HAND SANITIZER- alcohol gel
Fareva Morton Grove, 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.

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)

a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (78%, 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. Glycerin (1.72% v/v).
c. Hydroxypropylcellulose (1.28% v/v).
d. Sterile distilled water or boiled cold water.

Active Ingredient(s)

Alcohol 78% 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

water (aqua), glycerin, hydroxypropylcellulose

Package Label - Principal Display Panel

59 mL NDC: 72686-180-02

Viva2oztube.jpg

HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72686-180(NDC:75444-104)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	78 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	1.72 mL in 100 mL
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	1.28 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:72686-180-02	59 mL in 1 TUBE; 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 - Fareva Morton Grove, Inc. (116752326)

Establishment			
Name	**Address**	**ID/FEI**	**Business Operations**
Fareva Morton Grove, Inc.		116752326	manufacture(72686-180) , analysis(72686-180) , label(72686-180) , pack(72686-180) , relabel(72686-180) , repack(72686-180)

Revised: 4/2020 Fareva Morton Grove, Inc.