

**SHISEIDO EXTRA SMOOTH SUN PROTECTION N- octinoxate, octocrylene, and zinc oxide lotion**

**SHISEIDO AMERICAS 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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**SHISEIDO EXTRA SMOOTH SUN PROTECTION LOTION N**

***Drug Facts***

<b><i>ACTIVE INGREDIENTS:</i></b>	<b><i>Purpose</i></b>
OCTINOXATE 4.9%	Sunscreen
OCTOCRYLENE 3.0%	Sunscreen
ZINC OXIDE 12.5%	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 product is swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

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 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-sleeve shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

**Inactive Ingredients**

DIMETHICONE, WATER, DIPROPYLENE GLYCOL, ETHYLHEXYL PALMITATE, SD ALCOHOL 40-B, PEG-10 DIMETHICONE, TALC, POLYBUTYLENE GLYCOL/PPG-9/1

COPOLYMER, TRIMETHYLSILOXYSILICATE, XYLITOL, GLYCERIN, PEG-9  
POLYDIMETHYLSILOXYETHYL DIMETHICONE, METHYL GLUCETH-10, SCUTELLARIA  
BAICALENSIS ROOT EXTRACT, ECTOIN, ISOSTEARIC ACID, HYDROGEN DIMETHICONE,  
DISTEARDIMONIUM HECTORITE, BUTYLENE GLYCOL, CALCIUM STEARATE, TRISODIUM  
EDTA, ALUMINA, BHT, TRIETHOXYCAPRYLYLSILANE, SYZYGIUM JAMBOS LEAF  
EXTRACT, TOCOPHEROL, PHENOXYETHANOL, FRAGRANCE, TITANIUM DIOXIDE,

**Other information**

- protect this product in this container from excessive heat and direct sun.

**Questions or comments?**

Call toll free 1-800-906-7503

SHISEIDO AMERICA INC.  
NEW YORK, N.Y. 10022

SHISEIDO DIST.  
NEW YORK • PARIS • MILANO

**PRINCIPAL DISPLAY PANEL - 100 mL Bottle Carton**

**SHISEIDO**  
**GINZA TOKYO**

Extra Smooth  
Sun Protection Lotion N

**38**

BROAD SPECTRUM  
SPF 38

For Face/Body

WATER RESISTANT  
(80 MINUTES)

SUNSCREEN

100mL 3.3 FL. OZ.



## SHISEIDO EXTRA SMOOTH SUN PROTECTION N

octinoxate, octocrylene, and zinc oxide lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58411-349
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	5424 mg in 110.7 g
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	3321 mg in 110.7 g

ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	13.84 g in 110.7 g
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### Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	
WATER (UNII: 059QF0K00R)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
TALC (UNII: 7SEV7J4R1U)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
XYLITOL (UNII: VCQ006KQ1E)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYL GLUCETH-10 (UNII: N0MWT4C7WH)	
SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S)	
ECTOINE (UNII: 7GXZ3858RY)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CALCIUM STEARATE (UNII: 776XM7047L)	
EDETATE TRISODIUM (UNII: 420IP921MB)	
ALUMINUM OXIDE (UNII: LM26O6933)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)	
SYZYGIUM JAMBOS LEAF (UNII: 407Z4W5LFF)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-349-10	1 in 1 CARTON	02/01/2013	
1		110.7 g in 1 BOTTLE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	02/01/2013	

**Labeler** - SHISEIDO AMERICAS CORPORATION (193691821)

### Establishment

Name	Address	ID/FEI	Business Operations
SHISEIDO AMERICA INC.		782677132	MANUFACTURE(58411-349) , ANALYSIS(58411-349)

