

**EC PURE INSTANT CREAM HAND SANITIZER ZEN- alcohol cream**  
**Ec 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.*

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**Eveline Charles Pure Instant Cream Hand Sanitizer Zen**

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 63% w/w. Purpose: Antimicrobial

**Purpose**

Antimicrobial, Hand Sanitizer

**Use**

Eliminates bacteria and germs.

**Warnings**

Flammable. Keep away from open flame and sources of heat. This product is intended for external use only.

**Do not use**

Do not use in children less than 2 months of age and on open wounds.

When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water.

Stop use if irritation or redness develops and consult a doctor.

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

### **Directions**

Apply a small amount to hands and spread evenly.

Rub thoroughly into hands for at least 30 seconds.

Allow to dry.

For occasional and personal use.

Supervise children under 6 years of age when using this product.

### **Other information**

- Store between 59-86F
- Avoid freezing and excessive heat above 104F

### **Inactive ingredients**

glycerin, hydrogen peroxide, purified water USP

### **Package Label - Principal Display Panel**

ZEN



60g NDC:76555-005-01

## EC PURE INSTANT CREAM HAND SANITIZER ZEN

alcohol cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76555-005
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	37.8 g in 60 g

### Inactive Ingredients

Ingredient Name	Strength
AMMONIUM ACRYLOYLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED (45000 MPA.S) (UNII: Q7UI015FF9)	0.78 g in 60 g

<b>MANDARIN OIL</b> (UNII: NJO720F72R)	0.0048 g in 60 g
<b>ORANGE OIL</b> (UNII: AKN3KSD11B)	0.0744 g in 60 g
<b>LEMON OIL</b> (UNII: I9GRO824LL)	0.0036 g in 60 g
<b>CYCLOMETHICONE</b> (UNII: NMQ347994Z)	1.02 g in 60 g
<b>PEG/PPG-18/12 DIMETHICONE</b> (UNII: 2AY8NFX9E4)	5.1 g in 60 g
<b>SODIUM ACRYLOYLDIMETHYLTAURATE</b> (UNII: 2T9Q6EKI0G)	1.74 g in 60 g
<b>LAVENDER OIL</b> (UNII: ZBP1YXW0H8)	0.00132 g in 60 g
<b>POGOSTEMON CABLIN LEAF OIL</b> (UNII: F3IN55X5PO)	0.0064 g in 60 g
<b>CITRUS NOBILIS</b> (UNII: 8MFF77J91V)	0.0024 g in 60 g
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	0.3 g in 60 g
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	0.06 g in 60 g
<b>WATER</b> (UNII: 059QF0K00R)	13.09 g in 60 g
<b>ROSEWOOD OIL</b> (UNII: F2522O5L7B)	0.00192 g in 60 g
<b>CITRUS AURANTIUM FLOWER OIL</b> (UNII: D4BGE91OXH)	0.0064 g in 60 g

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76555-005-01	60 g in 1 TUBE; Type 0: Not a Combination Product	07/31/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/31/2020	

**Labeler** - Ec Labs Inc (205510751)

**Registrant** - Ec Labs Inc (205510751)

### Establishment

Name	Address	ID/FEI	Business Operations
Ec Labs Inc		205510751	manufacture(76555-005) , pack(76555-005) , sterilize(76555-005)