

**HAND SANITIZER- isopropyl alcohol solution**  
**Universal Beauty Products Inc.**

*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. 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**

purified water USP, hydrogen peroxide, glycerin, alcohol

**Package Label - Principal Display Panel**



<p>3400 W. 48th Place Chicago, IL 60632 T. 773.523.7500 F. 773.523.7571</p>	<p><b>Specifications</b></p> <p>Client: UNIVERSAL Date: 04/01/2020 Part no.: PKVHLBL00099 Size: 3.875 x 2.694 in Barcode: 123456789005</p>	<p>Number Colors: 5</p> <ul style="list-style-type: none"> <li>Process Black</li> <li>PANTONE 251 C</li> <li>WHITE</li> <li>PANTONE 265 C</li> <li>PANTONE 186 C</li> </ul>	<p><b>Finishing</b></p> <p>Approved <input type="checkbox"/> Approved w/changes <input type="checkbox"/></p> <p>client signature _____ date _____</p>
	<p>Please check and verify all aspects of this proof and technical spec. With your approval you are assuming responsibility for content, design and specification of this label.</p>		<p>Colors shown are only for color break and are not intended to be an exact representation of color. Please mark any changes or corrections clearly and return with original signed proof.</p>

59 ml NDC: 74169-7559-1

<b>HAND SANITIZER</b>			
isopropyl alcohol solution			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:74169-7559
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>

ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75.6818 mL in 100 mL
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### Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.4544 mL in 100 mL
WATER (UNII: 059QF0KO0R)	22.663 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
ALCOHOL (UNII: 3K9958V90M)	0.0758 mL in 100 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74169-7559-1	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/06/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/06/2020	

**Labeler** - Universal Beauty Products Inc. (948009709)

**Registrant** - Shabbir Haque (948009709)

### Establishment

Name	Address	ID/FEI	Business Operations
Universal Beauty Products Inc.		948009709	manufacture(74169-7559)

Revised: 4/2020

Universal Beauty Products Inc.