

FIORI HAND SANITIZER 16 OZ- 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

Drug Facts

Active Ingredients Ethyl alcohol 70% -----	Purpose Antiseptic
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DIRECTIONS
To decrease bacterias on the skin that could cause disease. Recommended for repeated use.
Wet hand thoroughly with product and allow to dry without wiping. For childrens under 6, use only under adult supervision. Not recommended for infants.

WARNINGS
*Do not store above 105°F. May discolor some fabrics.
Harmful to wood finishes ands plastics.*

For hands external use only

EXTERNAL USE ONLY

FOR HANDS EXCEPT USE ONLY

▪ *Flammable, keep away from fire or flame* ▪

When using this products: 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 appears or if 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.

Inactive Ingredients

Aqua/Water, Acrylates/C 10-30 Alkyl Acrylate Crosspolymer, Carbomer, Aminomethyl Propanol.

INSTANT HAND SANITIZER FOR EXTERNAL USE ONLY

AL0420-003



INTERNATIONAL
MERCHANDISE
GROUP
MIRAMAR FL.33027



MADE IN EL SALVADOR



70% Alcohol

hand sanitizer

Kills the most germs

NET CONTENTS 16.2 Fl. Oz. / 480 ml

000 ml NDC: 00000-000-00

FIORI HAND SANITIZER 16 OZ

hand sanitizer gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:73971-162

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
WATER (UNII: 059QF0KO0R)	70 mL in 70 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73971-162-48	480 mL in 1 BOTTLE, DISPENSING; 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	label(73971-162)

Establishment

Name	Address	ID/FEI	Business Operations
Distribuidora Custcatlan		851247924	manufacture(73971-162)

Revised: 5/2020

International Merchandise Group