

SERENE CLEAN AND PURE HAND SANITIZER GEL- ethanol gel

Serene Clean & Pure LLC

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.

Serene Clean & Pure Ethanol Gel Hand Sanitizer

Active ingredient

Ethyl Alcohol 65% v/v.

Purpose

Antiseptic

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.

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

Water, glycerin, carbomer, aloe

Package Label - Principal Display Panel

Serene Clean & Pure

Be Wise & Sanitize

Gel Hand Sanitizer

www.serenepure.com

(424) 329-2515

ABOUT

Serene Clean & Pure is a family owned company that believes in honest and helpful products.

Serene Clean & Pure is a quickly drying hand sanitizer that leaves hands feeling gentle and soft, while moisturizing them. Use as often as needed for a germ and bacteria free life

Manufactured by:

CALIFORNIA CHEMICAL

(424) 292-3424

Costa Mesa, CA 92626

www.calichemical.com

Drug Facts

Active Ingredient	Purpose
Ethyl alcohol 65% v/v	Antiseptic

Uses ■ 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 mouth. In case of contact with eyes, rinse eyes thoroughly with water.


Stop use and ask a doctor if irritation or rash occurs.

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 at room temperature 59-86°F (15-30°C)
 ■ Avoid freezing and excessive heat above 104°F (40°C)

Inactive ingredients Water, Glycerin, Carbomer, Aloe



Serene
CLEAN & PURE


BE WISE & SANITIZE



GEL HAND SANITIZER
www.serenepure.com
 (424) 329-2515
 NET CONTENTS: 128 fl. oz. (1-Gallon)

ABOUT
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 **MADE IN THE USA**
 USE BY: 01/2023

SERENE CLEAN AND PURE HAND SANITIZER GEL

ethanol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78643-300
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	65 mL in 100 mL
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Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78643-300-01	3785.41 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/05/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	11/05/2020	

Labeler - Serene Clean & Pure LLC (117539963)

Registrant - Serene Clean & Pure LLC (117539963)