

HAND SANITIZER- alcohol liquid
Bebidas, Sabores y Aguas, 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.

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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

Maximum 1000000000 mL in 1 CONTAINER (78460-400-02)



HAND SANITIZER

ANTISEPTIC

CITRUS

FREE: ·TRICLOSAN
·PARABENS
·BENZALKONIUM CHLORIDE
·METHYLISOTHIAZOLINONE

Drug Facts	
Active Ingredients	Purpose
Ethyl alcohol (70% v/v)	Antiseptic
Uses ■ to help reduce bacteria on the skin.	
Warnings For external use only. Flammable. Keep away from fire or flame.	
When using this product do not use on damaged or broken skin. Do not leave near fire. Wash with enough water, if it gets into eyes. Do not drink.	
Stop use and ask a doctor if skin irritation or redness develops.	
Keep out of reach of children. In case of accidental ingestion, get medical help or contact Poison Control Center immediately.	
Directions ■ apply enough gel to wet hands and rub together until dry. Use 1 to 3 times daily.	
Other information ■ store below 73.4°F (23°C).	
Inactive Ingredients: Water, carbomer, triethanolamine, glycerin, aloe barbadensis (aloe vera) extract, propylene glycol, citrus nobilis(mandarin) essential oil, citrus tangerina (tangerine) essential oil, citrus aurantifolia (mexican lime) essentialoil, citrus grandis (grapefruit) essential oil, benzoic acid, FD&C Yellow No. 6	
Questions, Comments ■ Call 956-943-7121	

DUNS Number:
951578537



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Distributed by: VIDANOS
EASY CLEANING RENTALS
LLC 1211 SAN DARIO AVE
M-433 LAREDO, TX 78040.
Made in México by:
Bebidas y Sabores, SA de CV

33.8 fl oz
e1L

1000 mL NDC: 78460-400-02

HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78460-400
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78460-400-02	1000 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 - Bebidas, Sabores y Aguas, S.A. de C.V. (951578537)**Registrant** - Bebidas, Sabores y Aguas, S.A. de C.V. (951578537)**Establishment**

Name	Address	ID/FEI	Business Operations
Bebidas, Sabores y Aguas, S.A. de C.V.		951578537	manufacture(78460-400)

Revised: 12/2020

Bebidas, Sabores y Aguas, S.A. de C.V.