HAND SANITIZER- alcohol aerosol, spray
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.

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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
c. Sterile distilled water or boiled cold water.

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Active Ingredient(s)

Alcohol 78% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

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 develops and lasts.

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 develops and lasts.

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Directions

- Spray enough product on hands to cover all surfaces. Rub hands together until dry.
- For children under 6, use only under adult supervision.

Other information

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

Inactive ingredients

glycerin, water

Package Label - Principal Display Panel

66 mL NDC: 72686-183-10

fridababy_2oz_BOV.jpg

HAND SANITIZER

alcohol aerosol, spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72686-183
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)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72686-183-10	66 mL in 1 CAN; Type 0: Not a Combination Product	12/03/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	12/03/2020	

Labeler - Fareva Morton Grove, Inc. (116752326)

Establishment

Name	Address	ID/FEI	Business Operations
Fareva Richmond, Inc.		969523245	manufacture(72686-183) , label(72686-183) , analysis(72686-183) , pack(72686-183) , relabel(72686-183) , repack(72686-183)

Revised: 12/2020 Fareva Morton Grove, Inc.