

HAND SANITIZER- alcohol spray
Heritage Distilling Company, 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.

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

000 mL NDC:00000-000-00

236 mL 73910-001-09



HERITAGE.
DISTILLING CO

HAND SANITIZER

ANTISEPTIC SPRAY REFILL

Formula based on FDA Compounding Guidelines for consumer and healthcare personnel use, issued March 2020.
Made to refill a spray bottle. Unscented.
Not for human consumption. External use only.



Produced by Heritage Distilling Co.
Gig Harbor, WA. Natural separation may occur.
Shake well.

8 FL OZ (236.58 ML)

Drug Facts

Active ingredient(s) Purpose(s)
Denatured Ethyl Alcohol 80% v/v.....Antiseptic

Use(s)

Hand sanitizer to help reduce bacteria that can potentially cause disease. For use when soap or water are not available.

Warnings

For external use only. Flammable. Keep away from heat or flame.

Do not use

- on 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 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

- Spray 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 ingredient(s)

- Distilled or Boiled Water, Hydrogen Peroxide, Glycerin.



059 mL NDC:73910-001-01





HERITAGE[®]
DISTILLING CO

**HAND
SANITIZER**

— **ANTISEPTIC** —



**Formula based on FDA Compounding
Guidelines for consumer and healthcare
personnel use, issued March 2020.**

**Not for human consumption.
External use only. Produced by
Heritage Distilling Co. Gig Harbor, WA**

Active Ingredient:
Denatured Ethyl Alcohol - 80% v/v
Inactive Ingredients:
*Distilled Water, Hydrogen Peroxide,
Glycerol or Fractionated Coconut Oil*

2 FL OZ (59 ML)

050 mL NDC:73910-001-02

Drug Facts
Active ingredient(s) Purpose(s) Denatured Ethyl Alcohol 80% v/v... Antiseptic
Use(s) Hand sanitizer to help reduce bacteria that can potentially cause disease. For use when soap or water are not available.
Warnings For external use only. Flammable. Keep away from heat or flame.
Do not use - on 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 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 Poison Control right away.
Directions - Spray enough product on hands to cover all surfaces. Rub hands together until dry. - Children under 6 years of age should be supervised when using this product.
Other information - Store between 15-30C (59-86F) - Avoid freezing and excessive heat above 40C (104F)
Inactive ingredient(s) - Distilled Water, Hydrogen Peroxide, Glycerol or Fractionated Coconut Oil.



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**HAND
SANITIZER**

— ANTISEPTIC —



1.69 FL OZ
(50ML).

FORMULA BASED ON FDA COMPOUNDING GUIDELINES FOR CONSUMER AND HEALTHCARE PERSONNEL USE, ISSUED MARCH 2020. EXTERNAL USE ONLY.
NOT FOR HUMAN CONSUMPTION. UNSCENTED.
PRODUCED BY HERITAGE DISTILLING CO., GIG HARBOR, WA.
NATURAL SEPARATION MAY OCCUR. SHAKE WELL.





HERITAGE[®]
DISTILLING CO

HAND SANITIZER

— ANTISEPTIC —

Formula based on FDA Compounding Guidelines for consumer and healthcare personnel use, issued March 2020.

**Not for human consumption.
External use only. Unscented.**



**Produced by Heritage Distilling Co.
Gig Harbor, WA. Natural separation
may occur. Shake well.**

3.4 FL OZ (100 ML)

Drug Facts

Active ingredient(s)

Denatured Ethyl Alcohol 80% v/v

Purpose(s)

Antiseptic

Use(s)

Hand sanitizer to help reduce bacteria that can potentially cause disease. For use when soap or water are not available.

Warnings

For external use only. Flammable. Keep away from heat or flame.

Do not use

- on 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 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 Poison Control right away.

Directions

- Spray enough product on hands to cover all surfaces. Rub hands together until dry.
- Children under 6 years of age should be supervised when using this product.

Other information

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

Inactive ingredient(s)

- Distilled Water, Hydrogen Peroxide, Glycerol or Fractionated Coconut Oil.





HERITAGE[®]
DISTILLING CO

HAND SANITIZER

— ANTISEPTIC —

**Formula based on FDA Compounding
Guidelines for consumer and healthcare
personnel use, issued March 2020.
Not for human consumption.
External use only. Unscented.**



**Produced by Heritage Distilling Co.
Gig Harbor, WA. Natural separation
may occur. Shake well.**

25.36 FL OZ (750 ML)

Drug Facts

Active ingredient(s) Purpose(s)

Denatured Ethyl Alcohol 80% v/v..... Antiseptic

Use(s)

Hand sanitizer to help reduce bacteria that can potentially cause disease. For use when soap or water are not available

Warnings

For external use only. Flammable. Keep away from heat or flame.

Do not use

- on 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 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

- Spray enough product on hands to cover all surfaces. Rub hands together until dry.
- Children under 6 years of age should be supervised when using this product.

