

**HAND SANITIZER- isopropyl alcohol gel**  
**Natural Cosmetic Labs USA, 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.*

-----

**Hand Sanitizer**

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.

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**

- 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**

<p><b>Drug Facts</b></p> <table border="1"> <tr> <th style="text-align: left;">Active Ingredient[s]</th> <th style="text-align: left;">Purpose</th> </tr> <tr> <td>Isopropyl Alcohol 75% w/v.....</td> <td>Antiseptic</td> </tr> </table> <p><b>Use[s]</b> Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.</p> <p><b>Warnings</b> <i>For external use only. Flammable. Keep away from heat and flame</i></p> <p><b>Do not use</b> *in children less than 2 months of age *on open skin wounds</p> <p><b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</p> <p><b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be sign of serious condition.</p> <p><b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b> *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.</p> <p><b>Other information</b> *store between 15-30C (59-86F) *Avoid freezing and excessive heat above 40C (104F)</p> <p><b>Inactive ingredients</b> glycerin, Carbomer, hydrogen peroxide, Aminomethyl Propanol, purified water USP</p> <p><b>Manufactured by NCL</b> Placentia, CA 92870 info@Naturalcosmeticlabs.com</p> <p> <b>Made in U.S.A.</b></p>	Active Ingredient[s]	Purpose	Isopropyl Alcohol 75% w/v.....	Antiseptic	 <h1 style="margin: 0;">HIGH IMPACT</h1> <h2 style="margin: 0;">HAND SANITIZER</h2> <hr style="width: 20%; margin: 10px auto;"/> <p><b>Isopropyl Alcohol Antiseptic 75% Topical Solution Non-sterile Solution</b></p>  <p><b>236 ML</b></p>
Active Ingredient[s]	Purpose				
Isopropyl Alcohol 75% w/v.....	Antiseptic				
659436212282					

236 ml NDC: 75493-092-02

<b>HAND SANITIZER</b>		
isopropyl alcohol gel		
<b>Product Information</b>		
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b> NDC:75493-092
<b>Route of Administration</b>	TOPICAL	
<b>Active Ingredient/Active Moiety</b>		
Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 mL in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
AMINOMETHYL PROPANEDIOL (UNII: CZ7BU4QZJZ)	0.0375 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	
CARBOMER 940 (UNII: 4Q93RCW27E)	0.5 mL in 100 mL

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75493-092-02	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/22/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/22/2020	

**Labeler** - Natural Cosmetic Labs USA, Inc. (066288480)

## Establishment

Name	Address	ID/FEI	Business Operations
Natural Cosmetic Labs USA, Inc.		066288480	manufacture(75493-092)

Revised: 5/2020

Natural Cosmetic Labs USA, Inc.