

## **AURORA FRESH EA- alcohol solution**

### **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.*

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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.

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 World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, 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. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold 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)**

Alcohol 80% v/v. Purpose: Antiseptic

### **Purpose**

Antiseptic, Hand Sanitizer

### **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 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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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**

glycerin, hydrogen peroxide, purified water USP

**Package Label - Principal Display Panel**

000 L (000 mL) NDC: 77807-002-00

## Aurora Fresh 80

Alcohol Antiseptic 80%  
Topical Solution

Hand Sanitizer  
Non-sterile Solution

1 L (1000 mL)

NDC: 77807-002-01

Drug Facts	
Active ingredient[s]	Purpose
Alcohol 80% v/v.....	Antiseptic
Use[s]	
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	
<ul style="list-style-type: none"><li>in children less than 2 months of age</li><li>on open skin wounds</li></ul>	
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.	
Directions	
<ul style="list-style-type: none"><li>Place enough product on hands to cover all surfaces. Rub hands together until dry.</li><li>Supervise children under 6 years of age when using this product to avoid swallowing.</li></ul>	
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Inactive ingredients glycerin, hydrogen peroxide, purified water USP	



## AURORA FRESH EA

alcohol solution

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77807-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	80 L in 100 L	
Inactive Ingredients				
Ingredient Name		Strength		
GLYCERIN (UNII: PDC6A3C0OX)		1.45 L in 100 L		
HYDROGEN PEROXIDE (UNII: BBX060AN9V)		0.125 L in 100 L		
WATER (UNII: 059QF0KO0R)		18.425 L in 100 L		
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77807-002-01	1 L in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	05/14/2020	

**Labeler** - Aurora Specialty Chemistries (108423153)

## Establishment

Name	Address	ID/FEI	Business Operations
Aurora Specialty Chemistries		108423153	manufacture(77807-002)

Revised: 5/2020

Aurora Specialty Chemistries