

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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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

Maximum 1000000000 mL in 1 CONTAINER (78460-100-13)

PROYECTO
HAND SANITIZER 1L

Fecha: 16.Junio.2020

254 mm

180 mm

Drug Facts

Active Ingredient.....Purpose
 Ethyl Alcohol 75%.....Antiseptic

Uses

- Hand sanitizer to help reduce bacteria on the skin

Warnings
Flammable. Keep away from fire or flame.

For external use only.

When using this product do not use in or near the eyes. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and consult with a doctor if irritation and rash develop and persist.

Keep out of reach of children. If swallowed, get medical help promptly

Other Information
 -Store below 110F (43 C). May discolor certain fabrics or surfaces.

Directions

- Put enough product in your palm to cover hands and rub hands together thoroughly until dry.
- Children under 12 years of age should be supervised when using.

Inactive ingredients: Purified water, Carbomer (polymer crosslinked), Alcohol, Propylene Glycol, Glycerin, Tocopheryl Acetate (Vitamin E), Triethanolamine, Fragrance, Isothiazolinone.

mymelabs

MOISTURIZING
HAND SANITIZER

75% ALCOHOL

Keeps your hands perfectly moisturized!

with **Vitamin E**

Net Content: 33.3oz / 1 Liter

DUNS No. 951578537
 Made in Mexico

6 47166 46749 2

Distributed by: MyMe, Inc.
 Miami, Fl 33172
 www.mymelabs.com

DATOS

Tintas / TD

Material
 Couche Satin

Medida
 180 x 254 mm

Acabado
 Barniz UV

FLEXOGRAFÍA

INFORMACIÓN

TIPO DE SALIDA

CENTRO DEL ROLLO: 3"

NOTA IMPORTANTE:
 ESPERANDO QUE ESTA PRUEBA ES SOLO PARA LA APROBACION DE TRABAJO DE LA ETIQUETA, DESER, POSICION DE ELEMENTOS Y CORRECCIONES PROGRAMADAS. LA IMPRESION DE ESTA PRUEBA ESTA HECHA EN INYECCION DE TINTA POR LO QUE NO ES MUY BUENA PARA LA REPRESENTACION DE COLORES. PARA EN SU CASO QUERE REALIZAR DE ESTE TIPO DE PRUEBA CONSULTAR CON SU PAGINA PANTONE. POR FAVOR REVISAR CUIDADOSAMENTE E INDICAR EN ESTA HOJA CUALQUIER ERROR QUE ENCUENTRE.

APROBACIÓN

Firma del Vo. Bo. _____

Nombre y Firma del Vo. Bo. _____

Corrección: 0001 FDI-015

1000 mL NDC: 78460-100-13

HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78460-100
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)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78460-100-13	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(78460-100)

Revised: 7/2020

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