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% 60 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.

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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



60 mL NDC: 79095-005

HAND SANITIZER alcohol gel Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:79095-005 Route of Administration TOPICAL Active Ingredient/Active Moiety

	Ingredient Name	Basis of Strength	Strength
ı	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	42 mL in 60 mL

Inactive Ingredients			
Ingredient Name	Strength		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	1.2 mL in 60 mL		
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.12 mL in 60 mL		
WATER (UNII: 059QF0KO0R)	16.65 mL in 60 mL		
CARBOMER 940 (UNII: 4Q93RCW27E)	0.036 mL in 60 mL		

ı	P	Packaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:79095-005- 01	$60\ mL$ 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)

$\pmb{Registrant - } \ \ \text{Wet Look Janitorial and Gardening Corp. (204175181)}$

Establishment			
Name	Address	ID/FEI	Business Operations
Soluciones Cosméticas, S.A. de C.V.		814818001	manufacture(79095-005)

Revised: 6/2020 Wet Look Janitorial and Gardening Corp.