

**SUN-KISSED SUNCREAM- octinoxate, octisalate, zinc oxide cream  
LEE & GEN GLOBAL CORPORATION**

*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.*

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**78493-001 Sun-Kissed Suncream**

OCTINOXATE 7.5%  
OCTISALATE 3.0%  
ZINC OXIDE 8.0%

Sunscreen

Helps prevent sunburn

For sunscreen use:

- apply liberally 15 minutes before sun exposure
- reapply: after 80 minutes of swimming or sweating, immediately after towel drying, at least every 2 hours.
- Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
  - limit time in the sun, especially from 10 a.m. - 2 p.m.
  - wear long-sleeved shirts, pants, hats and sunglasses
- children under 6 months of age: ask a doctor

For external use only.

Do not use on damaged or broken skin.

When using this product, keep out of eyes. Rinse with water to remove.

Stop using and ask a doctor if rash occurs.

Keep out of reach of the children. If product is swallowed, get medical help or contact a poison control center right away.

Water, Cyclopentasiloxane, Ethylhexyl Isononanoate, Butylene Glycol, Lauryl PEG-9 Polydimethylsiloxylethyl Dimethicone, Dimethicone, Phenoxyethanol, Sodium Chloride, Triethoxycaprylylsilane, Dimethicone/PEG-10/15 Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Iodopropynyl Butylcarbamate, Ascorbyl Palmitate, BHT, Retinyl Palmitate, Dipropylene Glycol, Zea Mays (Corn) Oil, Tocopherol

Protect the product in this container from excessive heat and direct sunlight

FILA

FILA

**HYDRATING + SOFTNESS  
NO WHITE CAST**

A fast-absorbing, lightweight sun cream. Creates a powerful shield to protect skin from the sun. Helps keep your skin smooth, soft, and healthy without leaving a white cast.

**Drug Facts**

Active Ingredients	Purpose
Octinoxate 7.5%	Sunscreen
Octisalate 3.0%	Sunscreen
Zinc Oxide 8.0%	Sunscreen

**Uses**

- helps prevent sunburn

**Warnings**

**For external use only**

**Do not use** on damaged or broken skin

**When using this product** keep out of eyes, Rinse with water to remove

**Stop use and ask a doctor** if rash occurs

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away

**Directions**

- apply liberally 15 minutes before sun exposure
- reapply:
  - after 80 minutes of swimming or sweating
  - immediately after towel drying
  - at least every 2 hours
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
  - limit time in the sun, especially from 10 a.m. - 2 p.m.
  - wear long-sleeved shirts, pants, hats, and sunglasses
  - children under 6 months of age: Ask a doctor

**Other information**

protect the product in this container from excessive heat and direct sun

**Inactive Ingredients**

Water, Cyclopentasiloxane, Ethylhexyl Isononanoate, Butylene Glycol, Lauryl PEG-9 Polydimethylsiloxethyl Dimethicone, Dimethicone, Phenoxyethanol, Sodium Chloride, Triethoxycaprylylsilane, Dimethicone/PEG-10/15 Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Iodopropynyl Butylcarbamate, Ascorbyl Palmitate, BHT, Retinyl Palmitate, Dipropylene Glycol, Zea Mays (Corn) Oil, Tocopherol

Distributed by I-World Co, Cerritos, CA 90703, USA  
www.iworldus.com



Made in USA with thoughtfully sourced global ingredients and materials.

Skin that fits YOU



**SUN-KISSED  
SUN  
CREAM**

SUNSCREEN  
BROAD SPECTRUM SPF 40  
WATER RESISTANT  
(80 MINUTES)

FOR FACE

88,7 ml / 3,0 oz



PARABENS  
FREE



PHTHALATES  
FREE



OXYBENZONE  
FREE



FRAGRANCE  
FREE



BROAD  
SPECTRUM  
SPF 40



WATER  
RESISTANT  
80 MIN

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# SUN-KISSED SUNCREAM

octinoxate, octisalate, zinc oxide cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78493-001
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	8 g in 100 mL
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	3 g in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)	
<b>ETHYLHEXYL ISONONANOATE</b> (UNII: I6KB4GE3K4)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE</b> (UNII: 25G622K2RA)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>DIMETHICONE/PEG-10/15 CROSSPOLYMER</b> (UNII: 21AS8B1BSS)	
<b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (HARD PARTICLE)</b> (UNII: H895X08VNQ)	
<b>IODOPROPYNYL BUTYLCARBAMATE</b> (UNII: 603P14DHEB)	
<b>ASCORBYL PALMITATE</b> (UNII: QN83US2B0N)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>VITAMIN A PALMITATE</b> (UNII: 1D1K0N0VVC)	
<b>DIPROPYLENE GLYCOL</b> (UNII: E107L85C40)	
<b>CORN OIL</b> (UNII: 8470G57WFM)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78493-001-02	1 in 1 CARTON	05/04/2022	
1	NDC:78493-001-01	88.7 mL in 1 TUBE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	05/04/2022	

**Labeler** - LEE & GEN GLOBAL CORPORATION (038129947)

**Registrant** - LEE & GEN GLOBAL CORPORATION (038129947)

## Establishment

Name	Address	ID/FEI	Business Operations
Swiss-American CDMO, LLC		080170933	manufacture(78493-001)

Revised: 5/2022

LEE & GEN GLOBAL CORPORATION