

## **HAND SANITIZER- isopropyl alcohol liquid**

### **Alpha Aromatics**

*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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### **Hand Sanitizer 70% IPA**

This is a hand sanitizer manufactured with:

- a. Isopropyl Alcohol (70%, v/v) in an aqueous solution.
- 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)**

Isopropyl Alcohol 75% 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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### **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**

210890 ml NDC: 75009-070-01

<p>ISOPROPYL ALCOHOL ANTISEPTIC 70%</p> <p>TOPICAL SOLUTION</p> <p>Hand Sanitizer Non-Sterile Solution</p> <p>210.89 L/180 kg</p>	<p><b>Drug Facts</b></p> <table border="1"> <thead> <tr> <th>Active ingredient[s]</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Isopropyl Alcohol 70% (v/v)</td> <td>Antiseptic</td> </tr> </tbody> </table>	Active ingredient[s]	Purpose	Isopropyl Alcohol 70% (v/v)	Antiseptic
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902170 ml NDC: 75009-070-01

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**HAND SANITIZER**

isopropyl alcohol liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:75009-070
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	70 mL in 100 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

**Packaging**

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:75009-070-01	210890 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75009-070-02	902170 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	03/30/2020	

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part333A	03/30/2020	

**Labeler** - Alpha Aromatics (041723545)**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Alpha Aromatics		041723545	manufacture(75009-070)

Revised: 4/2020

Alpha Aromatics