

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 ZESTY CITRUS

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. IRON OXIDES (CI 77492)
 - 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.

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.

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 (PARFUM), GLYCERIN, HYDROXYPROPYL METHYLCELLULOSE, IRON OXIDES (CI 77492), MANNITOL, MICROCRYSTALLINE CELLULOSE, POTASSIUM SORBATE, SODIUM BENZOATE, TOCOPHERYL ACETATE, WATER (AQUA).

Package Label - Principal Display Panel

50 mL NDC: 72686-190-05

Sample, not for sale

Contact us
beautysales.usa@fareva.com

or visit our website
www.fareva.com

Tubes courtesy of



albea-group.com

HAND SANITIZER GEL

ZESTY CITRUS

1.7oz / 50mL

FAREVA

Drug Facts

Active ingredient	Purpose
Ethyl Alcohol 78%V/V	Antiseptic

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Inactive ingredients Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, Aminomethyl Propanol, Citric Acid, Fragrance (Parfum), Glycerin, Hydroxypropyl Methylcellulose, Iron Oxides (CI 77492), Mannitol, Microcrystalline Cellulose, Potassium Sorbate, Sodium Benzoate, Tocopheryl Acetate, Water (Aqua)

Fareva, Morton Grove, IL, Made in USA.

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72686-190
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
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
HYPROMELLOSES (UNII: 3NXW29V3WO)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)
MANNITOL (UNII: 3OWL53L36A)
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
SODIUM BENZOATE (UNII: OJ245FE5EU)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
GLYCERIN (UNII: PDC6A3C0OX)
FRAGRANCE LEMON ORC2001060 (UNII: K1725A7G95)
WATER (UNII: 059QF0KO0R)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72686-190-05	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(72686-190) , analysis(72686-190) , label(72686-190) , pack(72686-190) , relabel(72686-190) , repack(72686-190)

Revised: 2/2021

Fareva Morton Grove, Inc.