

AURORA FRESH GEL 71- 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 71 Gel Hand Sanitizer with Vitamin E 1 Gallon (3.785L) 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).

Hydroxymethyl Cellulose (0.7% v/v).

Isopropyl Myristate (0.07% v/v)

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

Sterile distilled water (27.77% v/v).

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, hydroxypropyl cellulose, tocopheryl acetate, isopropyl myristate

Package Label - Principal Display Panel

1 Gallon (3.785 L) NDC: 77807-005-04

<p>Drug Facts</p> <p>Active ingredient(s) Isopropyl Alcohol 70%</p> <p>Purpose Antiseptic / Hand Sanitizer</p> <p>Use(s) Hand Sanitizer to help reduce bacteria that potentially cause disease. For use when soap and water are not available.</p> <p>Warnings For external use only. Flammable. Keep away from flame.</p> <p>Do Not Use</p> <ul style="list-style-type: none"> • In children less than 2 months of age • On open skin wounds <p>When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</p> <p>Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none"> • 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. <p>Other information • Avoid freezing and excessive heat above 40C (104F)</p> <p>Inactive ingredients deionized water, glycerin, hydroxypropyl cellulose, tocopheryl acetate, isopropyl myristate</p>	 <p>1 GAL (3.785 L)</p>	
 <p>0 377807 005041</p>	 <p>MADE IN THE USA</p>	 <p>ASC Aurora Specialty Chemistry</p>

AURORA FRESH GEL 71			
alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77807-005
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 L in 1 L

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	27.77 L in 1 L
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	0.7 L in 1 L
GLYCERIN (UNII: PDC6A3C0OX)	1.39 L in 1 L
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	0.07 L in 1 L
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	0.07 L in 1 L

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77807-005-04	3.785 L in 1 BOTTLE; Type 0: Not a Combination Product	01/13/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	01/13/2021	

Labeler - Aurora Specialty Chemistries (108423153)

Establishment

Name	Address	ID/FEI	Business Operations
Aurora Specialty Chemistries		117783355	manufacture(77807-005)

Revised: 1/2021

Aurora Specialty Chemistries