

HAND SANITIZER- alcohol gel

Kenher Servicios Industriales, S.de R.L. 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) (70%, 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 (0.2% v/v).
- c. 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 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.

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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, purified water USP



www.kenher.com.mx

Gel Hand Sanitizer

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Net Content: 3,800 mL
Use-by: April 2023



Made in Mexico by:
KENHER Servicios Industriales
S. de R.L. de C.V.
Saltillo, Coahuila, 25207
ventas@kenher.com.mx
+52 844-869-7560

3800mL NDC 76539-111-38

Gel Hand Sanitizer

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Net Content: 4,000 mL
Use-by: April 2023



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4000 mL NDC 76539-11-40

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Net Content: 1,000 mL
Use-by: April 2023



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1000 mL NDC 76539-11-10

Gel Hand Sanitizer

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Net Content: 550 mL

Use-by: April 2023



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550 mL NDC 76539-11-40

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Net Content: 500 mL

Use-by: April 2023



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500 mL NDC 76539-11-50

HAND SANITIZER

alcohol gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:76539-111

Route of Administration		TOPICAL		
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	70 mL in 100 mL	
Inactive Ingredients				
Ingredient Name		Strength		
GLYCERIN (UNII: PDC6A3C0OX)		0.2 mL in 100 mL		
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76539-111-38	3800 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:76539-111-40	4000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:76539-111-10	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:76539-111-50	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
5	NDC:76539-111-55	550 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 - Kenher Servicios Industriales, S.de R.L. de C.V. (951576728)

Establishment			
Name	Address	ID/FEI	Business Operations
Kenher Servicios Industriales, S.de R.L. de C.V.		951576728	manufacture(76539-111)

Revised: 4/2020

Kenher Servicios Industriales, S.de R.L. de C.V.