

**ALCOHOL- 73938-2020 liquid**  
**Louisville Distilling Company, 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.*

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Alcohol 80% v/v

Antiseptic

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

- in children less than 2 months of age
- on open skin wounds

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.

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

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

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

LOUISVILLE DISTILLING CO



# ANGELS ENVY DISTILLERY

## HAND SANITIZER

*Non-sterile solution*

## ALCOHOL ANTISEPTIC 80%

*Topical solution*

<b>Drug Facts</b>	
<b>Active ingredient[s]</b> Alcohol 80% v/v .....	<b>Purpose</b> Antiseptic
<b>Use[s]</b> Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b> <b>For external use only. Flammable. Keep away from heat or flame</b> <b>Do not use</b> <ul style="list-style-type: none"><li>• in children less than 2 months of age</li><li>• on open skin wounds</li></ul> <b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. <b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition. <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> <ul style="list-style-type: none"><li>• Place enough product on hands to cover all surfaces. Rub hands together until dry.</li><li>• Supervise children under 6 years of age when using this product to avoid swallowing.</li></ul>	
<b>Other information</b> <ul style="list-style-type: none"><li>• Store between 15-30C (59-86F)</li><li>• Avoid freezing and excessive heat above 40C (104F)</li></ul>	
<b>Inactive ingredients</b> glycerin, hydrogen peroxide, purified water USP	

xx ML

73938-2020 liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73938-2020
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL

### Packaging

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:73938-2020-1	56780 mL in 1 DRUM; Type 0: Not a Combination Product	03/24/2020	
2	NDC:73938-2020-2	208190 mL in 1 DRUM; Type 0: Not a Combination Product	03/24/2020	

### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part333A	03/24/2020	

**Labeler** - Louisville Distilling Company, LLC (939097189)

**Registrant** - Louisville Distilling Company LLC, (939097189)

### Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Louisville Distilling Company, LLC		939097189	manufacture(73938-2020)

Revised: 3/2020

Louisville Distilling Company, LLC