

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.

- 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
- d. Sterile distilled water or boiled cold water.
- e. Acrylates/C10-30 Alkyl Acrylate Crosspolymer
- f. Butylene Glycol
- g. Aloe Barbadensis Leaf Juice
- h. Aminomethyl Propanol
- i. Titanium Dioxide
- j. 1,2-Hexanediol
- k. Agar
- l. Gellan Gum
- m. Calcium Alginate
- n. Ultramarines
- o. Phenoxyethanol
- p. Propylene Glycol
- q. Citric Acid
- r. Sodium Benzoate
- s. Potassium Sorbate

Active Ingredient(s)

Alcohol 77% 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 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

1,2-Hexanediol, Acrylates /C10-30 Alkyl Acrylate Crosspolymer, Agar, Aloe Barbadosensis Leaf Juice, Aminomethyl Propanol, Butylene Glycol, Calcium Alginate, Citric Acid, Fragrance (Parfum), Gellan Gum, Glycerin, Phenoxyethanol, Potassium Sorbate, Propylene Glycol, Sodium Benzoate, Titanium Dioxide (CI 77891), Ultramarines (CI 77007), Water (Aqua)

Package Label - Principal Display Panel

50 mL NDC: 72686-184-05

NO PRINT AREA

Sample, not for sale

Contact us
beautysales.usa@fareva.com

or visit our website
www.fareva.com

Tubes courtesy of
ALBEA
albea-group.com

**HAND
SANITIZER
GEL**

**FLORAL
STORM**

1.7oz / 50mL

FAREVA

NO PRINT AREA

Drug Facts	
Active ingredient Ethyl Alcohol 77%V/V	Purpose Antiseptic
Uses Hand sanitizer. Reduces 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 1,2-Hexanediol, Acrylates /C10-30 Alkyl Acrylate Crosspolymer, Agar, Aloe Barbadosensis Leaf Juice, Aminomethyl Propanol, Butylene Glycol, Calcium Alginate, Citric Acid, Fragrance (Parfum), Gellan Gum, Glycerin, Phenoxyethanol, Potassium Sorbate, Propylene Glycol, Sodium Benzoate, Titanium Dioxide (CI 77891), Ultramarines (CI 77007), Water (Aqua)	

Sample 1/24

QUIET AREA 1/32

Fareva, Merion Grove, IL, Made in USA

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72686-184
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
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
AGAR, UNSPECIFIED (UNII: 89T13OHQ2B)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
GLYCERIN (UNII: PDC6A3C0OX)	
FRAGRANCE FLORAL ORC0902236 (UNII: R66Z4YW3X0)	
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
GELLAN GUM (LOW ACYL) (UNII: 7593U09I4D)	
CALCIUM ALGINATE (UNII: 8P20S56HZI)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ULTRAMARINE BLUE (UNII: I39WR998BI)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72686-184-05	50 mL in 1 TUBE; Type 0: Not a Combination Product	11/03/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	11/03/2020	

Labeler - Fareva Morton Grove, Inc. (116752326)

Establishment

Name	Address	ID/FEI	Business Operations
Fareva Morton Grove, Inc.		116752326	manufacture(72686-184) , analysis(72686-184) , label(72686-184) , pack(72686-184) , relabel(72686-184) , repack(72686-184)

Revised: 11/2020

Fareva Morton Grove, Inc.