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.

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 iin 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 lease 30 secconds.

Allow to dry.

For occasional and personal use.

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

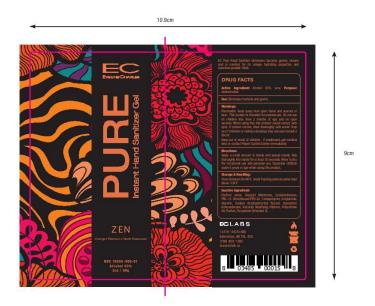
Other information

- Store between 59-86F
- Avoid freezing and excessive heat above104F

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel



60g NDC:76555-005-01

EC PURE INSTANT CREAM HAND SANITIZER ZEN

alcohol cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76555-005
Route of Administration	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
	0 00 10

MANDARIN OIL (UNII: NJO720F72R)	บ.บบ48 g in 60 g
ORANGE OIL (UNII: AKN3KSD11B)	0.0744 g in 60 g
LEMON OIL (UNII: 19GRO824LL)	0.0036 g in 60 g
CYCLOMETHICONE (UNII: NMQ347994Z)	1.02 g in 60 g
PEG/PPG-18/12 DIMETHICONE (UNII: 2AY8NFX9E4)	5.1 g in 60 g
SODIUM ACRYLOYLDIMETHYLTAURATE (UNII: 2T9Q6EKI0G)	1.74 g in 60 g
LAVENDER OIL (UNII: ZBP1YXW0H8)	0.00132 g in 60 g
POGOSTEMON CABLIN LEAF OIL (UNII: F3IN55X5PO)	0.0064 g in 60 g
CITRUS NOBILIS (UNII: 8MFF77J91V)	0.0024 g in 60 g
GLYCERIN (UNII: PDC6A3C0OX)	0.3 g in 60 g
TOCOPHEROL (UNII: R0ZB2556P8)	0.06 g in 60 g
WATER (UNII: 059QF0KO0R)	13.09 g in 60 g
ROSEWOOD OIL (UNII: F2522O5L7B)	0.00192 g in 60 g
CITRUS AURANTIUM FLOWER OIL (UNII: D4BGE910XH)	0.0064 g in 60 g

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	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	
Tinai			

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)

Revised: 1/2022 Ec Labs Inc