

**HAND SANITIZER- alcohol liquid**  
**SanitizeNow 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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The hand sanitizer is manufactured using only the following ingredients in the preparation of the product:

Alcohol (ethanol) (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.

Sterile distilled water or boiled cold water.

Hydrogen Peroxide

Glycerin

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

**Active Ingredient(s)**

Alcohol 80% v/v. Purpose: Antiseptic

**Purpose**

Antiseptic, Hand Sanitizer

**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

**Do not use**

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

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

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.

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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

## Directions

- 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.

## Other information

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

## Inactive ingredients

Water, Hydrogen Peroxide, Glycerin.

## Package Label - Principal Display Panel

59 mL NDC: 74988-737-20



## Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 80%	Antiseptic

**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 fire or flame.

**Do not use** • on open skin wounds • on children under the age of 2 months

**When using this product** keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

**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.

**Directions** • 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.

**Other Information** • Store between 59° - 86°F (15° - 30°C) • Avoid freezing and excessive heat above 104°F (40°C)

**Inactive Ingredients** Water, Hydrogen Peroxide, Glycerin.

PRO: 6/3/2020

EXP: 6/3/2022

Made in USA • 74988-737-20  
Distributed by  
Clover Imaging Group  
Hoffman Estates, IL 60169



118 mL NDC: 74988-737-40

RESPONSIBLE™

# HAND SANITIZER

Advanced Moisturizing Formula With Vitamin E

Kills 99.99% of Germs

80% Alcohol

118 mL (4 oz)

Drug Facts	
<b>Active Ingredient</b> Ethyl Alcohol 80%	<b>Purpose</b> Antiseptic
<b>Use:</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings:</b> For external use only. Flammable. Keep away from fire or flame.	
<b>Do not use</b> • on open skin wounds • on children under the age of 2 months	
<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> • 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.	
<b>Other Information</b> • Store between 59° - 86°F (15° - 30°C) • Avoid freezing and excessive heat above 104°F (40°C)	
<b>Inactive Ingredients</b> Water, Hydrogen Peroxide, Glycerin.	

Made in USA • 74988-737-40  
Distributed by Clover Imaging Group  
Hoffman Estates, IL 60169

236 mL NDC: 74988-737-80

RESPONSIBLE™

# HAND SANITIZER

Advanced Moisturizing Formula With Vitamin E

Kills 99.99% of Germs

80% Alcohol

8 fl oz 236mL

Drug Facts	
<b>Active Ingredient</b> Ethyl Alcohol 80%	<b>Purpose</b> Antiseptic
<b>Use:</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings:</b> For external use only. Flammable. Keep away from fire or flame.	
<b>Do not use</b> • on open skin wounds • on children under the age of 2 months	
<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> • 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.	
<b>Other Information</b> • Store between 59° - 86°F (15° - 30°C) • Avoid freezing and excessive heat above 104°F (40°C)	
<b>Inactive Ingredients</b> Water, Hydrogen Peroxide, Glycerin.	

Made in USA • 74988-737-80  
Distributed by Clover Imaging Group  
Hoffman Estates, IL 60169

473 mL NDC: 74988-737-16

RESPONSIBLE.

# HAND SANITIZER

Advanced Moisturizing Formula With Vitamin E

Kills 99.99% of Germs

80% Alcohol

16 fl oz 473mL

Made in USA  
74988-737-16  
Distributed by Clover Imaging Group  
Hoffman Estates, IL 60169

0 374988 737167

Drug Facts	
<b>Active Ingredient</b> Ethyl Alcohol 80%	<b>Purpose</b> Antiseptic
<b>Use:</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings:</b> For external use only. Flammable. Keep away from fire or flame.	
<b>Do not use</b> • on open skin wounds • on children under the age of 2 months	
<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> • 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.	
<b>Other Information</b> • Store between 59° - 86°F (15° - 30°C) • Avoid freezing and excessive heat above 104°F (40°C)	
<b>Inactive Ingredients</b> Water, Hydrogen Peroxide, Glycerin.	

3.78 L NDC: 74988-737-37

RESPONSIBLE.

# HAND SANITIZER

Advanced Moisturizing Formula With Vitamin E

Kills 99.99% of Germs

80% Alcohol

1 GAL (128 fl oz) 3.78L

Made in USA • 74988-737-37  
Distributed by Clover Imaging Group  
Hoffman Estates, IL 60169

0 374988 737372

Drug Facts	
<b>Active Ingredient</b> Ethyl Alcohol 80%	<b>Purpose</b> Antiseptic
<b>Use:</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings:</b> For external use only. Flammable. Keep away from fire or flame.	
<b>Do not use</b> • on open skin wounds • on children under the age of 2 months	
<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> • 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.	
<b>Other Information</b> • Store between 59° - 86°F (15° - 30°C) • Avoid freezing and excessive heat above 104°F (40°C)	
<b>Inactive Ingredients</b> Water, Hydrogen Peroxide, Glycerin.	

## HAND SANITIZER

alcohol liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:74988-737
<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: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74988-737-20	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/26/2020	
2	NDC:74988-737-40	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/26/2020	
3	NDC:74988-737-80	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/26/2020	
4	NDC:74988-737-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/26/2020	
5	NDC:74988-737-37	3780 mL in 1 JUG; Type 0: Not a Combination Product	06/26/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/26/2020	

**Labeler** - SanitizeNow Inc. (117475870)

**Registrant** - SanitizeNow Inc. (117475870)

### Establishment

Name	Address	ID/FEI	Business Operations
SanitizeNow Inc.		117475870	manufacture(74988-737)