

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% 1000 L

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

	Lot #..... Expiry Date..... 	Volumen del producto 1,000 lts. Product Volume 1,000 lts. 
	HEAD OFFICE: TOLL FREE 1-877-432-1540 PANAMA OFFICE: 507-836-6261	
Drug Facts. Información del Medicamento. Faits sur les drogues		
Active Ingredients. Ingredientes activos. Ingrédients actifs Alcohol, Alcohol 70% v / v		Purpose. Propósito. Objectif Antiseptic. Antiséptico. Antiseptique
Use [d] Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.		
Uso [d] Desinfectante de manos para ayudar a reducir las bacterias que potencialmente pueden causar enfermedades. Para usar cuando no hay agua y jabón disponibles.		
Utilisez [d] Désinfectant pour les mains pour aider à réduire les bactéries qui peuvent potentiellement causer des maladies. À utiliser lorsque le savon et l'eau ne sont pas disponibles.		
Warnings For external use only. Flammable. Keep away from heat or flame.		
Advertencias Sólo para uso externo. Inflamable. Mantener alejado del calor o las llamas.		
Avertissements Pour usage externe uniquement. Inflammable. Tenir éloigné de la chaleur ou des flammes		
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.		
No utilize • 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.		
Ne pas utiliser • chez les enfants de moins de 2 mois • sur des plaies cutanées ouvertes Lorsque vous utilisez ce produit, gardez hors des yeux, des oreilles et de la bouche. En cas de contact avec les yeux, rincez abondamment les yeux à l'eau.		
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. Suspenda su uso y consulte a un médico si se produce irritación o sarpullido. Estos pueden ser signos de una afección grave. Mantener fuera del alcance de los niños. En caso de ingestión, obtenga ayuda médica o comuníquese con un Centro de Control de Eventos de Inmediato. Arrêtez l'utilisation et demandez à un médecin si une irritation ou une éruption cutanée se produit. Ceux-ci peuvent être des signes d'une maladie grave. Tenir hors de portée des enfants. En cas d'ingestion, consultez un médecin ou contactez immédiatement un centre antipoison.		
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.		
Direcciones • Coloque suficiente producto en las manos para cubrir todas las superficies. Frotar 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.		
Instructions • Placez suffisamment de produit sur les mains pour couvrir toutes les surfaces. Frottez-vous les mains jusqu'à ce qu'elles soient sèches. • Surveillez les enfants de moins de 6 ans lors de l'utilisation de ce produit pour éviter d'avaler.		
Other information Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)		
Otra información Almacenar entre 15-30C (59-86F) • Evite la congelación y el calor excesivo por encima de 40C (104F)		
Les autres informations Conserver entre 15-30C (59-86F) • Évitez le gel et la chaleur excessive au-dessus de 40C (104F)		
Inactive ingredients: Carbomer, Propylene Glycol, Aminomethyl propanol, Distilled. Ingredientes inactivos: Carbómero, propilenglicol, aminometilpropanol, agua destilada. Ingrédients inactifs: carboxymère, propylène glycol, aminométhylpropanol, distillé		
Distributed By: WLI Distribution (A Division of Wet Look Janitorial & Gardening Corp.) Made in Mexico		

1000 L NDC: 79095-006

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79095-006
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	700 L in 1000 L

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	20 L in 1000 L
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	2 L in 1000 L
WATER (UNII: 059QF0K00R)	277.4 L in 1000 L
CARBOMER 940 (UNII: 4Q93RCW27E)	0.6 L in 1000 L

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79095-006-01	1000 L in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; 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(79095-006)

Revised: 6/2020

Wet Look Janitorial and Gardening Corp.