#### 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.

-----

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.

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

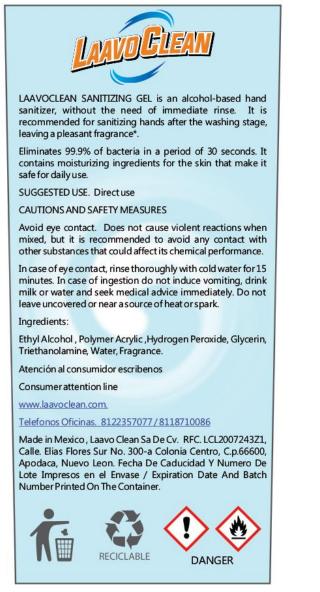
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

## **Inactive ingredients**

glycerin, hydrogen peroxide, purified water USP

# Package Label - Principal Display Panel

60 mL NDC: 80806-421-11





# HAND SANITIZER

alcohol gel									
Product Informa	tion								
Product T ype		HUMAN OTC DRUG Item Code (Sourc			e) NDC:80806-421				
Route of Administra	ition	TOPICAL							
Active Ingredient/Active Moiety									
Ingredient Name				<b>Basis of Strength</b>		strength			
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)				ALCOHOL		80 mL in 100 mL			
Inactive Ingredie	ents								
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)									
Packaging									
# Item Code		Package Description	ľ	Marketing Start Date		Marketing End Date			
<b>1</b> NDC:80806-421-11	DC:80806-421-11 60 mL in 1 BOTTLE; Type 0: Not a Combination Product 03/30/		3/30/2020	30/2020					
Marketing Information									
Marketing Catego		ion Number or Monograph C	itation	Marketin	g Start Date	Marketing End Date			
OTC monograph not fi	nal part333A		C	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(80806-421)						

Revised: 11/2020

Laavo Clean S.A. de C.V.