

HAND SANITIZER GEL- alcohol gel
The Highway Distillery LLC

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

glycerin, hydrogen peroxide, purified water USP, hydroxypropylcellulose

Package Label - Principal Display Panel

1,000 mL/1 Gallon NDC: 74931-002-01

<p>Alcohol Antiseptic 80% Topical Solution</p> <p>Hand Sanitizer Non-sterile Solution</p> <div style="border: 2px solid green; padding: 5px; text-align: center;">COMMERCIAL GRADE GEL</div> <p>For external use only</p> <ul style="list-style-type: none">• Avoid contact with eyes• Keep out of the reach of children• Use: Apply a palmful of alcohol-based handrub and cover all surfaces of the hands. Rub hands until dry• Composition: denatured ethanol, glycerol, hydrogen peroxide, Klucel™, and Ceraphyl™• Flammable: keep away from flame and heat <p>Production Date:</p> <p>Manufactured by The Highway Distillery, LLC info@thehighwaydistillery.com</p>	<div style="border: 2px solid green; padding: 10px;"><h1>HIGHWAY</h1><h1>160</h1><h1>PROOF</h1><p>ANTIBACTERIAL HAND SANITIZER</p><p>Manufactured according to the World Health Organization's recommended handrub formulation</p></div>	 <p>8 63488 00046 3</p> <p>1 Gallon/3785.41 ML</p> <table border="1"><tr><td colspan="2">Drug Facts</td></tr><tr><td>Active ingredient(s) Alcohol 80% v/v</td><td>Purpose Antiseptic</td></tr><tr><td colspan="2">Use(s) Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.</td></tr><tr><td colspan="2">Warnings</td></tr><tr><td colspan="2">For external use only. Flammable. Keep away from heat or flame</td></tr><tr><td colspan="2">Do not use</td></tr><tr><td colspan="2">• in children less than 2 months of age</td></tr><tr><td colspan="2">• on open skin wounds</td></tr><tr><td colspan="2">When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</td></tr><tr><td colspan="2">Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.</td></tr><tr><td colspan="2">Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</td></tr><tr><td colspan="2">Directions</td></tr><tr><td colspan="2">• Place enough product on hands to cover all surfaces. Rub hands together until dry.</td></tr><tr><td colspan="2">• Supervise children under 6 years of age when using this product to avoid swallowing.</td></tr><tr><td colspan="2">Other information</td></tr><tr><td colspan="2">• Store between 15-30C (59-86F)</td></tr><tr><td colspan="2">• Avoid freezing and excessive heat above 40C (104F)</td></tr><tr><td colspan="2">Inactive ingredients glycerin, hydrogen peroxide, purified water USP</td></tr></table>	Drug Facts		Active ingredient(s) Alcohol 80% 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		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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177.44 mL/6oz NDC: 74931-002-02

<p>Alcohol Antiseptic 80% Topical Solution</p> <p>Hand Sanitizer Non-sterile Solution</p> <div style="border: 2px solid green; padding: 5px; text-align: center;">COMMERCIAL GRADE GEL</div> <p>For external use only</p> <ul style="list-style-type: none">• Avoid contact with eyes• Keep out of the reach of children• Use: Apply a palmful of alcohol-based handrub and cover all surfaces of the hands. Rub hands until dry• Composition: denatured ethanol, glycerol, hydrogen peroxide, Klucel™, and Ceraphyl™• Flammable: keep away from flame and heat <p>Production Date:</p> <p>Manufactured by The Highway Distillery, LLC info@thehighwaydistillery.com</p>	<div style="border: 2px solid green; padding: 10px;"><h1>HIGHWAY</h1><h1>160</h1><h1>PROOF</h1><p>ANTIBACTERIAL HAND SANITIZER</p><p>Manufactured according to the World Health Organization's recommended handrub formulation</p></div>	 <p>8 63488 00046 3</p> <p>6 Ounces/177.44 ML</p> <table border="1"><tr><td colspan="2">Drug Facts</td></tr><tr><td>Active ingredient(s) Alcohol 80% v/v</td><td>Purpose Antiseptic</td></tr><tr><td colspan="2">Use(s) Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.</td></tr><tr><td colspan="2">Warnings</td></tr><tr><td colspan="2">For external use only. Flammable. Keep away from heat or flame</td></tr><tr><td colspan="2">Do not use</td></tr><tr><td colspan="2">• in children less than 2 months of age</td></tr><tr><td colspan="2">• on open skin wounds</td></tr><tr><td colspan="2">When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</td></tr><tr><td colspan="2">Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.</td></tr><tr><td colspan="2">Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</td></tr><tr><td colspan="2">Directions</td></tr><tr><td colspan="2">• Place enough product on hands to cover all surfaces. Rub hands together until dry.</td></tr><tr><td colspan="2">• Supervise children under 6 years of age when using this product to avoid swallowing.</td></tr><tr><td colspan="2">Other information</td></tr><tr><td colspan="2">• Store between 15-30C (59-86F)</td></tr><tr><td colspan="2">• Avoid freezing and excessive heat above 40C (104F)</td></tr><tr><td colspan="2">Inactive ingredients glycerin, hydrogen peroxide, purified water USP</td></tr></table>	Drug Facts		Active ingredient(s) Alcohol 80% 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		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 GEL

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74931-002
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: 059QF0KO0R)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	1.1 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74931-002-01	3785.41 mL in 1 JUG; Type 0: Not a Combination Product	07/28/2020	
2	NDC:74931-002-02	177.44 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/28/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/28/2020	

Labeler - The Highway Distillery LLC (117476343)

Registrant - The Highway Distillery LLC (117476343)

Establishment

Name	Address	ID/FEI	Business Operations
The Highway Distillery LLC		117476343	manufacture(74931-002)