

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

1000000 mL in 1 CONTAINER (78460-100-06)

PROYECTO ▾

VERIO GEL
8oz (236ml)

Fecha: 16.Junio.2020

130 mm

100 mm

DRUG FACTS	
Active Ingredient(s) Alcohol 70% v/v.	Purpose Antiseptic
Use(s) 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 mix use with other household chemicals.	
Do not use - On children less than two 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 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 age when using this product to avoid swallowing.	
Other information - Store between 15-30C (58-86F) - Avoid freezing and excessive heat above 40C (104F)	
Inactive ingredients Distilled water (Aqua), Carbomer, Propylene Glycol, AMP-Ultra	

ALCOHOL ANTISEPTIC TOPICAL SOLUTION

Antiseptic Hand Rub Non-sterile Solution

Instant cleaning for hands

8 FL OZ (236 mL)

70% Alcohol

Alcohol Antiseptic Topical Solution

Use VERIO Alcohol Antiseptic Topical Solution to take care of your family as its formula aids to eliminate germs and prevent diseases. No rinsing required.

Manufactured By:
Tier 1 Formulations
Dallas, TX

DUNS No. 951578537

7 503027 952572

RUBBING HANDS WITH GEL HELPS KILL GERMS AND PREVENT DISEASES

DATOS

- Tintas / TD
C M Y K
- Medida
100 x 130 mm

FLEXOGRAFÍA

- Material
Couche Satin Autoadherible
- Acabado
Barniz UV

INFORMACIÓN



TIPO DE SALIDA



CENTRO DEL ROLLO: 3"

NOTA IMPORTANTE: ESTA PRUEBA ES SOLO PARA LA APROBACIÓN DE TAMAÑO DE LA ETIQUETA, DISEÑO, POSICIÓN DE ELEMENTOS Y CORRECCIONES TIPOGRÁFICAS. LA IMPRESIÓN DE ESTA PRUEBA ESTA HECHA EN INYECCIÓN DE TINTA POR LO QUE NO ES VALIDA PARA LA AUTORIZACIÓN DE COLORES. PARA VER LOS COLORES REALES DE LA ETIQUETA DEBERÁ CONSULTAR CON UNA GUÍA PANTONE. POR FAVOR REVISE CUIDADOSAMENTE E INDIQUE EN ESTA HOJA CUALQUIER ERROR QUE ENCUENTRE.

APROBACIÓN

Firma del Vo. Bo.

Nombre y Firma del Vo. Bo.

Corrección: 0001

FDI-015

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78460-100-06	236 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.