, tocopheryl acetate, acrylates/C10-30 alkyl acrylate crosspolymer, fragrance, benzophenone-4). To the right of the 'Drug Facts' panel, there is vertical text: 'WASH YOUR HANDS THOROUGHLY WITH SOAP AND WATER'. At the bottom left is a barcode, and at the bottom right is the 'INTERNATIONAL MERCHANDISE GROUP' logo with a location pin icon and the address 'MIRAMAR FL. 33027'.

Active Ingredients	Purpose
Ethyl alcohol 70%	Antiseptic

Uses • to decrease bacteria on the skin that could cause disease.
• recommends for repeated use.

Warnings
For external use only; hands

Flammable, keep away from fire or flame

When using this product • keep out of eyes. In case of contact with eyes, flush thoroughly with water. • Avoid contact with broken skin
• do not inhale or ingest.

Stop use and ask a doctor if • irritation and redness develop
• condition persists for more than 72 hours.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions • wet hand thoroughly with product and allow to dry without wiping • for children under 6, use only under adult supervision
• not recommended for infants.

Other information • do not store above 105°F • may discolor some fabrics
• harmful to wood finishes and plastics.

Inactive ingredients water, glyceryl caprylate/caprate, glycerin, isopropyl myristate, tocopheryl acetate, acrylates/C10-30 alkyl acrylate crosspolymer, fragrance, benzophenone-4.

WASH YOUR HANDS THOROUGHLY WITH SOAP AND WATER

INTERNATIONAL
MERCHANDISE
GROUP
MIRAMAR FL. 33027



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FIORI GALLON HAND SANITIZER

hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73971-378
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 70 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	70 mL in 70 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	70 mL in 70 mL
WATER (UNII: 059QF0K00R)	70 mL in 70 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73971-378-80	3780 mL in 1 JUG; 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 - International Merchandise Group (555630446)**Establishment**

Name	Address	ID/FEI	Business Operations
International Merchandise Group		555630446	manufacture(73971-378)

Revised: 4/2020

International Merchandise Group