

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.

WLJ Hand Sanitizer Gel 70% 1L

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.

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

Propylene glycol, Aminomethyl Propanol, purified water USP, Carbomer

Package Label - Principal Display Panel

<table border="1"> <tr> <th colspan="2">Data Facts</th> </tr> <tr> <th>Active Ingredient (s)</th> <th>Purpose</th> </tr> <tr> <td>Antiseptic</td> <td>Antiseptic</td> </tr> <tr> <th colspan="2">Uses</th> </tr> <tr> <td colspan="2">Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.</td> </tr> <tr> <th colspan="2">Warnings</th> </tr> <tr> <td colspan="2">For external use only. Flammable. Keep away from heat or flame.</td> </tr> <tr> <th colspan="2">Do not use</th> </tr> <tr> <td colspan="2">• In children less than 2 months of age</td> </tr> <tr> <td colspan="2">• On open skin wounds</td> </tr> <tr> <td colspan="2">When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</td> </tr> <tr> <td colspan="2">Stop use and ask a doctor if irritation or rash occurs. There may be signs of a serious condition.</td> </tr> <tr> <td colspan="2">Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</td> </tr> <tr> <th colspan="2">Directions</th> </tr> <tr> <td colspan="2">• Place enough product on hands to cover all surfaces. Rub hands together until dry.</td> </tr> <tr> <td colspan="2">• Supervise children under 6 years of age when using this product to avoid swallowing.</td> </tr> <tr> <th colspan="2">Other information</th> </tr> <tr> <td colspan="2">Store between 15-30C (59-86F)</td> </tr> <tr> <td colspan="2">• Avoid freezing and excessive heat above 40C (104F)</td> </tr> <tr> <td colspan="2">Inactive Ingredients: Carbomer, Propylene Glycol, Aminomethyl propanol, Distilled</td> </tr> </table>	Data Facts		Active Ingredient (s)	Purpose	Antiseptic	Antiseptic	Uses		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. There 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: Carbomer, Propylene Glycol, Aminomethyl propanol, Distilled		 <p>HAND SANITIZER GEL Alcohol 70% v/v</p> <p>A Division of Wet Look Janitorial & Gardening Corp. North America: 1-877-322-5104 Panama Office: 517-838-8281</p>	<table border="1"> <tr> <th colspan="2">Información del medicamento</th> </tr> <tr> <th>Ingredientes activos (s)</th> <th>Propósito</th> </tr> <tr> <td>Alcohol 70% v/v</td> <td>Antiséptico</td> </tr> <tr> <th colspan="2">Usos</th> </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> <th colspan="2">Advertencias</th> </tr> <tr> <td colspan="2">Solo para uso externo. Inflamable. Mantener alejado del calor o las flamas.</td> </tr> <tr> <th colspan="2">No utilizar</th> </tr> <tr> <td colspan="2">• en niños menores de 2 meses de edad</td> </tr> <tr> <td colspan="2">• en heridas abiertas de la piel</td> </tr> <tr> <td colspan="2">Cuando use este producto, manténgalo fuera de los ojos, oídos y boca. En caso de contacto con los ojos, enjuague bien los ojos con agua.</td> </tr> <tr> <td colspan="2">Suspenda su uso y consulte a un médico si se produce irritación o sarpullido. Estos pueden ser signos de una reacción grave.</td> </tr> <tr> <td colspan="2">Mantener fuera del alcance de los niños. En caso de ingestión, obtenga ayuda médica o comuníquese con un Centro de Control de Envenenamiento de inmediato.</td> </tr> <tr> <th colspan="2">Direcciones</th> </tr> <tr> <td colspan="2">• Coloque suficiente producto en las manos para cubrir todas las superficies. Frotae las manos juntas hasta que se sequen.</td> </tr> <tr> <td colspan="2">• Supervise a los niños menores de 6 años cuando use este producto para evitar que se lo traguen.</td> </tr> <tr> <th colspan="2">Otra información</th> </tr> <tr> <td colspan="2">Almacenar entre 15-30C (59-86F)</td> </tr> <tr> <td colspan="2">• Evite la congelación y el calor excesivo por encima de 40C (104F)</td> </tr> <tr> <td colspan="2">Ingredientes Inactivos: Carbómero, propilenglicol, aminomilopropanol, agua destilada.</td> </tr> </table>	Información del medicamento		Ingredientes activos (s)	Propósito	Alcohol 70% v/v	Antiséptico	Usos		Desinfectante de manos para ayudar a reducir las bacterias que potencialmente pueden causar enfermedades. Para usar cuando no hay agua y jabón disponibles.		Advertencias		Solo para uso externo. Inflamable. Mantener alejado del calor o las flamas.		No utilizar		• en niños menores de 2 meses de edad		• en heridas abiertas de la piel		Cuando use este producto, manténgalo fuera de los ojos, oídos y boca. En caso de contacto con los ojos, enjuague bien los ojos con agua.		Suspenda su uso y consulte a un médico si se produce irritación o sarpullido. Estos pueden ser signos de una reacción grave.		Mantener fuera del alcance de los niños. En caso de ingestión, obtenga ayuda médica o comuníquese con un Centro de Control de Envenenamiento de inmediato.		Direcciones		• Coloque suficiente producto en las manos para cubrir todas las superficies. Frotae las manos juntas hasta que se sequen.		• Supervise a los niños menores de 6 años cuando use este producto para evitar que se lo traguen.		Otra información		Almacenar entre 15-30C (59-86F)		• Evite la congelación y el calor excesivo por encima de 40C (104F)		Ingredientes Inactivos: Carbómero, propilenglicol, aminomilopropanol, agua destilada.	
