

## **DOUNDRINS DISTILLING HAND SANITIZER- hand sanitizer liquid**

### **Doundrins Distilling**

*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.*

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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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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

**Package Label - Principal Display Panel**

118.29 mL NDC: 74547-002-01

# HAND SANITIZER

## Drug Facts

<b>Active Ingredient</b>	<b>Purpose</b>
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Ethyl alcohol 80%.....Antiseptic

## Uses

-to decrease bacteria on the skin that could cause disease -recommended for repeated use

## Warnings

**For external use only: hands**

**Flammable.** Keep away from heat and flame.

### When using this product

-keep out of eyes. In case of contact with eyes, flush thoroughly with water. -avoid contact with broken skin. -do not inhale or ingest

### Stop use and ask a doctor if

-irritation or redness develops -condition persists for more than 72 hours

### Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

## Directions

-wet hands thoroughly with product and allow to dry without wiping. -for children under 6, use only under adult supervision -not recommended for infants

## Other Information

-do not store above 105 degrees fahrenheit -may discolor some fabrics -harmful to wood finishes and plastics

## Inactive Ingredients

Glycerol, hydrogen peroxide, water



Produced and Bottled by  
Doundrins Distilling, Cottage Grove, WI

doundrinsdistilling.com



4 FL OZ  
(118.3 mL)

236.59 mL NDC: 74547-002-02

# HAND SANITIZER

## Drug Facts

<b>Active Ingredient</b>	<b>Purpose</b>
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Ethyl alcohol 80%.....Antiseptic

### Uses

-to decrease bacteria on the skin that could cause disease -recommended for repeated use

### Warnings

**For external use only: hands**

**Flammable.** Keep away from heat and flame.

### When using this product

-keep out of eyes. In case of contact with eyes, flush thoroughly with water. -avoid contact with broken skin. -do not inhale or ingest

### Stop use and ask a doctor if

-irritation or redness develops -condition persists for more than 72 hours

### Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

### Directions

-wet hands thoroughly with product and allow to dry without wiping. -for children under 6, use only under adult supervision -not recommended for infants

### Other Information

-do not store above 105 degrees fahrenheit -may discolor some fabrics -harmful to wood finishes and plastics

### Inactive Ingredients

Glycerol, hydrogen peroxide, water



Produced and Bottled by  
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8 FL OZ  
(236.6 mL)

473.18 mL NDC: 74547-002-03

HAND SANITIZER

**Drug Facts**

**Active Ingredient**      **Purpose**  
Ethyl alcohol 80%.....Antiseptic

**Uses**

-to decrease bacteria on the skin that could cause disease -recommended for repeated use

**Warnings**

**For external use only: hands**

**Flammable.** Keep away from heat and flame.

**When using this product**

-keep out of eyes. In case of contact with eyes, flush thoroughly with water. -avoid contact with broken skin. -do not inhale or ingest

**Stop use and ask a doctor if**

-irritation or redness develops -condition persists for more than 72 hours

**Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

-wet hands thoroughly with product and allow to dry without wiping. -for children under 6, use only under adult supervision -not recommended for infants

**Other Information**

-do not store above 105 degrees farenheit -may discolor some fabrics -harmful to wood finishes and plastics

**Inactive Ingredients**

Glycerol, hydrogen peroxide, water



Produced and Bottled by  
Doundrins Distilling, Cottage Grove, WI  
[doundrinsdistilling.com](http://doundrinsdistilling.com)

16 FL OZ  
(473.2 mL)



3785 mL NDC: 74547-002-04

# HAND SANITIZER

**Drug Facts**  
**Active Ingredient Purpose**  
 Ethyl alcohol 80%.....Antiseptic

**Uses**  
 -to decrease bacteria on the skin that could cause disease -recommended for repeated use

**Warnings**  
**For external use only: hands**  
**Flammable.** Keep away from heat and flame.  
**When using this product**  
 -keep out of eyes. In case of contact with eyes, flush thoroughly with water. -avoid contact with broken skin.  
 -do not inhale or ingest  
**Stop use and ask a doctor if**  
 -irritation or redness develops -condition persists for more than 72 hours  
**Keep out of reach of children.**  
 If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**  
 -wet hands thoroughly with product and allow to dry without wiping. -for children under 6, use only under adult supervision -not recommended for infants

**Other Information**  
 -do not store above 105 degrees fahrenheit -may discolor some fabrics -harmful to wood finishes and plastics

**Inactive Ingredients**  
 Glycerol, hydrogen peroxide, water



Produced and Bottled by  
 Doundrins Distilling, Cottage Grove, WI  
 doundrinsdistilling.com



1 GALLON  
 (3.79 L)

## DOUNDRINS DISTILLING HAND SANITIZER

hand sanitizer liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:74547-002
<b>Route of Administration</b>	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)	1.6 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.14 mL in 100 mL
WATER (UNII: 059QF0K00R)	18.26 mL in 100 mL

### Packaging

Marketing Start

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74547-002-01	118.29 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/27/2020	
2	NDC:74547-002-02	236.59 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/27/2020	
3	NDC:74547-002-03	473.18 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/27/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/27/2020	

**Labeler** - Doundrins Distilling (116818466)

### Establishment

Name	Address	ID/FEI	Business Operations
Doundrins Distilling		116818466	manufacture(74547-002)

Revised: 4/2020

Doundrins Distilling