

**HAND SANITIZER- alcohol gel**  
**Wet Look Janitorial and Gardening Corp.**

*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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**WLJ Hand Sanitizer Gel 70% 4L**

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. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (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)**

Alcohol 70% 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

Propylene glycol, Aminomethyl Propanol, purified water USP, Carbomer

### Package Label - Principal Display Panel

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North America: 1-877-533-5164 Peru Office: 517-834-6261</p>	<table border="1"> <tr> <th colspan="2">Información del Medicamento</th> </tr> <tr> <td>Ingrediente activo(s)</td> <td>Propósito</td> </tr> <tr> <td>Alcohol 70% v/v</td> <td>Antiséptico</td> </tr> <tr> <td colspan="2">Uso(s)</td> </tr> <tr> <td colspan="2">Desinfectante de manos para ayudar a reducir las bacterias que potencialmente pueden causar enfermedades. Para usar cuando no hay agua y jabón disponibles.</td> </tr> <tr> <td colspan="2">Advertencias</td> </tr> <tr> <td colspan="2">Sólo para uso externo. Inflamable. Mantener alejado del calor o las flamas.</td> </tr> <tr> <td colspan="2">No utilizar</td> </tr> <tr> <td colspan="2">• en niños menores de 2 meses de edad</td> </tr> <tr> <td colspan="2">• en heridas abiertas o de la piel</td> </tr> <tr> <td colspan="2">Cuando use este producto, evítelo fuera de los ojos, oídos y boca. 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4 L NDC: 79095-003

HAND SANITIZER			
alcohol gel			
Product Information			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:79095-003
<b>Route of Administration</b>	TOPICAL		

<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>			<b>Basis of Strength</b>	<b>Strength</b>
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)			ALCOHOL	2.8 L in 4 L
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			0.08 L in 4 L	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)			0.008 L in 4 L	
WATER (UNII: 059QF0K00R)			1.108 L in 4 L	
CARBOMER 940 (UNII: 4Q93RCW27E)			0.0024 L in 4 L	
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79095-003-01	4 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/22/2020	
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	06/22/2020		

**Labeler** - Wet Look Janitorial and Gardening Corp. (204175181)

**Registrant** - Wet Look Janitorial and Gardening Corp. (204175181)

### **Establishment**

Name	Address	ID/FEI	Business Operations
Soluciones Cosméticas, S.A. de C.V.		814818001	manufacture(79095-003)

Revised: 6/2020

Wet Look Janitorial and Gardening Corp.