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.

HAND SANITIZER GEL SPRING DROPS

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

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. WATER (AQUA)
   c. GLYCERIN
   d. FRAGRANCE (PARFUM)
   e. ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER
   f. MANNITOL
   g. ALOE BARBADENSIS LEAF JUICE
   h. AMINOMETHYL PROPANOL
   i. MICROCRYSTALLINE CELLULOSE
   j. TOCOPHERYL ACETATE
   k. CHROMIUM HYDROXIDE GREEN (CI 77289)
   l. HYDROXYPROPYL METHYLCELLULOSE
   m. CITRIC ACID
   n. SODIUM BENZOATE
   o. POTASSIUM SORBATE

Active Ingredient(s)

Alcohol 77% 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.

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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

ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, ALOE BARBADENSIS LEAF JUICE, AMINOMETHYL PROPANOL, CHROMIUM HYDROXIDE GREEN (CI 77289), CITRIC ACID, FRAGRANCE (PARFUM), GLYCERIN, HYDROXYPROPYL METHYLCELLULOSE, MANNITOL, MICROCRYSTALLINE CELLULOSE, POTASSIUM SORBATE, SODIUM BENZOATE, TOCOPHERYL ACETATE, WATER (AQUA).

Package Label - Principal Display Panel

50 mL NDC: 72686-189-05

HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72686-189
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**

AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
FRAGRANCE FLORAL ORC0902236 (UNII: R66Z4YW3X0)	
WATER (UNII: 059QF0KO0R)	
CHROMIUM HYDROXIDE GREEN (UNII: RV8FT8XF5R)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MANNITOL (UNII: 3OWL53L36A)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72686-189-05	50 mL in 1 TUBE; Type 0: Not a Combination Product	02/22/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	02/22/2021	

Labeler - Fareva Morton Grove, Inc. (116752326)

Establishment

Name	Address	ID/FEI	Business Operations
Fareva Morton Grove, Inc.		116752326	manufacture(72686-189) , analysis(72686-189) , label(72686-189) , pack(72686-189) , relabel(72686-189) , repack(72686-189)

Revised: 2/2021 Fareva Morton Grove, Inc.