

## **ROOTS AROMATHERAPY- isopropyl alcohol cloth**

### **Vision Chemical Systems**

*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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### **Sanitizing Wipes**

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. Isopropyl Alcohol (75%, 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)**

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**

3282 ml NDC: 76789-030-02



## sanitizing wipes

ISOPROPYL ALCOHOL ANTISEPTIC 75%

TOPICAL SOLUTION • NON-STERILE SOLUTION

3282 mL (111 US/EU FL OZ) 730 WIPES



### Drug Facts

Active Ingredient(s)	Purpose
Isopropyl Alcohol 75% v/v	Antiseptic

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**Inactive Ingredients**  
Glycerin, Hydrogen Peroxide, Purified Water USP

**Questions? 1-888-827-4968**



Distributed by **Hotel Emporium Inc.**  
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 Manufactured by **Vision Chemical Systems Inc.**  
Aurora, CO 80011 • 888-827-4968 • 602-315-7341  
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**Made in the USA**

## ROOTS AROMATHERAPY

isopropyl alcohol cloth

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76789-030
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 mL in 100 mL

### Inactive Ingredients

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76789-030-02	3282 mL in 1 CANISTER; Type 0: Not a Combination Product	12/01/2020	

  

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	12/01/2020	

**Labeler** - Vision Chemical Systems (143308000)

**Registrant** - Vision Chemical Systems (143308000)

**Establishment**

Name	Address	ID/FEI	Business Operations
Vision Chemical Systems		143308000	manufacture(76789-030)

Revised: 1/2022

Vision Chemical Systems