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.

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a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (77%, 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. FRAGRANCE (PARFUM)
d. ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER
e. ALOE BARBADENSIS LEAF JUICE
f. AMINOMETHYL PROPANOL
g. YELLOW 5 (CI 19140)
h. CITRIC ACID
i. SODIUM BENZOATE
j. POTASSIUM SORBATE

Active Ingredient(s)

Alcohol 78% v/v. Purpose: Antiseptic

Purpose

Antiseptic

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 and redness develops and persists.

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

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, Aminomethyl Propanol, Citric Acid, Fragrance, Glycerin, Potassium Sorbate, Sodium Benzoate, Water, Yellow 5 (CI 19140)

Package Label - Principal Display Panel

50 mL NDC: 72686-187-05

HAND SANITIZER alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72686-187

Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	77 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
FRAGRANCE LEMON ORC2001060 (UNII: K1725A7G95)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ALOE (UNII: V5VD430YW9)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72686-187-05	50 mL in 1 TUBE; Type 0: Not a Combination Product	12/15/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	12/15/2020	

Labeler - Fareva Morton Grove, Inc. (116752326)

Establishment

Name	Address	ID/FEI	Business Operations
Fareva Morton Grove, Inc.		116752326	manufacture(72686-187) , analysis(72686-187) , label(72686-187) , pack(72686-187) , relabel(72686-187) , repack(72686-187)

Revised: 12/2020 Fareva Morton Grove, Inc.