

## **HAND SANITIZER- alcohol solution**

**Ava Food Labs, 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.*

-----

### **Hand Sanitizer by Ava Food Labs, Inc. dba Endless West**

#### **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.

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 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)
- You may report serious side effects to 2325 3rd St. #405, San Francisco, CA 94107

#### **Inactive ingredients**

glycerin, hydrogen peroxide, purified water

## Package Label - Principal Display Panel

60 mL NDC: 74065-001-01

<h1>HAND SANITIZER</h1> <p>Spread joy, not germs.</p>  <p>Made in San Francisco by</p> <h2>ENDLESS WEST</h2> <p>Alcohol Antiseptic 80% Topical Solution • Hand Sanitizer</p> <p>Non-sterile solution 2 oz (60 ml)</p> <p>Endless West • San Francisco, CA 94107</p>	<b>Drug Facts</b>				
	<table border="1"><thead><tr><th>Active Ingredient[s]</th><th>Purpose</th></tr></thead><tbody><tr><td>Alcohol 80% v/v.....</td><td>Antiseptic</td></tr></tbody></table>	Active Ingredient[s]	Purpose	Alcohol 80% v/v.....	Antiseptic
	Active Ingredient[s]	Purpose			
	Alcohol 80% v/v.....	Antiseptic			
	<b>Use[s]:</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.				
	<b>Warnings:</b> <b>For external use only. Flammable. Keep away from heat or flame.</b>				
<b>Do not use:</b> • In children less than 2 months of age • On open skin wounds					
<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 15-30°C (59-86°F) • Avoid freezing and excessive heat above 40°C (104°F) • You may report serious side effects to 2325 3rd St. #405, San Francisco, CA 94107					
<b>Inactive Ingredients:</b> Glycerin, hydrogen peroxide, purified water					
Expiration Date: 04/2023					

3785 mL NDC: 74065-001-02

# HAND SANITIZER

Spread joy, not germs.



Made in San Francisco by

**ENDLESS WEST**

Alcohol Antiseptic 80%  
Topical Solution • Hand Sanitizer

Non-sterile solution  
128 oz (1 gallon)

Endless West • San Francisco, CA 94107

## Drug Facts

<b>Active Ingredient[s]</b>	<b>Purpose</b>
Alcohol 80% v/v.....	Antiseptic

**Use[s]:** 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.

**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 15-30°C (59-86°F) • Avoid freezing and excessive heat above 40°C (104°F) • You may report serious side effects to 2325 3rd St. #405, San Francisco, CA 94107

**Inactive Ingredients:** Glycerin, hydrogen peroxide, purified water

Expiration Date: 04/2023

3785 mL NDC: 74065-001-03

# HAND SANITIZER

Spread joy, not germs.



Made in San Francisco by

**ENDLESS WEST**

Alcohol Antiseptic 80%  
Topical Solution • Hand Sanitizer

Non-sterile solution  
128 oz (1 gallon)

Endless West • San Francisco, CA 94107

## Drug Facts

<b>Active Ingredient[s]</b>	<b>Purpose</b>
Alcohol 80% v/v.....	Antiseptic

**Use[s]:** 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.

**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 15-30°C (59-86°F) • Avoid freezing and excessive heat above 40°C (104°F) • You may report serious side effects to 2325 3rd St. #405, San Francisco, CA 94107

**Inactive Ingredients:** Glycerin, hydrogen peroxide, purified water

Expiration Date: 04/2023

208000 mL NDC: 74065-001-04

# HAND SANITIZER

Spread joy, not germs.



Made in San Francisco by

**ENDLESS WEST**

Alcohol Antiseptic 80%  
Topical Solution • Hand Sanitizer

Non-sterile solution  
208 Liters

Endless West • San Francisco, CA 94107

## Drug Facts

<b>Active Ingredient[s]</b>	<b>Purpose</b>
Alcohol 80% v/v.....	Antiseptic

**Use[s]:** 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.

**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 15-30°C (59-86°F) • Avoid freezing and excessive heat above 40°C (104°F) • You may report serious side effects to 2325 3rd St. #405, San Francisco, CA 94107

**Inactive Ingredients:** Glycerin, hydrogen peroxide, purified water

Expiration Date: 04/2023

1000000 mL NDC: 74065-001-05

# HAND SANITIZER

Spread joy, not germs.



Made in San Francisco by

**ENDLESS WEST**

Alcohol Antiseptic 80%  
Topical Solution • Hand Sanitizer

Non-sterile solution  
1000 Liters

Endless West • San Francisco, CA 94107

## Drug Facts

<b>Active Ingredient[s]</b>	<b>Purpose</b>
Alcohol 80% v/v.....	Antiseptic

**Use[s]:** 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.

**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 15-30°C (59-86°F) • Avoid freezing and excessive heat above 40°C (104°F) • You may report serious side effects to 2325 3rd St. #405, San Francisco, CA 94107

**Inactive Ingredients:** Glycerin, hydrogen peroxide, purified water

Expiration Date: 04/2023

60 mL NDC: 74065-001-06

# HAND SANITIZER

Spread joy, not germs.



Made in San Francisco by

## ENDLESS WEST

Alcohol Antiseptic 80%  
Topical Solution • Hand Sanitizer

Non-sterile solution  
2 oz (60 ml)

Endless West • San Francisco, CA 94107

### Drug Facts

Active Ingredient[s]	Purpose
Alcohol 80% v/v.....	Antiseptic

**Use[s]:** 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.

**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 15-30°C (59-86°F)  
• Avoid freezing and excessive heat above 40°C (104°F)  
• You may report serious side effects to 2325 3rd St. #405, San Francisco, CA 94107

**Inactive Ingredients:** Glycerin, hydrogen peroxide, purified water

Expiration Date: 04/2023

375 mL NDC: 74065-001-07



# HAND SANITIZER

Spread joy, not germs.



Made in San Francisco by

## ENDLESS WEST

Alcohol Antiseptic 80%  
Topical Solution • Hand Sanitizer

Non-sterile solution  
12.7oz (375 ml)

Endless West • San Francisco, CA 94107

### Drug Facts

Active Ingredient[s]	Purpose
Alcohol 80% v/v.....	Antiseptic

**Use[s]:** 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.

**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 15-30°C (59-86°F) • Avoid freezing and excessive heat above 40°C (104°F) • You may report serious side effects to 2325 3rd St. #405, San Francisco, CA 94107

**Inactive Ingredients:** Glycerin, hydrogen peroxide, purified water

Expiration Date: 04/2023

## HAND SANITIZER

alcohol solution

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74065-001
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
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:74065-001-01	60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
2	NDC:74065-001-02	3785 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
3	NDC:74065-001-03	3785 mL in 1 POUCH; Type 0: Not a Combination Product	03/30/2020	
4	NDC:74065-001-04	208000 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
5	NDC:74065-001-05	1000000 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
6	NDC:74065-001-06	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
7	NDC:74065-001-07	375 mL in 1 BOTTLE; 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** - Ava Food Labs, Inc. (024506747)

### Establishment

Name	Address	ID/FEI	Business Operations
Ava Food Labs, Inc.		024506747	manufacture(74065-001) , pack(74065-001) , label(74065-001)

Revised: 3/2020

Ava Food Labs, Inc.