HAND SANITIZER GEL- alcohol gel JE INDUSTRIAS QUIMICAS SA 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 Sanitaizer Gel

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.

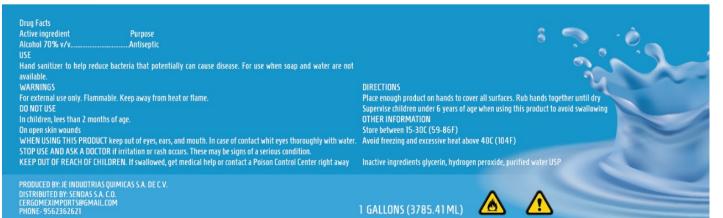
The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)



Hand sanitizer Kills 99.99% of germs

Alcohol antiseptic 70% Topical solution Non-sterile solution 3785.41 ML



Alcohol 70% 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.

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.

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



Industrias Químicas

Hand sanitizer Kills 99.99% of germs

Alcohol antiseptic 70% Topical solution Non-sterile solution 3785.41 ML





	AND SANIT	IZER GEL								
Product Information										
Product Type			HUMAN OTC DRUG Item Code (Source		e) NDC:75107-500					
Route of Administration TOPICAL										
Active Ingredient/Active Moiety										
Ingredient Name						of Strength	Strength			
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)					ALCOHOL		70 mL in 100 mL			
Inactive Ingredients										
		Ing		Strength						
	LYCERIN (UNII: PD			1.45 mL in 100 mL						
	YDRO GEN PERO X		0AN9V)		0.125 mL in 100 mL					
WATER (UNII: 059QF0KO0R)										
Packaging										
#	Item Code		Package Description		Marketing Start Date		Marketing End Date			
1	NDC:75107-500- 10	1000000 mL in 1 Product	l TANK; Type 0: Not a Combinati	on (03/30/2020					
Marketing Information										
Marketing Category		ory Applicat	ion Number or Monograph C	itation N	Marketin	g Start Date	Marketing End Date			
0	TC monograph not f	inal part333A		0	03/30/2020					

Labeler - JE INDUSTRIAS QUIMICAS SA DE CV (951576355)

Registrant - JE INDUSTRIAS QUIMICAS SA DE CV (951576355)

Establishment

Name	Address	ID/FEI	Business Operations
JE INDUSTRIAS QUIMICAS SA DE CV		951576355	manufacture(75107-500)

Revised: 5/2020

JE INDUSTRIAS QUIMICAS SA DE CV