

**BLAUM BROS. DISTILLING CO. HAND SANITIZER- alcohol liquid**

**Blaum Bros. Distilling Co.**

*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.

**Blaum Bros. Distilling Co.**  
**Formulation based on WHO guidelines**  
**For External Use Only**  
**Avoid Contact With Eyes**  
**Keep Out Of Reach Of Children**

*Use: Apply a palmful of alcohol-based handrub and cover all surfaces of the hands. Rub hands until dry.*

*Composition: ethanol, glycerol and hydrogen peroxide.*

*Flammable: Keep away from flame and heat.*

<b>Drug Facts</b>
<b>Active ingredient[s]</b> Alcohol 80% v/v.....
<b>Use[s]</b> Hand sanitizer to help reduce b
<b>Warnings</b> For external use only. Flammat
<b>Do not use</b> <ul style="list-style-type: none"><li>• in children less than 2 months</li><li>• on open skin wounds</li></ul>
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<b>Directions</b> <ul style="list-style-type: none"><li>• Place enough product on han</li><li>• Supervise children under 6 ye</li></ul>
<b>Other information</b> <ul style="list-style-type: none"><li>• Store between 15-30C (59-86</li><li>• Avoid freezing and excessive</li></ul>
<b>Inactive ingredients</b> glycer

**Purpose**  
.....Antiseptic

acteria that potentially can cause disease. For use when soap and water are not available.

**Use:** Keep away from heat or flame

Age

Use: Avoid contact with eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Warnings: Avoid contact with eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

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

Directions: Use to cover all surfaces. Rub hands together until dry.

Precautions: Avoid contact with eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

