# SKINCEUTICALS DAILY BRIGHTENING UV DEFENSE BROAD SPECTRUM SPF 30 SUNSCREEN- avobenzone, homosalate, octisalate and octocrylene lotion L'Oreal USA Products Inc

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#### **Drug Facts**

#### **Active ingredients**

Avobenzone 3%

Homosalate 5%

Octisalate 5%

Octocrylene 7.2%

#### **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**

- 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:

- 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

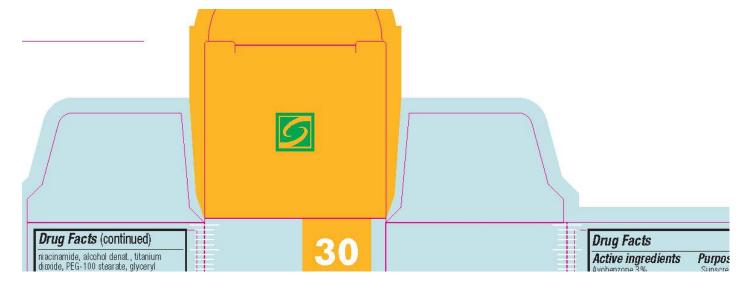
#### **Inactive ingredients**

water, glycerin, silica, dimethicone, niacinamide, alcohol denat., titanium dioxide, PEG-100 stearate, glyceryl stearate, mica, tranexamic acid, stearic acid, phenoxyethanol, citric acid, palmitic acid, ammonium polyacryloyldimethyl taurate, hydroxyacetophenone, dicaprylyl carbonate, steareth-100, phenylethyl resorcinol, caprylyl glycol, xanthan gum, dimethicone/vinyl dimethicone crosspolymer, trisodium ethylenediamine disuccinate, synthetic fluorphlogopite, tocopherol, sodium hyaluronate, cymbopogon schoenanthus oil, citral, myristic acid, iron oxides, tin oxide, geraniol, limonene, linalool, citronellol

#### Questions or comments?

Call 1-800-811-1660

Monday - Friday (9 a.m. - 5 p.m. CST)



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855345 55 (CODE F.L.: D269624/1)

#### SKINCEUTICALS'

Skin Ceuticals LLC, Dallas, TX 75241 Made in USA of US and/or Imported Ingredients w.skjnæuticals.com



SKINCEUTICALS

PROTECT

#### DAILY BRIGHTENING UV DEFENSE SUNSCREEN

BROAD SPECTRUM SPF 30

**BRIGHTENS AND EVENS SKIN TONE** 

LOTION

30 ml / 1 fl oz

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Octocrylene 7.2%	Sunscre

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water, glycerin, silica, dimethicone,







#### Drug Facts (continued)

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avobenzone, homosalate, octisalate and octocrylene lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-861
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	50 mg in 1 mL	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	72 mg in 1 mL	

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
NIACINAMIDE (UNII: 25X5118RD4)	
ALCOHOL (UNII: 3K9958V90M)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PEG-100 STEARATE (UNII: YD01N1999R)	
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)	
MICA (UNII: V8A1AW0880)	
TRANEXAMIC ACID (UNII: 6T84R30KC1)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
PALMITIC ACID (UNII: 2V16EO95H1)	
AMMONIUM POLYACRYLOYLDIMETHYL TAURATE (55000 MPA.S) (UNII: F01RIY4371)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
STEARETH-100 (UNII: 4OH5W9UM87)	
PHENYLETHYL RESORCINOL (UNII: G37UFG1620)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
XANTHAN GUM (UNII: TTV12P4NEE)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
TRISODIUM ETHYLENEDIAMINE DISUCCINATE (UNII: YA22H34H9Q)	
TOCOPHEROL (UNII: R0ZB2556P8)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	

CYMBOPOGON SCHOENANTHUS OIL (UNII: XE7K568ILO)	
CITRAL (UNII: T7EU0O9VPP)	
MYRISTIC ACID (UNII: 013V7S25AW)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
STANNIC OXIDE (UNII: KM7N50LOS6)	
GERANIOL (UNII: L837108USY)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.BETACITRONELLOL, (R)- (UNII: P010UT964K)	

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-861- 01	1 in 1 CARTON	04/01/2021	
1		30 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:49967-861- 02	4 mL in 1 TUBE; Type 0: Not a Combination Product	04/01/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	04/01/2021	

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

Establishment				
Name	Address	ID/FEI	Business Operations	
Englewood Lab, Inc.		172198223	manufacture(49967-861)	

Revised: 12/2023 L'Oreal USA Products Inc