

SERENE CLEAN AND PURE ANTIBACTERIAL HAND- benzalkonium chloride liquid
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 Antibacterial Hand Soap

Active ingredient

Benzalkonium Chloride 0.13%

Purpose

Antibacterial

Use

For handwashing to help reduce bacteria on the skin

Warnings

For external use only.

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 redness develops and condition persists for more than 72 hours.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Pump into wet hands and work into a lather for at least 15 seconds
- Rinse thoroughly and dry

Inactive ingredients

Water, EDTA, Glycerin, Sodium Dodecylbenzenesulfonate, Coco-betaine, Sodium Laureth Sulfate, Phenoxyethanol

Package Label - Principal Display Panel

Serene Clean & Pure

Kills 99.99% of Germs & Bacteria

Benzalkonium Chloride

Antibacterial Hand Soap

16 fl oz

www.serenepure.com

ABOUT

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

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

Distributed by:

Serene Clean & Pure

555 Anton Blvd. Suite 105

Costa Mesa, CA 92626



Serene
CLEAN & PURE

KILLS 99.99% OF
GERMS & BACTERIA



BENZALKONIUM CHLORIDE
ANTIBACTERIAL
HAND SOAP

16 oz (473ML)

Drug Facts	
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Warnings	
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Dist By:
California Chemical
555 Anton Blvd. Suite 105,
Costa Mesa, CA 92626

ABOUT

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SERENE CLEAN AND PURE ANTIBACTERIAL HAND

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78643-200
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM -	BENZALKONIUM	0.13 g

UNII:7N6JUD5X6Y)		CHLORIDE	in 100 mL	
Inactive Ingredients				
Ingredient Name			Strength	
GLYCERIN (UNII: PDC6A3C0OX)			1.45 mL in 100 mL	
WATER (UNII: 059QF0K00R)				
EDETIC ACID (UNII: 9G34HU7RV0)				
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)				
SODIUM DODECYLBENZENESULFONATE (UNII: 554127163Y)				
COCO-BETAINE (UNII: 03DH2IZ3FY)				
PHENOXYETHANOL (UNII: HIE492ZZ3T)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78643-200-01	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/09/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	07/09/2020		

Labeler - Serene Clean & Pure LLC (117539963)

Registrant - Serene Clean & Pure LLC (117539963)

Establishment

Name	Address	ID/FEI	Business Operations
Morgan Gallacher Inc.		028311595	manufacture(78643-200)

Revised: 7/2020

Serene Clean & Pure LLC