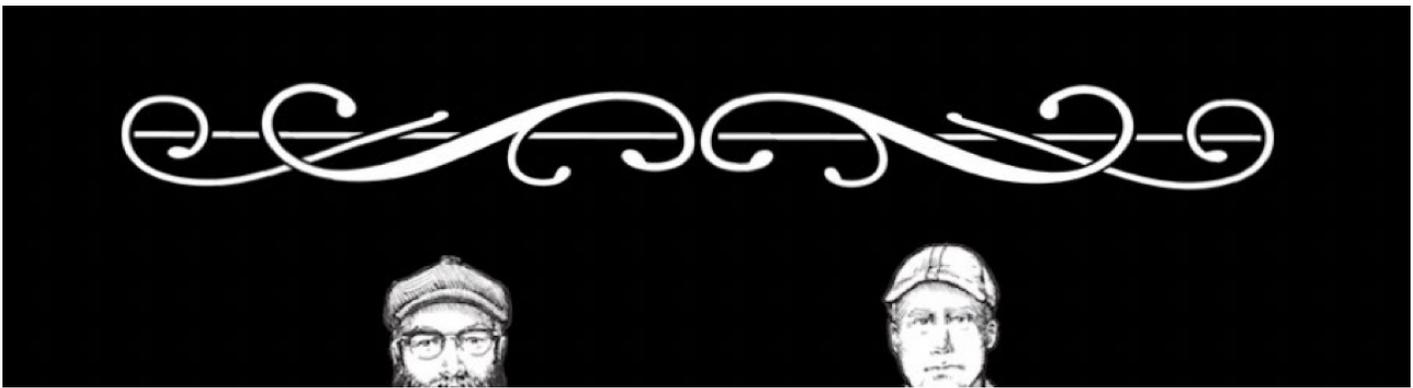
Other

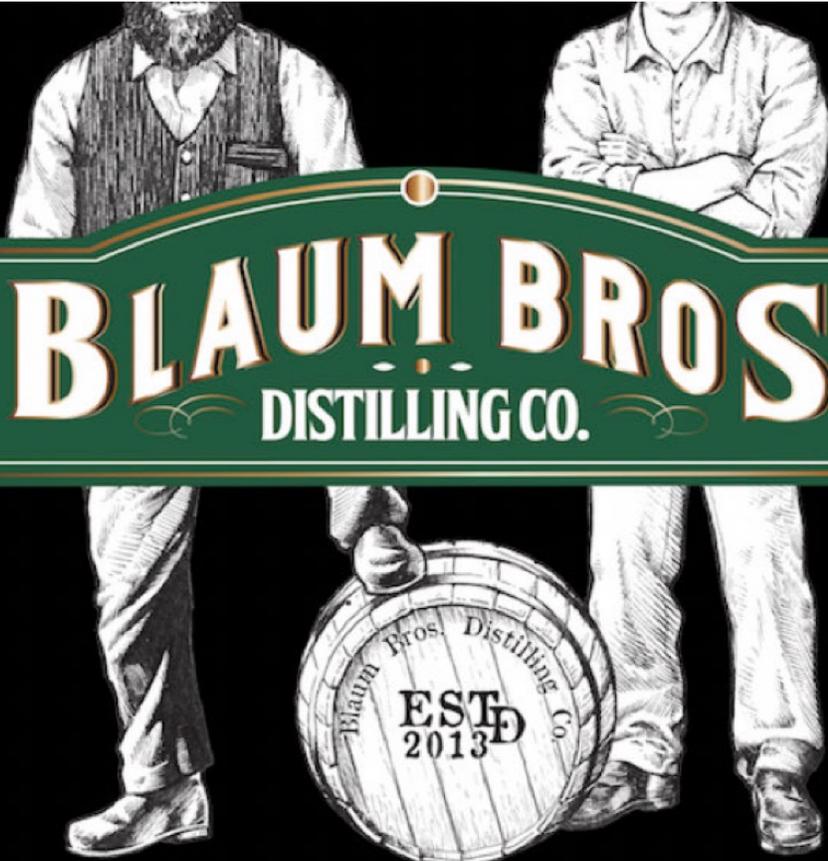
Heat above 40C (104F)