Data Facts																																																																																		
Active Ingredient (s)	Purpose																																																																																	
Antiseptic	Antiseptic																																																																																	
Uses																																																																																		
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. There 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: Carbomer, Propylene Glycol, Aminomethyl propanol, Distilled																																																																																		
Información del medicamento																																																																																		
Ingredientes activos (s)	Propósito																																																																																	
Alcohol 70% v/v	Antiséptico																																																																																	
Usos																																																																																		
Desinfectante de manos para ayudar a reducir las bacterias que potencialmente pueden causar enfermedades. Para usar cuando no hay agua y jabón disponibles.																																																																																		
Advertencias																																																																																		
Solo para uso externo. Inflamable. Mantener alejado del calor o las flamas.																																																																																		
No utilizar																																																																																		
• en niños menores de 2 meses de edad																																																																																		
• en heridas abiertas de la piel																																																																																		
Cuando use este producto, manténgalo fuera de los ojos, oídos y boca. En caso de contacto con los ojos, enjuague bien los ojos con agua.																																																																																		
Suspenda su uso y consulte a un médico si se produce irritación o sarpullido. Estos pueden ser signos de una reacción grave.																																																																																		
Mantener fuera del alcance de los niños. En caso de ingestión, obtenga ayuda médica o comuníquese con un Centro de Control de Envenenamiento de inmediato.																																																																																		
Direcciones																																																																																		
• Coloque suficiente producto en las manos para cubrir todas las superficies. Frotae las manos juntas hasta que se sequen.																																																																																		
• Supervise a los niños menores de 6 años cuando use este producto para evitar que se lo traguen.																																																																																		
Otra información																																																																																		
Almacenar entre 15-30C (59-86F)																																																																																		
• Evite la congelación y el calor excesivo por encima de 40C (104F)																																																																																		
Ingredientes Inactivos: Carbómero, propilenglicol, aminomilopropanol, agua destilada.																																																																																		
<p>Distributed By: WLU Distribution (A Division of Wet Look Janitorial & Gardening Corp.) Made in Mexico</p> <p>FOR EXTERNAL USE ONLY. AVOID CONTACT WITH EYES. IF CONTACT OCCURS, FLUSH EYES WITH WATER. KEEP OUT OF THE REACH OF CHILDREN.</p> <p>Lot #01 _____ Expiry Date _____</p>  <p>NLJ-79095G-S1000</p>	<p>Kills 99.9% of Germs/Bacteria Mata el 99.9% de Gérmenes / Bacterias 1 Litre</p>	<p>Distributed By: WLU Distribution (A Division of Wet Look Janitorial & Gardening Corp.) Made in Mexico</p> <p>SÓLO PARA USO EXTERNO. EVITAR CONTACTO VISUAL. EN CASO DE CONTACTO,</p>  <p>SOLD BY / Vendido por: WLU DISTRIBUTION A Division of Wet Look Janitorial & Gardening Corp. North America: 1-877-322-5104 Panama Office: 517-838-8281</p>																																																																																

1 L NDC: 79095-000

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79095-000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 L in 1 L

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.02 L in 1 L
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.002 L in 1 L
WATER (UNII: 059QF0KO0R)	0.277 L in 1 L
CARBOMER 940 (UNII: 4Q93RCW27E)	0.0006 L in 1 L

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79095-000-01	1 L in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	06/22/2020	

Marketing Information

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(79095-000)

Revised: 6/2020

Wet Look Janitorial and Gardening Corp.