

**SANI HANDS- ethyl alcohol gel**  
**Maine Craft Distilling, 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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**sani hands HYPOALLERGENIC HAND SANITIZER GEL**

***Drug Facts***

***Active ingredient***

Ethyl Alcohol 72%

***Purpose***

Antiseptic

***Uses***

Hand Sanitizer to help reduce bacteria on the skin that can cause disease.

***Directions***

Apply liberally to front and back of hands.

Allow to dry. Recommended for repeat use.

***Warnings***

**For external use only: hands**

**Flammable, keep away from fire or flame.**

**When using this product** avoid contact with the eyes. In case of contact, rinse eyes thoroughly with water.

**Stop use and ask a doctor if** irritation or redness appears and lasts.

**Do not use** on children less than 2 months of age and on open wounds. Do not inhale or ingest.

Supervise children under 6 years of age when using this product to avoid swallowing

**If swallowed**, get medical help or contact a Poison Control Center immediately.

***Other information***

Store between 0°C (32°F) - 41°C (105°F)

***Inactive ingredients***

Methylcellulose, water, Fragrance

***Customer Service***

+1 800 960 4814

**MADE IN USA**

**\*INSTANTLY KILLS 99.99% OF TESTED GERMS**

**72% ALCOHOL**

Triclosan Sulfate and Paraben free

\*Eliminates 99.99% of tested germs, bacteria and viruses in as little as 15 seconds.

**WWW.SANI-LABS.COM**

**Packaging**

EXP JULY 2021

**Drug Facts** NDC 79359-001-16

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**SANI HANDS**

ethyl alcohol gel

**Product Information**

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:79359-001

Route of Administration TOPICAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	72 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
METHYLCELLULOSE, UNSPECIFIED (UNII: Z944H5SN0H)	
WATER (UNII: 059QF0K00R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79359-001-16	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/17/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/17/2020	

**Labeler** - Maine Craft Distilling, LLC (079283895)

### Establishment

Name	Address	ID/FEI	Business Operations
Maine Craft Distilling, LLC		079283895	manufacture(79359-001)

Revised: 7/2020

Maine Craft Distilling, LLC