

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

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.

SHISEIDO EXTRA SMOOTH SUN PROTECTION CREAM N

Drug Facts

<i>ACTIVE INGREDIENTS:</i>	<i>Purpose</i>
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

WATER, ISODODECANE, BUTYLENE GLYCOL, CYCLOMETHICONE, DIMETHICONE, POLYMETHYL METHACRYLATE, LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL

DIMETHICONE, GLYCERIN, SD ALCOHOL 40-B, DISTEARDIMONIUM HECTORITE, XYLITOL, METHYL GLUCETH-10, SCUTELLARIA BAICALENSIS ROOT EXTRACT, ONONIS SPINOSA ROOT EXTRACT, ECTOIN, HYDROGENATED POLYDECENE, HYDROGEN DIMETHICONE, ISOSTEARIC ACID, TRISODIUM EDTA, SILICA, PEG-150, POLYBUTYLENE GLYCOL/PPG-9/1 COPOLYMER, 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 - 50 mL Tube Carton

SHISEIDO
GINZA TOKYO

Extra Smooth
Sun Protection Cream_N

38

BROAD SPECTRUM
SPF 38

For Face

WATER RESISTANT
(80 MINUTES)

SUNSCREEN

50mL NET WT. 2 OZ.



SHISEIDO EXTRA SMOOTH SUN PROTECTION N

octinoxate, octocrylene, and zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-348
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2766 mg in 56.45 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	1694 mg in 56.45 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	7056 mg in 56.45 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISODODECANE (UNII: A8289P68Y2)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERIN (UNII: PDC6A3C0OX)	
XYLITOL (UNII: VCQ006KQ1E)	
METHYL GLUCETH-10 (UNII: N0MWT4C7WH)	
SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S)	
ONONIS SPINOSA ROOT (UNII: FD2FMC53M1)	
ECTOINE (UNII: 7GXZ3858RY)	
HYDROGENATED POLYDECENE (550 MW) (UNII: U333RI6EB7)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
EDETATE TRISODIUM (UNII: 420IP921MB)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLYETHYLENE GLYCOL 7000 (UNII: Q0JET65GEL)	
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:58411-348-60	1 in 1 CARTON	02/01/2013	
1		56.45 g 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 NOT FINAL	part352	02/01/2013	

Establishment

Name	Address	ID/FEI	Business Operations
SHISEIDO AMERICA INC.		782677132	MANUFACTURE(58411-348) , ANALYSIS(58411-348)

Revised: 12/2019

SHISEIDO AMERICAS CORPORATION