

HAND SANITIZER GEL- 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.

SAN-A Hand Sanitizer Gel 75% Isopropyl Alcohol

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, glycerin, hydrogen peroxide, alcohol, polyacrylic acid, aminomethyl propanol, acrylic acid, dichloromethane

Package Label - Principal Display Panel



<p>3400 W. 48th Place Chicago, IL 60632 T. 773.523.7500 F. 773.523.7571</p>	Specifications Client: UNIVERSAL Date: 04/01/2020 Part no.: PKVHBL00098 Size: 3.875 x 2.694 in Bar code: 123456789005 <input type="checkbox"/> dieline does not print <input type="checkbox"/>	Number Colors: 5 <input type="checkbox"/> Process Black <input type="checkbox"/> PANTONE 286 C <input type="checkbox"/> PANTONE 292 C <input type="checkbox"/> WHITE <input type="checkbox"/> PANTONE 186 C	Finishing 1 [Image] 2 [Image] 4 [Image] 3 [Image] X [Image] <input type="checkbox"/> Approved <input type="checkbox"/> Approved w/changes client signature _____ date _____
	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.		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.

59 ml NDC: 74169-7558-1

HAND SANITIZER GEL			
isopropyl alcohol solution			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74169-7558
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75.6818 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ACRYLIC ACID (UNII: J94PBK7X8S)	0.0013 mL in 100 mL
METHYLENE CHLORIDE (UNII: 588X2YUY0A)	0.0003 mL in 100 mL
ALCOHOL (UNII: 3K9958V90M)	0.0758 mL in 100 mL
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.6685 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	3.3 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	19.6524 mL in 100 mL
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	0.495 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74169-7558-1	59 mL in 1 BOTTLE, DISPENSING; 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(74169-7558)

Revised: 4/2020

Universal Beauty Products Inc.