Ingredients: Hydrogen peroxide, purified water USP

**Active Ingredient(s)**

Alcohol 80% v/v. Purpose: Antiseptic





**BLAUM BROS.**  
DISTILLING CO.

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# HAND SANITIZER

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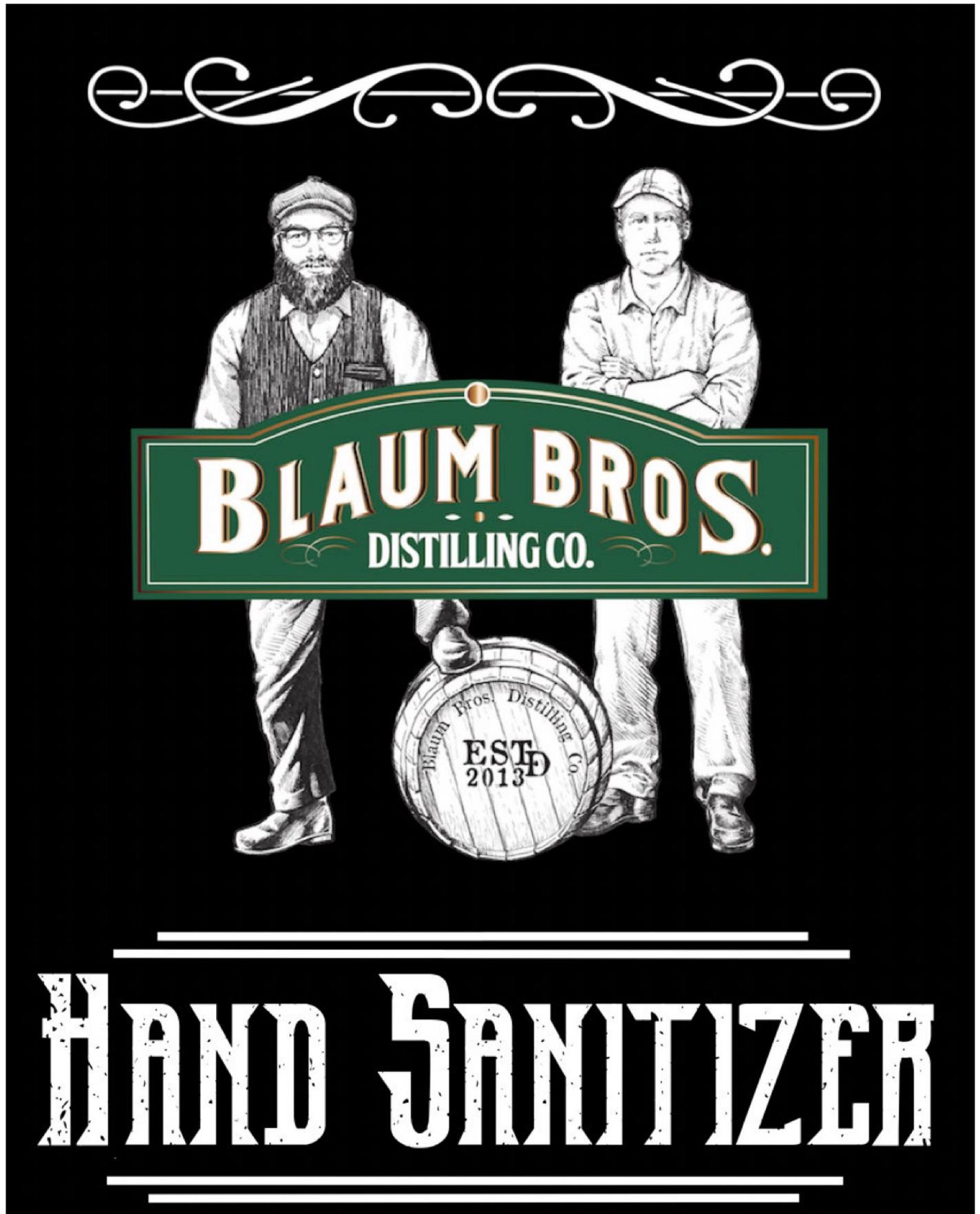
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TOPICAL SOLUTION  
NON-STERILE SOLUTION  
ALCOHOL ANTI-SEPTIC 80%



**Purpose**

Antiseptic, Hand Sanitizer



**TOPICAL SOLUTION**  
**NON-STERILE SOLUTION**  
**ALCOHOL ANTI-SEPTIC 80%**



**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

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<b>Inactive ingredient</b>

17

**Purpose**

Antiseptic

Reduce bacteria that potentially can cause disease. For use when soap and water are not available.

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

2 months of age

Do not use on children under 2 months of age. Do not use on open skin wounds. Do not use on face, neck, or hands. Do not use on eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Do not use if irritation or rash occurs. These may be signs of a serious condition.

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

Do not use on hands to cover all surfaces. Rub hands together until dry.

Do not use under 6 years of age when using this product to avoid swallowing.

USP (59-86F)

Do not use above 40C (104F)

USP glycerin, hydrogen peroxide, purified water USP

**Do not use**

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

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**Purpose**

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**Warnings:** Flammable. Keep away from heat or flame

For use in 2 months of age

For use on hands

Do not use if you have a wound, cut, or burn. Do not use if you have an eye infection or if you have a skin condition such as eczema or psoriasis. Do not use if you have a fever, sore throat, or other symptoms of infection. Do not use if you have a rash or other skin irritation.

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**BLAUM BROS. DISTILLING CO. HAND SANITIZER**

alcohol liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:74286-0001
<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)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74286-0001-1	236.59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:74286-0001-2	946.35 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
3	NDC:74286-0001-3	3785.41 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/25/2020	

**Labeler** - Blaum Bros. Distilling Co. (061333406)**Registrant** - Blaum Bros. Distilling Co. (061333406)**Establishment**

Name	Address	ID/FEI	Business Operations
Blaum Bros. Distilling Co.		061333406	manufacture(74286-0001)

Revised: 3/2020

Blaum Bros. Distilling Co.