

AURORA FRESH GEL- alcohol gel
Aurora Specialty Chemistries

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.

Aurora Fresh Gel Lime Citrus Scented Hand Sanitizer with Vitamin E 5 Gallons (18.9 L) Container

This is a gel hand sanitizer with citrus fragrance manufactured according to standard CGMP.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with existing hand sanitizer products sold OTC throughout the United States and Globally:

Isopropyl Alcohol (70%, v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.

Glycerin (1.39% v/v).

Carbomer-980 (0.7% v/v).

Isopropyl Myristate (0.07% v/v)

DL-Alpha-Tocopherol Acetate (0.07% v/v)

Trolamine (0.7% v/v)

Citral (0.07% v/v)

Sterile distilled water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Isopropyl Alcohol 70%

Purpose

Antiseptic / Hand Sanitizer

Use(s)

Hand Sanitizer to help reduce bacteria that potentially cause disease.
For use when soap and water are not available.

Warnings

For external use only. Flammable. Keep away from 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 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.

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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

Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

deionized water, glycerin, trolamine, carbomer, tocopheryl acetate, isopropyl myristate, fragrance

Package Label - Principal Display Panel

5 GAL (18.9 L) NDC: 77807-003-05

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5 GAL (18.9 L)

**AURORA FRESH GEL**

alcohol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:77807-003 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|-----------------|
| ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302) | ISOPROPYL ALCOHOL | 70 mL in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|-------------------|
| WATER (UNII: 059QF0KO0R) | 27 mL in 100 mL |
| CARBOMER 980 (UNII: 4Q93RCW27E) | 0.7 mL in 100 mL |
| GLYCERIN (UNII: PDC6A3C0OX) | 1.39 mL in 100 mL |
| ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS) | 0.07 mL in 100 mL |
| .ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WP17EW8) | 0.07 mL in 100 mL |
| TROLAMINE (UNII: 9O3K93S3TK) | 0.7 mL in 100 mL |
| CITRAL (UNII: T7EU009VPP) | 0.07 mL in 100 mL |

| Product Characteristics | | | |
|-------------------------|-------|--------------|--|
| Color | white | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

| Packaging | | | | |
|-----------|------------------|--|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:77807-003-05 | 18927 mL in 1 CONTAINER; Type 0: Not a Combination Product | 08/03/2020 | |

| Marketing Information | | | |
|-------------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part333A | 08/03/2020 | |

Labeler - Aurora Specialty Chemistries (108423153)

| Establishment | | | |
|------------------------------|---------|-----------|------------------------|
| Name | Address | ID/FEI | Business Operations |
| Aurora Specialty Chemistries | | 108423153 | manufacture(77807-003) |

Revised: 1/2022

Aurora Specialty Chemistries