

HAND SANITIZER- alcohol liquid
Maquiladora La Central, 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.

Hand sanitizer

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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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 (77217-100-01)

ALCOHOL GEL HAND SANITIZER

BG/901 ING

Ingredientes: Ethyl alcohol, deionized water, carbomer, triethanolamine, glycerin

H225 - Highly flammable liquid and vapor. H303 - May be harmful if swallowed. H320 - Causes eye irritation. H241 - Heating may cause a fire or explosion. H270 - May cause or intensify fire; oxidizer.

P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking. P233 - Keep container tightly closed. P280 - Wear protective gloves/protective clothing/eye protection/face protection. P303+P361+P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. P403+P235 - Store in a well-ventilated place. Keep cool. P370+P378 - In case of fire: Use foam, carbon dioxide or dry powder to extinguish. P501 - Dispose of contents/container to accordance with local regulations. P101 - If medical advice is needed, have product container or label at hand. P103 - Read label before use. P102 - Keep out of reach of children.



WARNING

Cont. Net.: 1000 liters

LOT No. 2704201-01

Made in Mexico by:

Exp. 05-2021

Maquiladora La Central, S.A. DE C.V. Emiliano No. 11-3, Col. San Jeronimo Tepetlaco, Tlalnepantla, Estado de México. C.P. 54090, Teléfonos (55) 11063368, (55) 11062029 elbuengenio@elbuengenio.com

www.elbuengenio.com

DUNS 812810862

ALCOHOL EN GEL PARA MANOS

BG/901

Ingredientes: Alcohol etílico, Agua desionizada, carbomero, trietanolamina, glicerina

H225 - Líquido y vapores muy inflamables. H303 - H320 - H241 - Peligro de incendio o explosión en caso de calentamiento. H270 - Puede provocar o agravar un incendio; comburente.

P210 - Mantener alejado del calor, de superficies calientes, de chispas, de llamas abiertas y de cualquier otra fuente de ignición. No fumar. P233 - Mantener el recipiente herméticamente cerrado. P280 - Llevar guantes/prendas/gafas/máscara de protección.

P303+P361+P353 - EN CASO DE CONTACTO CON LA PIEL (o el pelo): Quitar inmediatamente toda la ropa contaminada. Enjuagar la piel con agua [o ducharse]. P370+P378 - En caso de incendio, utilizar espuma, dióxido de carbono o polvo seco para la extinción. P403+P235 - Almacenar en un lugar bien ventilado. Mantener en lugar fresco. P501 - Eliminar el contenido / recipiente de acuerdo a las regulaciones locales. P101 - Si se necesita consejo médico, tener a mano el envase o la etiqueta. P103 - Leer la etiqueta antes del uso. P102 - Mantener fuera del alcance de los niños.



ADVERTENCIA

Cont. Net.: 1000 litros

LOTE No. 2704201-01

Hecho en México por:

Fecha de Caducidad: Mayo 2021

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HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77217-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 80 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:77217-100-01	80 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 - Maquiladora La Central, S.A. de C.V. (812810862)

Establishment

Name	Address	ID/FEI	Business Operations
Maquiladora La Central, S.A. de C.V.		812810862	manufacture(77217-100)

Revised: 5/2020

Maquiladora La Central, S.A. de C.V.