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 8.4 oz (250 mL) Container

This is a gel hand sanitizer 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 besigns 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

8.4 oz (250 mL) NDC: 77807-005-02

Aurora

Fresh Gel 71

VITAMIN E

HAND SANITIZER

8.4 FL OZ (250 ML)

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0 377807 005027

MADE IN THE USA

ASC Aurora Specialty Chemistries

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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:77807-005-02	0.25 L in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/24/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/24/2021	

Labeler - Aurora Specialty Chemistries (108423153)

Establishment

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

Revised: 3/2021 Aurora Specialty Chemistries