

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% 236 mL

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> <td>Active ingredient(s)</td> <td>Propolis</td> </tr> <tr> <td>Antibiotic(s)</td> <td>Antibiotics</td> </tr> <tr> <td colspan="2">Use(s)</td> </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> <td colspan="2">Warnings</td> </tr> <tr> <td colspan="2">For external use only. Flammable. Keep away from heat or flame.</td> </tr> <tr> <td colspan="2">Do not use</td> </tr> <tr> <td colspan="2">• In children less than 2 months of age</td> </tr> <tr> <td colspan="2">• For 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> <td colspan="2">Directions</td> </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> <td colspan="2">Other Information</td> </tr> <tr> <td colspan="2">Store between 25-30C (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, Antimonomyl propenol, Purified</td> </tr> </table>	Data Facts		Active ingredient(s)	Propolis	Antibiotic(s)	Antibiotics	Use(s)		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		• For 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 25-30C (59-86F)		• Avoid freezing and excessive heat above 40C (104F)		Inactive ingredients: Carbomer, Propylene Glycol, Antimonomyl propenol, Purified		 <p>HAND SANITIZER GEL Alcohol 70% v/v</p>	<table border="1"> <tr> <th colspan="2">Información del Medicamento</th> </tr> <tr> <td>Ingredientes activos(s)</td> <td>Propópolo</td> </tr> <tr> <td>Antibiótico(s)</td> <td>Antibióticos</td> </tr> <tr> <td colspan="2">Uso(s)</td> </tr> <tr> <td colspan="2">Desinfectante de manos para reducir y reducir las bacterias que potencialmente pueden causar enfermedades. Para usar cuando no hay agua ni jabón disponible.</td> </tr> <tr> <td colspan="2">Advertencias</td> </tr> <tr> <td colspan="2">• Evitar uso en niños. Inflamable. Mantener alejado del calor o las llamas.</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 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 erupción. Estas pueden ser signos de una afección seria.</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> <td colspan="2">Direcciones</td> </tr> <tr> <td colspan="2">• Coloque suficiente producto en las manos para cubrir todas las superficies. Frote 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> <td colspan="2">Otra información</td> </tr> <tr> <td colspan="2">Almacene entre 25-30C (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, etilmonomilpropenol, agua destilada.</td> </tr> </table>	Información del Medicamento		Ingredientes activos(s)	Propópolo	Antibiótico(s)	Antibióticos	Uso(s)		Desinfectante de manos para reducir y reducir las bacterias que potencialmente pueden causar enfermedades. Para usar cuando no hay agua ni jabón disponible.		Advertencias		• Evitar uso en niños. Inflamable. Mantener alejado del calor o las llamas.		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 erupción. Estas pueden ser signos de una afección seria.		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. Frote 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		Almacene entre 25-30C (59-86F)		• Evite la congelación y el calor excesivo por encima de 40C (104F)		Ingredientes Inactivos: Carbómero, propilenglicol, etilmonomilpropenol, agua destilada.	
Data Facts																																																																																		
Active ingredient(s)	Propolis																																																																																	
Antibiotic(s)	Antibiotics																																																																																	
Use(s)																																																																																		
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																																																																																		
• For 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 25-30C (59-86F)																																																																																		
• Avoid freezing and excessive heat above 40C (104F)																																																																																		
Inactive ingredients: Carbomer, Propylene Glycol, Antimonomyl propenol, Purified																																																																																		
Información del Medicamento																																																																																		
Ingredientes activos(s)	Propópolo																																																																																	
Antibiótico(s)	Antibióticos																																																																																	
Uso(s)																																																																																		
Desinfectante de manos para reducir y reducir las bacterias que potencialmente pueden causar enfermedades. Para usar cuando no hay agua ni jabón disponible.																																																																																		
Advertencias																																																																																		
• Evitar uso en niños. Inflamable. Mantener alejado del calor o las llamas.																																																																																		
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 erupción. Estas pueden ser signos de una afección seria.																																																																																		
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. Frote 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																																																																																		
Almacene entre 25-30C (59-86F)																																																																																		
• Evite la congelación y el calor excesivo por encima de 40C (104F)																																																																																		
Ingredientes Inactivos: Carbómero, propilenglicol, etilmonomilpropenol, agua destilada.																																																																																		
<p>Distributed by: NU Distributor (A Division of Wal-Lock, Antimonomyl & Gardening Corp.) Made in Mexico</p>	<p>A Division of Wal-Lock, Antimonomyl & Gardening Corp. North America: 1-877-325-5154 Panama Office: 507-884-4262</p>	<p>Distributed by: NU Distributor (A Division of Wal-Lock, Antimonomyl & 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>Kills 99.9% of Germs/Bacteria Mata el 99.9% de Gérmenes / Bacterias</p> <p>236 mL</p>	<p>SÓLO PARA USO EXTERNO. EVITE CONTACTO VISUAL. EN CASO DE CONTACTO, ENJUAGUE BIEN LOS OJOS CON AGUA.</p>  <p>236 mL Available per: NU DISTRIBUTION A Division of Wal-Lock, Antimonomyl & Gardening Corp. North America: 1-877-325-5154 Panama Office: 507-884-4262</p>																																																																																
<p>Lot No. _____ Expiry Date: _____</p>  <p>NLJ=79095-3236</p>																																																																																		

236 mL NDC: 79095-004

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79095-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	165.2 mL in 236 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	4.72 mL in 236 mL
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.47 mL in 236 mL
WATER (UNII: 059QF0K00R)	65.47 mL in 236 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.14 mL in 236 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79095-004-01	236 mL 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(79095-004)

Revised: 6/2020

Wet Look Janitorial and Gardening Corp.