

SERENE CLEAN AND PURE HAND SANITIZER GEL- isopropyl alcohol 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 Gel Hand Sanitizer

Active ingredient

Isopropyl Alcohol 75% v/v. Purpose: Antiseptic

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, carbomer, glycerin

Package Label - Principal Display Panel

Serene Clean & Pure

Kills 99.9% of All Germs & Bacteria

Gel Hand Sanitizer

70% Isopropyl Alcohol

www.serenepure.com

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

Distributed by:

Serene Clean & Pure

555 Anton Blvd. Suite 105

Costa Mesa, CA 92626

2 fl. oz.

Drug Facts	
Active Ingredient	Purpose
Isopropyl alcohol 75% w/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 ■ on open skin wounds ■ in children less than 2 months of age	
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. These may be sign 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 8 years of age when using this product to avoid swallowing.	
Inactive Information ■ Store at room temperature 59-86°F (15-30°C) ■ Avoid freezing and excessive heat above 104°F (40°C)	
Other ingredients Water, Carbomer, Glycerin	

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

MADE IN THE USA

4 fl. oz.

7
28886
97770
3

Drug Facts	
Active Ingredient	Purpose
Isopropyl alcohol 75% 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 ■ on open skin wounds ■ in children less than 2 months of age	
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 These may be sign 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.	
Inactive information ■ Store at room temperature 59-86°F (15-30°C) ■ Avoid freezing and excessive heat above 104°F (40°C)	
Other ingredients Water, Carbomer, Glycerin	



Serene

CLEAN & PURE

KILLS 99.9% OF
GERMS & BACTERIA



GEL HAND SANITIZER

75% ISOPROPYL ALCOHOL
www.serenepure.com

Distributed by:
Serene Clean & Pure
555 Anton Blvd. Suite 105, Costa Mesa, CA 92626

NET CONTENTS: 4 oz. (118 mL)

ABOUT
Serene Clean & Pure is a family owned company that believes in honest and helpful products.
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MADE IN THE USA

8 fl. oz.

Drug Facts	
Active Ingredient	Purpose
Isopropyl alcohol 75% 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.	
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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, Carbomer, Glycerin	



Serene

CLEAN & PURE

KILLS 99.9% OF
GERMS & BACTERIA



GEL HAND SANITIZER

75% ISOPROPYL ALCOHOL
www.serenepure.com

NET CONTENTS: 8 fl. oz. (236 mL)

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



MADE IN THE USA

7
28886
97771
0

Distributed by:
Serene Clean & Pure
555 Anton Blvd.
Suite 105
Costa Mesa, CA 92626

10 fl. oz.

Drug Facts	
Active Ingredient	Purpose
Isopropyl alcohol 75% 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 These may be sign 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 at room temperature 59-86°F (15-30°C) ■ Avoid freezing and excessive heat above 104°F (40°C)	
Inactive ingredients Water, Carbomer, Glycerin	



Serene CLEAN & PURE

KILLS 99.9% OF
GERMS & BACTERIA



GEL
HAND SANITIZER

75% ISOPROPYL ALCOHOL

www.serenepure.com

NET CONTENTS: 10 fl. oz. (296 mL)

ABOUT
Serene Clean & Pure is a family owned company that believes in honest and helpful products.
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MADE IN THE USA



Distributed by:
Serene Clean & Pure
555 Anton Blvd, Suite 105
Costa Mesa, CA 92626

16 fl. oz.

Drug Facts	
Active Ingredient	Purpose
Isopropyl alcohol 75% 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.	
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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, Carbomer, Glycerin	



Serene CLEAN & PURE

KILLS 99.9% OF ALL
GERMS & BACTERIA



GEL
HAND SANITIZER
75% ISOPROPYL ALCOHOL

www.serenepure.com

NET CONTENTS: 16 fl. oz. (473 mL)

ABOUT
Serene Clean & Pure is a family owned company that believes in honest and helpful products.
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MADE IN THE USA



Distributed by:
Serene Clean & Pure
555 Anton Blvd, Suite 105
Costa Mesa, CA 92626

SERENE CLEAN AND PURE HAND SANITIZER GEL

isopropyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78643-110
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78643-110-02	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/08/2020	
2	NDC:78643-110-04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/08/2020	
3	NDC:78643-110-08	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/08/2020	
4	NDC:78643-110-10	296 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/08/2020	
5	NDC:78643-110-16	296 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/08/2020	
6	NDC:78643-110-01	3785.41 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/16/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/08/2020	

Labeler - Serene Clean & Pure LLC (117539963)**Registrant** - Serene Clean & Pure LLC (117539963)

Revised: 7/2020

Serene Clean & Pure LLC