

## **HAND SANITIZER- alcohol liquid**

### **SVEDA Organics**

*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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### **Hand Sanitizer**

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.

### **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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### 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

glycerin, hydrogen peroxide, purified water USP

### Package Label - Principal Display Panel

**SVEDA LUXE**

**Hand Sanitizer Gel**

Moisturing  
Manufactured In The USA

8 fl oz / 237 mL

<b>Drug Facts</b>		<b>Drug Facts (continued)</b>
<b>Active ingredient[s]</b> Ethyl Alcohol 70% v/v.....	<b>Purpose</b> Antiseptic	<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>Use[s]</b> Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.		<b>Other information</b> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)
<b>Warnings</b> <b>For external use only. Flammable. Keep away from heat or flame</b>		<b>Inactive ingredients</b> Water, Acrylates Copolymer, Glycerin, Ethyl Palmate, Aminomethyl Propanol
<b>Do not use</b> • in children less than 2 months of age • on open skin wounds		MANUFACTURED FOR SVEDA ORGANICS INC. 1523 94TH LANE NE, BLAINE, MN 55449, USA INFO@SVEDAUSA.COM   WWW.SVEDAORGANICS.COM
<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.		

Manufactured for

**SVEDA®**  
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MN 55449.  
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www.svedaorganics.com

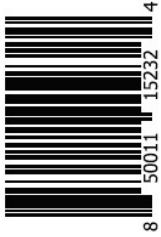


SVEDA KLENZ

Alcohol Antiseptic 80%  
Topical Solution

Hand Sanitizer  
Non-sterile Solution

1 Gallon / 3.8 L



**Drug Facts**

<b>Active ingredient[s]</b> Alcohol 80% v/v.....	<b>Purpose</b> .....Antiseptic
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<b>Inactive ingredients</b> glycerin, hydrogen peroxide, purified water USP	



SVEDA  
KLENZ

Alcohol Antiseptic 80%  
Topical Solution

Hand Sanitizer  
Non-sterile Solution

3.4 fl oz / 100 mL

**Drug Facts**

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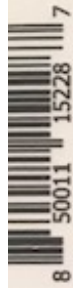
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SVEDA  
KLENZ

Alcohol Antiseptic 80%  
Topical Solution

**Hand Sanitizer**  
Non-sterile Solution

4 fl oz / 118 mL

### 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.

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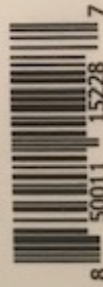
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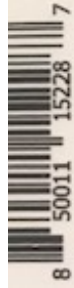
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**Inactive ingredients** glycerin, hydrogen peroxide, purified water USP

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Topical Solution

**Hand Sanitizer**  
Non-sterile Solution

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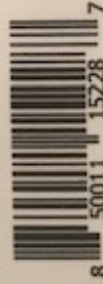
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KLENZ

