

**CERAVE DEVELOPED WITH DERMATOLOGISTS HYDRATING SUNSCREEN SPF 50  
BODY LIGHTWEIGHT, NON-GREASY FEEL 3 ESSENTIAL CERAMIDES MINERAL  
SUNSCREEN- titanium dioxide and zinc oxide lotion  
L'Oreal USA Products 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.*

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**Drug Facts**

**Active ingredients**

Titanium dioxide 9%

Zinc oxide 7%

**Purpose**

Sunscreen

**Uses**

- Helps prevent sunburn
- If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun

**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**

For sunscreen use:

- apply liberally 15 minutes before sun exposure
- reapply at least every 2 hours
- use a water resistant sunscreen if swimming or sweating

- 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:
  - o limit time in the sun, especially from 10 a.m. – 2 p.m.
  - o 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, glycerin, C12-15 alkyl benzoate, dimethicone, isododecane, styrene/acrylates copolymer, glyceryl stearate, butyloctyl salicylate, dicaprylyl carbonate, propanediol, stearic acid, aluminum hydroxide, PEG-100 stearate, sorbitan stearate, PEG-8 laurate, ceramide NP, ceramide AP, ceramide EOP, sorbitan isostearate, carbomer, cetaryl alcohol, cetearth-20, triethoxycaprylylsilane, dimethiconol, sodium citrate, sodium lauroyl lactylate, sodium dodecylbenzenesulfonate, myristic acid, sodium hyaluronate, cholesterol, palmitic acid, phenoxyethanol, chlorphenesin, tocopherol, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, caprylyl glycol, citric acid, xanthan gum, phytosphingosine, polyhydroxystearic acid, polysorbate 60, ethylhexylglycerin

### **Questions or comments?**

Toll-free number 1-888-768-2915

NEW

CeraVe®

DEVELOPED WITH DERMATOLOGISTS

Hydrating  
Sunscreen  
BROAD SPECTRUM SPF 50

50 BODY

Lightweight, non-greasy feel

3 essential ceramides

MINERAL SUNSCREEN

5 FL OZ (150 mL)



Hydrating Sunscreen BROAD SPECTRUM SPF 50

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**Questions or comments?**

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CeraVe® LLC, New York, NY 10001  
Made in USA of US and/or Imported Ingredients  
www.cerave.com

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titanium dioxide and zinc oxide lotion

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49967-911
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	90 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	70 mg in 1 mL

## Inactive Ingredients

	Ingredient Name	Strength
	<b>WATER</b> (UNII: 059QF0KO0R)	
	<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
	<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
	<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
	<b>ISODODECANE</b> (UNII: A8289P68Y2)	
	<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
	<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
	<b>DICAPRYLYL CARBONATE</b> (UNII: 609A3V1SUA)	
	<b>PROPANEDIOL</b> (UNII: 5965N8W85T)	
	<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
	<b>ALUMINUM HYDROXIDE</b> (UNII: 5QB0T2IUN0)	
	<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)	
	<b>SORBITAN MONOSTEARATE</b> (UNII: NVZ4I0H58X)	
	<b>PEG-8 LAURATE</b> (UNII: 762O8IWA10)	
	<b>CERAMIDE NP</b> (UNII: 4370DF050B)	
	<b>CERAMIDE AP</b> (UNII: F1X8L2B00J)	
	<b>CERAMIDE 1</b> (UNII: 5THT33P7X7)	
	<b>SORBITAN ISOSTEARATE</b> (UNII: 01S2G2C1E4)	
	<b>CARBOXYPOLYMETHYLENE</b> (UNII: 0A5MM307FC)	
	<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
	<b>POLYOXYL 20 CETOSTEARYL ETHER</b> (UNII: YRC528SWUY)	
	<b>TRIETHOXYCAPRYLSILANE</b> (UNII: LDC331P08E)	
	<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
	<b>SODIUM LAUROYL LACTYLATE</b> (UNII: 7243K85WFO)	
	<b>SODIUM DODECYLBENZENESULFONATE</b> (UNII: 554127163Y)	
	<b>MYRISTIC ACID</b> (UNII: 0IBV7S25AW)	
	<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)	
	<b>CHOLESTEROL</b> (UNII: 97C5T2UQ7J)	
	<b>PALMITIC ACID</b> (UNII: 2V16EO95HI)	
	<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
	<b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)	
	<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
	<b>HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPAS AT 1%)</b> (UNII: 86FQE96TZ4)	
	<b>caprylyl glycol</b> (UNII: 00YIU5438U)	
	<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
	<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
	<b>PHYTOSPHINGOSINE</b> (UNII: GIN46U9Q2Q)	
	<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)	
	<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)	
	<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-911-01	1 in 1 CARTON	02/01/2019	

1	150 mL in 1 TUBE; Type 0: Not a Combination Product		
<b>Marketing Information</b>			
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part352	02/01/2019	

**Labeler** - L'Oreal USA Products Inc (002136794)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
L'OREAL USA PRODUCTS, INC.		624244349	manufacture(49967-911)

Revised: 12/2018

L'Oreal USA Products Inc