Other information

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

Inactive ingredient(s)

- Distilled Water, Hydrogen Peroxide, Glycerol or Fractionated Coconut Oil.





HERITAGE[®]
DISTILLING CO

HAND SANITIZER

— ANTISEPTIC —

Formula based on FDA Compounding Guidelines
for consumer and healthcare personnel use,
issued March 2020. External use only.
Not for human consumption. Unscented.



Produced by Heritage Distilling Co., Eugene, OR.
Natural separation may occur. Shake well.

33.81 FL OZ (1 L)

Drug Facts

Active ingredient(s) Purpose(s)

Denatured Ethyl Alcohol 80% v/v..... Antiseptic

Use(s)

Hand sanitizer to help reduce bacteria that can potentially cause disease. For use when soap or water are not available.

Warnings

For external use only. Flammable. Keep away from heat or flame.

Do not use

- on 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 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

- Spray enough product on hands to cover all surfaces. Rub hands together until dry.
- Children under 6 years of age should be supervised when using this product.

Other information

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

Inactive ingredient(s)

- Distilled Water, Hydrogen Peroxide, Glycerol or Fractionated Coconut Oil.



22730 mL NDC:73910-001-06



HERITAGE[®]
DISTILLING CO

HAND SANITIZER

— ANTISEPTIC —

Formula based on FDA Compounding Guidelines
for consumer and healthcare personnel use,
issued March 2020. External use only.
Not for human consumption. Unscented.



Produced by Heritage Distilling Co. Gig Harbor, WA
Natural separation may occur. Shake well.

640 FL OZ (5 GAL)

Drug Facts

Active ingredient(s) Purpose(s)

Denatured Ethyl Alcohol 80% v/v..... Antiseptic

Use(s)

Hand sanitizer to help reduce bacteria that can potentially cause disease. For use when soap or water are not available.

Warnings

For external use only. Flammable. Keep away from heat or flame.

Do not use

- on 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 thoroughly with water.

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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Spray enough product on hands to cover all surfaces. Rub hands together until dry.
- Children under 6 years of age should be supervised when using this product.

Other information

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

Inactive ingredient(s)

- Distilled Water, Hydrogen Peroxide, Glycerol or Fractionated Coconut Oil.



1250000 mL NDC:73910-001-07



HERITAGE[®]
DISTILLING CO

HAND SANITIZER

— ANTISEPTIC —

Formula based on FDA Compounding
Guidelines for consumer and healthcare
personnel use, issued March 2020.
Not for human consumption.
External use only. Unscented.



Produced by Heritage Distilling Co.
Gig Harbor, WA. Natural separation
may occur. Shake well.

35,200 FL OZ (275 GAL)

Drug Facts

Active ingredient(s) Purpose(s)

Denatured Ethyl Alcohol 80% v/v..... Antiseptic

Use(s)

Hand sanitizer to help reduce bacteria that can potentially cause disease. For use when soap or water are not available

Warnings

For external use only. Flammable. Keep away from heat or flame.

Do not use

- on 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 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

- Spray enough product on hands to cover all surfaces. Rub hands together until dry.
- Children under 6 years of age should be supervised when using this product.

Other information

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

Inactive ingredient(s)

- Distilled Water, Hydrogen Peroxide, Glycerol or Fractionated Coconut Oil.





HERITAGE
DISTILLING CO

**HAND
SANITIZER**
— ANTISEPTIC —



Formula based on FDA Compounding Guidelines
for consumer and healthcare personnel use,
issued March 2020. External use only.
Not for human consumption. Unscented.

4 FL OZ (118 ML)

Drug Facts

Active ingredient(s)	Purpose(s)
Denatured Ethyl Alcohol 80% v/v.....	Antiseptic

Use(s)

Hand sanitizer to help reduce bacteria that can potentially cause disease.
For use when soap or water are not available.

Warnings

For external use only. Flammable. Keep away from heat or flame.

Do not use

- on 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 thoroughly with water.

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or contact a Poison Control Center right away.

Directions

- Spray enough product on hands to cover all surfaces.
- Rub hands together until dry.

Other information

- Store between 15-30C (59-86F)
- Children under 6 years of age should be supervised
when using this product.

Inactive ingredient(s)

- Distilled Water, Hydrogen Peroxide, Glycerol or Fractionated Coconut Oil.



Produced by Heritage Distilling Co.
Gig Harbor, WA
Natural separation may occur.
Shake well.



HAND SANITIZER

alcohol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73910-001
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: 059QF0KO0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73910-001-01	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:73910-001-02	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:73910-001-03	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:73910-001-04	750 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
5	NDC:73910-001-05	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
6	NDC:73910-001-06	22730 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
7	NDC:73910-001-07	1250000 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
8	NDC:73910-001-08	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
9	NDC:73910-001-09	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/13/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Heritage Distilling Company, Inc. (060675395)

Establishment

Name	Address	ID/FEI	Business Operations
Heritage Distilling Company, Inc.		060675395	manufacture(73910-001)

Revised: 5/2020

Heritage Distilling Company, Inc.