TOPICAL HAND SANITIZER- ethyl alcohol gel
Fragrance Manufacturing, 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.

Topical Hand Sanitizer

Active Ingredient(s)

Ethyl Alcohol 63%

Purpose

Antiseptic

Use(s)

Hand Sanitizer to help reduce bacteria on the skin. For use when soap and water are not available.

Warnings

For external use only. Flammable. Keep away from heat or flame.
Do not use on children less than 2 months of age or 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 immediately.

Directions

- Place enough product in palm to cover hands and rub together until dry.
- Supervise children under the age of 6 when using this product.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients:

Water (Aqua), Glycerin, Carbomer, Aminomethyl Propanol.

Package/Label Principal Display Panel

FMI – All In!

Topical Gel Hand Sanitizer
NDC: 13564-100-00

Mfg By: FMI, 100 Cascade Dr.
Allentown, PA 18109

2 fl. oz. (59.2 mL)

Label

TOPICAL HAND SANITIZER
ethyl alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:13564-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	63 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13564-100-00	59.2 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/03/2020	
2	NDC:13564-100-01	236.6 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/03/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/03/2020	

Labeler - Fragrance Manufacturing, Inc. (793406000)

Registrant - Fragrance Manufacturing, Inc. (793406000)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing, Inc.		793406000	MANUFACTURE(13564-100)

Revised: 4/2020 Fragrance Manufacturing, Inc.