### HAND SANITIZER- alcohol gel Laavo Clean S.A. de C.V.

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.

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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 80% 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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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**

glycerin, hydrogen peroxide, purified water USP

# **Package Label - Principal Display Panel**

125 mL NDC: 80806-420-04



LAAVOĞIFAN

LAAVOCLEAN SANITIZING GEL is an alcohol-based hand sanitizer, without the need of immediate rinse. It is recommended for sanitizing hands after the washing stage, leaving a pleasant fragrance\*.

Eliminates 99.9% of bacteria in a period of 30 seconds. It contains moisturizing ingredients for the skin that make it safe for daily use.

SUGGESTED USE. Direct use

#### CAUTIONS AND SAFETY MEASURES

Avoid eye contact. Does not cause violent reactions when mixed, but it is recommended to avoid any contact with other substances that could affect its chemical performance.

In case of eye contact, rinse thoroughly with cold water for 15 minutes. In case of ingestion do not induce vomiting, drink milk or water and seek medical advice immediately. Do not leave uncovered or near a source of heat or spark.

#### Ingredients:

Ethyl Alcohol , Polymer Acrylic ,Hydrogen Peroxide, Glycerin, Triethanolamine, Water.

Atención al consumidor escribenos

Consumer attention line

www.lavoclean.com.

### Telefonos Oficinas. 8122357077 / 8118710086

Made in Mexico , Laavo Clean SA de CV. RFC. LCL2007243Z1, Calle Elias Flores Sur No. 300-A Colonia Centro, CP 66600, Apodaca, Nuevo Leon. Fecha de Caducidad y Numero de Lote Impresos en el Envase / Expiration Date and Batch Number Printed on the Container.







### HAND SANITIZER

alcohol gel

### **Product Information**

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:80806-420

Route of Administration TOPICAL

## **Active Ingredient/Active Moiety**

Active ingredicity		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients				
Ingredient Name	Strength			
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL			
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL			
WATER (UNII: 059QF0KO0R)				

F	Packaging					
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>		
1	NDC:80806-420-04	125 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333A	03/30/2020			

# Labeler - Laavo Clean S.A. de C.V. (951584872)

Establishment				
Name	Address	ID/FEI	Business Operations	
Laavo Clean S.A. de C.V.		951584872	manufacture(80806-420)	

Revised: 11/2020 Laavo Clean S.A. de C.V.