Alcohol Antiseptic 80%  
Topical Solution

Hand Sanitizer  
Non-sterile Solution

8 fl oz / 237 mL

#### Drug Facts

Active ingredient(s)	Purpose
Alcohol 80% v/v	Antiseptic

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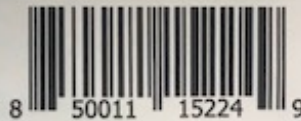
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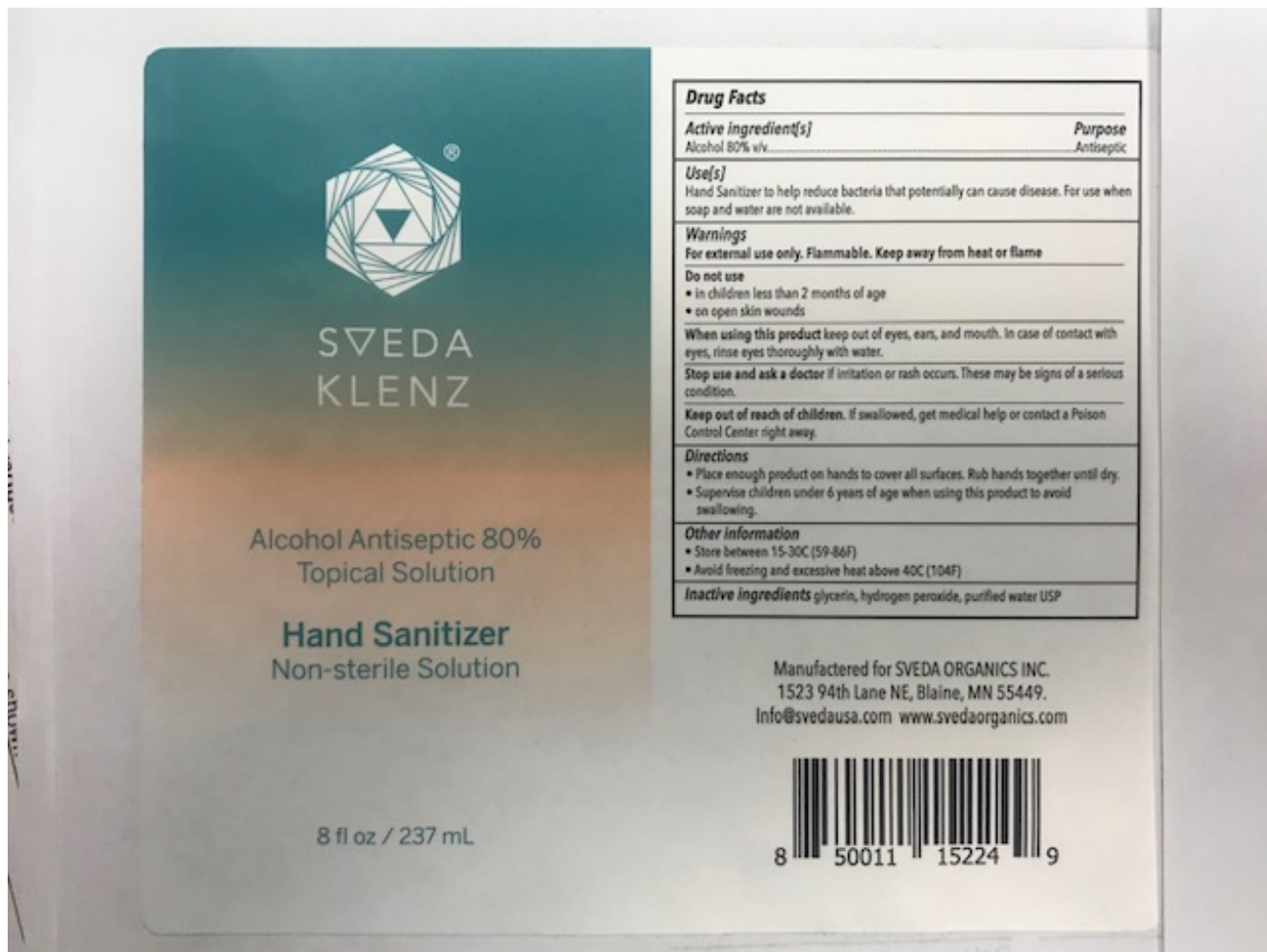
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## HAND SANITIZER

alcohol liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:74957-105
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
ETHYL PALMATE (UNII: PY7890FR5M)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
BUTYL ACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID CO POLYMER (18000 MW) (UNII: JZ1374NL9E)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74957-105-21	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/12/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/12/2020	

## HAND SANITIZER

alcohol liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74957-101
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:74957-101-25	237 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/02/2020	
2	NDC:74957-101-27	118 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/09/2020	
3	NDC:74957-101-26	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/07/2020	
4	NDC:74957-101-28	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/10/2020	
5	NDC:74957-101-24	100 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/22/2020	
6	NDC:74957-101-23	3800 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/28/2020	



## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

**Labeler** - SVEDA Organics (079951655)

## Establishment

Name	Address	ID/FEI	Business Operations
Evergreen Innovations LLC		024394560	manufacture(74957-101, 74957-105)

Revised: 6/2020

SVEDA Organics