

**HAND SANITIZER WHO FORMULATION- alcohol liquid**  
**AMASS Brands, 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.*

**Active Ingredients**

80% Ethyl Alcohol (v/v); Purpose: Antiseptic

<b>DRUG FACTS</b>	
<b>ACTIVE INGREDIENTS</b>	<b>PURPOSE</b>
80% Ethyl Alcohol (v/v) .....	Antiseptic

**Use**

Hand sanitizer to help reduce disease-causing bacteria.

<b>USE</b> Hand sanitizer to help reduce disease-causing bacteria.
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**Warnings**

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

<b>WARNINGS</b> <ul style="list-style-type: none"><li>• Flammable. Keep away from heat or flame.</li><li>• For external use only.</li></ul> <hr/> <p><b>Do not use</b> on children less than 2 months of age or on open skin wounds. Do not use in or near the eyes. In case of eye contact, rinse thoroughly with water.</p> <hr/> <p><b>Stop use and ask a doctor if</b> irritation or rash occurs.</p> <hr/> <p><b>Keep out of reach of children.</b> If swallowed, get medical attention or contact a poison center immediately.</p>
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Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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**Other information**

- Avoid freezing and excessive heat above 40C (104F)

**OTHER INFORMATION**

Avoid freezing and excessive heat above 104°F (40°C).

**Inactive ingredients**

glycerin, hydrogen peroxide, purified water

**INACTIVE INGREDIENTS**

Glycerin, Hydrogen Peroxide, Purified Water

**Use**

Hand sanitizer to help reduce disease-causing bacteria.

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Hand sanitizer to help reduce disease-causing bacteria.

Apply liberally to dry hands, rub briskly until evaporated.  
Children should be supervised when using this product.

**DIRECTIONS**

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- Children should be supervised when using this product.

**Package Label - Principal Display Panel**

80% ALCOHOL ANTISEPTIC TOPICAL SOLUTION

Antiseptic Hand Rub Non-Sterile Solution

12 oz | 355 mL

80% Alcohol v/v

**80% ALCOHOL  
ANTISEPTIC  
TOPICAL SOLUTION**

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Antiseptic  
Hand Rub  
Non-Sterile  
Solution

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**12 OZ | 355 ML**  
**80% ALCOHOL V/V**

**HAND SANITIZER WHO FORMULATION**

alcohol liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77419-0002
<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

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:77419-0002-2	118.294 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
2	NDC:77419-0002-1	59.1471 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
3	NDC:77419-0002-3	354.882 mL in 1 BOTTLE, SPRAY; 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	03/30/2020	

**Labeler** - AMASS Brands, Inc (121284034)

## Establishment

Name	Address	ID/FEI	Business Operations
AMASS Brands, Inc		121284034	manufacture(77419-0002)

Revised: 6/2020

AMASS Brands, Inc