

EVELINECHARLES PURE PURIFYING HAND CREAM MAX- 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 Purifying Hand Cream Max

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, Purifying Hand Cream

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 skin 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.

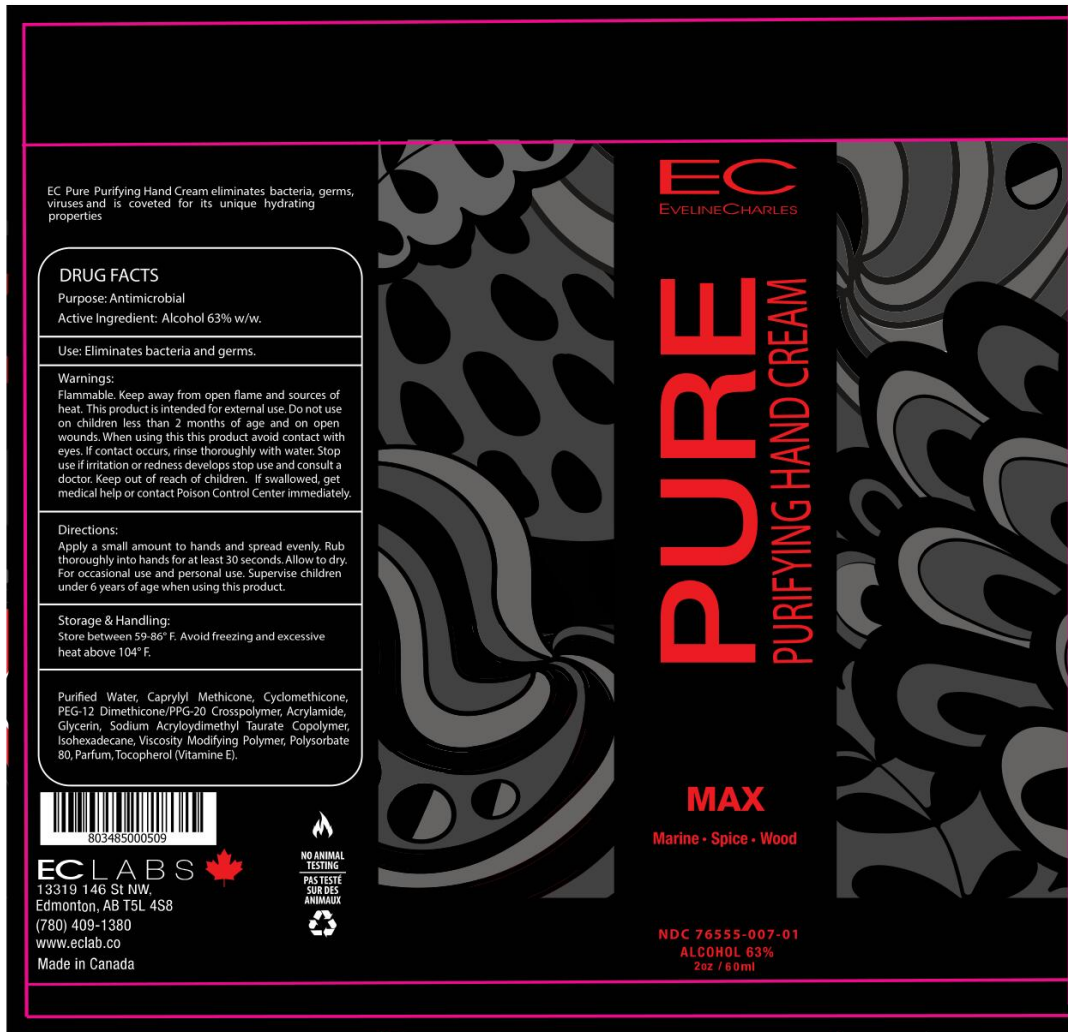
Other information

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

Inactive ingredients

glycerin, purified water USP

Package Label - Principal Display Panel



60g NDC: 76555-007-01

EVELINECHARLES PURE PURIFYING HAND CREAM MAX

alcohol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76555-007
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
GLYCERIN (UNII: PDC6A3C0OX)	0.29 g in 60 g
PEG/PPG 18/12 DIMETHICONE (UNII: 2AY8MEY9E4)	5.1 g

