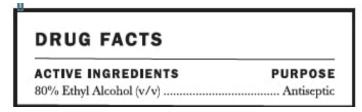
# HAND SANITIZER WHO FORMULATION- alcohol liquid AMASS Brands, Inc

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.

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## **Active Ingredients**

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



#### Use

Hand sanitizer to help reduce disease-causing bacteria.

USE

Hand sanitizer to help reduce disease-causing bacteria.

## Warnings

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

#### WARNINGS

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

**Do not use** 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.

Stop use and ask a doctor if irritation or rash occurs.

Keep out of reach of children. If swallowed, get medical attention or contact a poison center immediately.

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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 center immediately.

#### WARNINGS

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

**Do not use** 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.

Stop use and ask a doctor if irritation or rash occurs.

Keep out of reach of children. If swallowed, get medical attention or contact a poison center immediately.

#### 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**

- · Apply liberally to dry hands, rub briskly until evaporated.
- 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

Antiseptic Hand Rub Non-Sterile Solution

12 OZ | 355 ML 80% ALCOHOL V/V

# HAND SANITIZER WHO FORMULATION

alcohol liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77419-0002	
Route of Administration	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		
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL		
WATER (UNII: 059QF0KO0R)			

F	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