

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% 500 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

Data Facts	Información del Medicamento								
<table border="1"> <thead> <tr> <th>Active ingredient (s)</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Alcohol 70% v/v</td> <td>Antiséptico</td> </tr> </tbody> </table> <p>Usage Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.</p> <p>Warnings For external use only. Flammable. Keep away from heat or flame.</p> <p>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.</p> <p>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.</p> <p>Directions • Apply 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>Other Information Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)</p> <p>Inactive Ingredients Carbomer, Propylene Glycol, Aminomethyl propanol, Purified Water</p>	Active ingredient (s)	Purpose	Alcohol 70% v/v	Antiséptico	<table border="1"> <thead> <tr> <th>Ingrediente activo (s)</th> <th>Propósito</th> </tr> </thead> <tbody> <tr> <td>Alcohol 70% v/v</td> <td>Antiséptico</td> </tr> </tbody> </table> <p>Usos Desinfectante de manos para ayudar a reducir las bacterias que potencialmente pueden causar enfermedades. Para usar cuando no hay agua a grifo disponible.</p> <p>Advertencias Solo para uso externo. Inflamable. Manténgase alejado del calor o las flamas.</p> <p>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.</p> <p>Deje de usar y consulte a un médico si se produce irritación o erupción. Deje de usar si aparecen signos de una afección grave. Manténgase fuera del alcance de los niños. En caso de ingestión, obtenga ayuda médica o comuníquese con un Centro de Control de Envenenamiento de inmediato.</p> <p>Indicaciones • Coloque suficiente producto en las manos para cubrir todas las superficies. Frótese 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.</p> <p>Otra información Almacenar entre 15-30C (59-86F) • Evite la congelación y el calor excesivo por arriba de 40C (104F)</p> <p>Ingredientes Inactivos Carbomer, propilenglicol, amilo metilpropanol, agua destilada.</p>	Ingrediente activo (s)	Propósito	Alcohol 70% v/v	Antiséptico
Active ingredient (s)	Purpose								
Alcohol 70% v/v	Antiséptico								
Ingrediente activo (s)	Propósito								
Alcohol 70% v/v	Antiséptico								
<p>Distributed By: WJ Distribution (A Division of Wet Look, Lestoriel & Gardening Corp.) Made in Mexico</p> <p>FOR EXTERNAL USE ONLY. AVOID CONTACT WITH EYES. IN CASE OF CONTACT, FLUSH EYES WITH WATER. KEEP OUT OF THE REACH OF CHILDREN.</p> <p>Lot NO# _____ Expiry Date _____</p> <p> HLJ-79095-001</p>	<p>A Division of Wet Look, Lestoriel & Gardening Corp. North America: 1-877-203-5104 Panama Office: 507-436-6300</p> <p>Kills 99.9% of Germs/Bacteria Mata el 99.9% de Gérmenes / Bacterias</p> <p>500 mL</p> <p></p> <p>SOLD BY / Vendido por: WJ DISTRIBUTION A Division of Wet Look, Lestoriel & Gardening Corp. North America: 1-877-203-5104 Panama Office: 507-436-6300</p>								

500 mL NDC: 79095-001

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79095-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	350 mL in 500 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	10 mL in 500 mL
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	1 mL in 500 mL
WATER (UNII: 059QF0K00R)	138.7 mL in 500 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.3 mL in 500 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79095-001-01	500 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(79095-001)

Revised: 6/2020

Wet Look Janitorial and Gardening Corp.