## HAND SANITIZER- hand sanitizer solution 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:

- 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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# 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

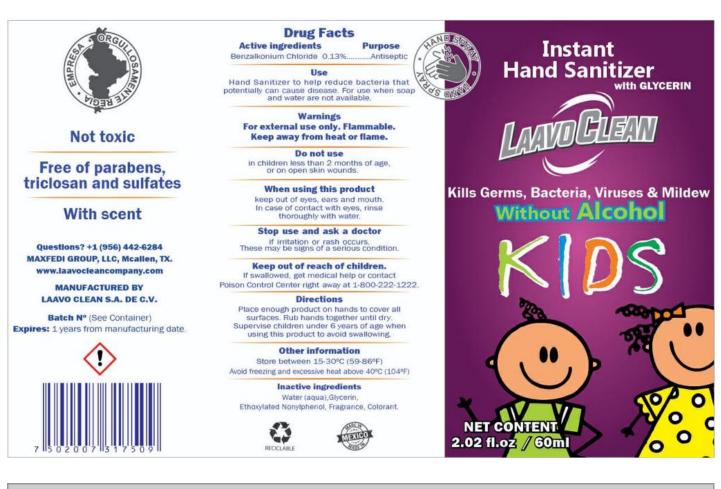
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

## Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

# Package Label - Principal Display Panel

60 mL NDC: 80806-510-01



HAND SANITIZEF
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hand sanitizer solution

Product Information								
Product Type	HUMAN OTC DRUG	ltem Code (Source)		NDC:	NDC:80806-510			
Route of Administration	TOPICAL							
Active Ingredient/Active Moiety								
Ingredient Name Basis o				Strength	Strength			
			BENZALKO CHLORIDE	NIUM	0.13 g in 100 mL			
Inactive Ingredients								
In	gredient Name			Str	ength			
GLYCERIN (UNII: PDC6A3C0OX)			1	4 mL in 10	0 mL			
POLYETHYLENE GLYCOL 10000	(UNII: H57W405143)		C	).4 mL in 10	0 mL			
WATER (UNII: 059QF0KO0R)								
Packaging								
	ckage Description	Mark	ceting Sta Date	art Mai	keting End Date			

	60 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	<b>Business Operations</b>					
Laavo Clean S.A. de C.V.		951584872	manufacture(80806-510)					

Revised: 1/2022

Laavo Clean S.A. de C.V.