

HAND SANITIZER 80% ETHANOL- alcohol liquid

Inner Mission, 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.

Inner Mission, Inc. Hand Sanitizer Label

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

59 mL NDC: 75731-001-01



Drug Facts

Active Ingredient(s)	Purpose
Ethyl Alcohol 80% v/v	Antiseptic

Use(s)

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water is not available

Warnings

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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

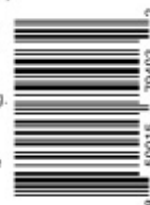
- Store between 15-30C (59-86F)

- Avoid freezing and excessive heat above

- 40C (104F)

Inactive ingredients glycerin, hydrogen

peroxide, purified water USP



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236 mL NDC: 75731-001-02



Drug Facts

Active Ingredient(s)

Ethyl Alcohol 80% v/vAntiseptic

Purpose

Use(s)

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water is 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.

Directions

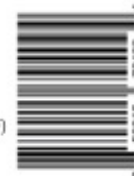
- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

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473 mL NDC: 75731-001-03



Drug Facts

Active Ingredient(s)

Ethyl Alcohol 80% v/vAntiseptic

Purpose

Use(s)

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water is 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.

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Directions

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- 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

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1892 mL NDC: 75731-001-04



Drug Facts

Active Ingredient(s)

Ethyl Alcohol 80% v/vAntiseptic

Purpose

Use(s)

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water is 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.

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



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HAND SANITIZER 80% ETHANOL

alcohol liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:75731-001

Route of Administration		TOPICAL		
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: 059QF0K00R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75731-001-02	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2020	
2	NDC:75731-001-01	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2020	
3	NDC:75731-001-03	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2020	
4	NDC:75731-001-04	1892 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	06/01/2020	

Labeler - Inner Mission, Inc. (117484880)

Revised: 4/2020

Inner Mission, Inc.