

HAND SANITIZER- alcohol gel
Acid Tech Inc

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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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

Alcohol 70% v/v. Purpose: Antiseptic

Package Label - Principal Display Panel

500 mL NDC: 75199-005-16



VHNY[®]



ADVANCED
Hand Sanitizer Gel

KILLS 99.9% OF MOST ILLNESS CAUSING GERMS

70% Alcohol

Wash Free

16.91 FL OZ (500ml)





Drug Facts	
Active ingredient[s] Ethyl alcoho 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 use •in children less than 2 months of age •on open skin wounds	
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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 Deionized water, Carbomer, Triethanolamine	

Distributed by :
 Acid Tech Inc.
 107 Mercer Street, New York,
 New York, USA 10012
 Phone: +1 (646) 648-3167

Manufactured by:
 Chongzhou Industrial Development Zone,
 Chengdu City, Sichuan Province, China



MADE IN PRC

Executive standard: Q/CLS 01-2019

Dosage form: gel

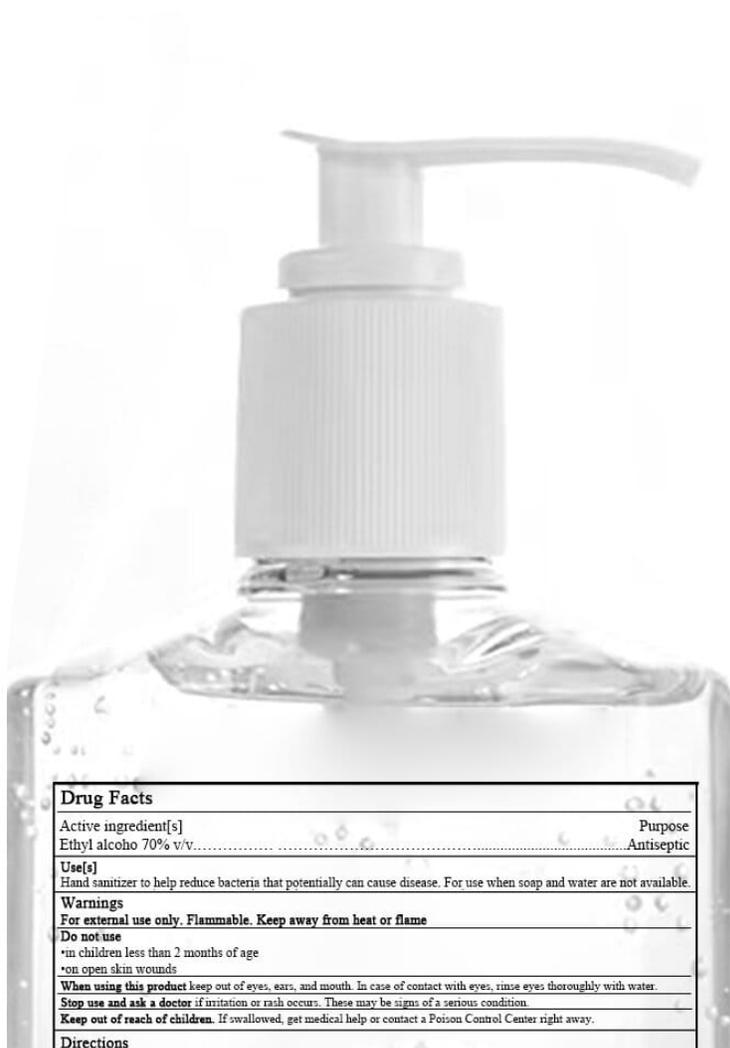
Specification: 500ml

Validity: 24 months



236 mL NDC: 75199-005-08





Drug Facts	
Active ingredient[s]	Purpose
Ethyl alcoho 70% v/v.....	Antiseptic
Use[s]	
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Do not use	
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Executive standard: Q/CLS 01-2019
 Dosage form: gel
 Specification: 8FL OZ(236ml)
 Validity: 24 months



HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75199-005
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)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
CARBOMER 1342 (UNII: 809Y72KV36)	0.5 mL in 100 mL

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75199-005-16	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75199-005-08	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 - Acid Tech Inc (117483502)

Registrant - Acid Tech Inc (117483502)

Establishment

Name	Address	ID/FEI	Business Operations
Acid Tech		117483502	manufacture(75199-005)