PEG/PPG-10/12 DIMETHICONE (UNII: ZAT0NFA9E4)	in 60 g
WATER (UNII: 059QF0KO0R)	13.14 g in 60 g
SODIUM ACRYLOYLDIMETHYLTAURATE (UNII: 2T9Q6EKI0G)	1.74 g in 60 g
AMMONIUM ACRYLOYLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED (45000 MPA.S) (UNII: Q7UI015FF9)	0.79 g in 60 g
TOCOPHEROL (UNII: R0ZB2556P8)	0.06 g in 60 g
2,6-DIMETHYL-5-HEPTENAL (UNII: Z331YX9EL9)	0.0012 g in 60 g
3-CARENE (UNII: H2M15SNR6N)	0.0012 g in 60 g
DIHYDROMYRCENOL (MIXED ISOMERS) (UNII: 7E6BIK8N98)	0.0036 g in 60 g
ETHYL LINALOOL (UNII: SF2JS9GF5T)	0.0012 g in 60 g
CEDRAMBER (UNII: 84S7T555CV)	0.0012 g in 60 g
CYMENE (UNII: 830CI19HHD)	0.0012 g in 60 g
LINALOOL, (+/-)- (UNII: D81QY6I88E)	0.0012 g in 60 g
CYCLOMETHICONE (UNII: NMQ347994Z)	1.02 g in 60 g
TETRAMETHYL ACETYLOCTAHYDRONAPHTHALENES (UNII: 2JU6ZH6GRE)	0.0072 g in 60 g
.BETA.-PINENE (UNII: 4MS8VHZ1HJ)	0.0012 g in 60 g
GERANIOL (UNII: L837108USY)	0.0012 g in 60 g
METHYL IONONES (UNII: EL78BGX1LO)	0.0012 g in 60 g
.ALPHA.-PINENE (UNII: JPF3YI7O34)	0.0012 g in 60 g
PENTADECALACTONE (UNII: OK17S3S98K)	0.0012 g in 60 g
BENZYL SALICYLATE (UNII: WAO5MKN9TU)	0.0024 g in 60 g
DIHYDRO PENTAMETHYLINDANONE (UNII: BZR4438MY4)	0.0024 g in 60 g
COUMARIN (UNII: A4VZ22K1WT)	0.0012 g in 60 g
LINALYL ACETATE (UNII: 5K47SSQ51G)	0.0024 g in 60 g
BOURGEONAL (UNII: H3XVS6E70V)	0.0012 g in 60 g
2-TERT-BUTYLCYCLOHEXYL ACETATE (UNII: 364FV60913)	0.0024 g in 60 g
LIMONENE, (+)- (UNII: GFD7C86Q1W)	0.0024 g in 60 g
.GAMMA.-TERPINENE (UNII: 4YGF4PQP49)	0.0012 g in 60 g
METHYL 3-METHYLORSELLINATE (UNII: 12YH9T04QE)	0.0012 g in 60 g
ALLYL CYCLOHEXANEBUTYRATE (UNII: 9JIF47RD7B)	0.0012 g in 60 g
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	0.0012 g in 60 g

3-(3,4-METHYLENEDIOXYPHENYL)-2-METHYLPROPANAL (UNII: L65EG8H6PA)	0.0024 g in 60 g
AMBREIN (UNII: 1N9JB373FJ)	0.0012 g in 60 g
CYCLOHEXANEPROPANOL, 2,2,6-TRIMETHYL-.ALPHA.-PROPYL- (UNII: CLV4EM4325)	0.0012 g in 60 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76555-007-01	60 g in 1 TUBE; Type 0: Not a Combination Product	10/28/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/28/2021	

Labeler - EC Labs Inc. (205510751)

Registrant - EC Labs Inc. (205510751)

Establishment

Name	Address	ID/FEI	Business Operations
EC Labs Inc.		205510751	manufacture(76555-007) , pack(76555-007) , label(76555-007)

Revised: 10/2021

EC Labs Inc.