

HAND SANITIZER- alcohol gel

Comdata laguna S de RL de CV

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

Package Label - Principal Display Panel



DESCRIPTION:

Antiseptic hand gel that does not require rinsing, formulated with ethyl alcohol; added with humectants and hypoallergenic emollients. Product specially formulated to meet the new needs of hand cleaning with the sole purpose of caring for HEALTH.

APPLICATIONS:

It is used with hand disinfection in clinics, doctor's offices, offices, schools, dining rooms, food plants, and fast-acting and drying establishments. Such properties allow its use on all skin types, as in adults and children.

NOTE: ALCOHOL IN GEL DOES NOT REPLACE HAND WASHING WITH ANTIBACTERIAL SOAP, NAIL BRUSH AND RINSING WITH WATER.

FIRST AID AND EMERGENCY: No

CONTACT WITH THE EYES: Wash immediately and completely with water for 15 minutes.

If conditions worsen and irritation persists contact a physician. **INGESTION:** Do not induce or cause vomiting. Drink plenty of water. Contact a doctor. **FIRE CONTROL:** extinguishing medium: Water or CO2.

SAFE HANDLING AND USE PRECAUTIONS: PERSONAL PRECAUTIONS: Avoid contact with eyes.

Don't drink it. Stay away from fire or flame. Stay covered. Keep out of reach of children.

DIRECTIONS FOR USE: With dry hands take a portion of GEL, rub the entire surface of the hands, interdigital spaces and wrists for 15-30 seconds until the alcohol dries. Do not towel dry or heat.

Classification of the substance: Acute ingestion toxicity,

Category 4: Acute Toxicity by Skin Contact

Category 4: Acute inhalation toxicity

Category 4: Eye injuries

Category 2B: Flammable liquids, **Category 4:**

Label elements: Hazard pictograms (GHS-MX)

Signal word (GHS-MX): Attention. Physical hazards (GHS-MX):

H226- Combustible liquid Health hazards (GHS-MX)

H302- Harmful if swallowed

H312- Harmful in contact with skin

H320- Causes eye irritation

H332- Harmful if inhaled.

Fabricated by:

Crylab Q&T Distribuidora Lagunera del Norte S.A de C.V

Av. Torre del Sol #846 col. Las Torres

Torreón Coahuila, México

Distributed by:

Comdata Laguna S de RL de CV

Bvld. Constitución #1864 col. San Isidro

Torreón Coahuila, México 27100

+52 871 7811708

+52 871 044361

70% ALCOHOL

70% ALCOHOL

1000 mL NDC: 76527-003-01

HAND SANITIZER

alcohol gel



Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76527-003
Route of Administration	TOPICAL, CUTANEOUS		

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)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76527-003-03	250 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	03/30/2020	
2	NDC:76527-003-01	1000 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	03/30/2020	
3	NDC:76527-003-02	500 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	03/30/2020	
4	NDC:76527-003-04	200 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	03/30/2020	
5	NDC:76527-003-05	200 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	03/30/2020	
6	NDC:76527-003-06	125 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	03/30/2020	
7	NDC:76527-003-07	19000 mL in 1 TANK; Type 0: Not a Combination Product	03/30/2020	
8	NDC:76527-003-08	3785.41 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	



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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Comdata laguna S de RL de CV (812626167)

Revised: 6/2020

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