

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

500 mL NDC: 80806-420-02

LAAVO CLEAN

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.laavoclean.com, Tel. 8123078182

Made in Mexico. LAAVO CLEAN SA DE CV. RFC. LCL2007243Z1, CALLE. ELIAS FLORES SUR No. 300-A COLONIA CENTRO, C.P.66600, APODACA, NUEVO LEON.
FECHA DE CADUCIDAD Y NUMERO DE LOTE IMPRESOS EN EL ENVASE.
EXPIRATION DATE AND BATCH NUMBER PRINTED ON THE CONTAINER.

80% ALCOHOL

LAAVO CLEAN

Hand Sanitizer
Gel Antibacterial
para Manos sin aroma

99.9% Kills Germs Viruses & Mildew
Mata germenes, Virus y Hongos

¡The Best Formula!

Libre de Triclosán y Parabenos

CONT. NET. 500ml
NET.WT. 16.90oz

RECYCLABLE

DANGER

210982051238579

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80806-420
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80806-420-02	500 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: 10/2020

Laavo Clean S.A. de C.V.