

SHISEIDO WASO COLOR-SMART DAY MOISTURIZER OIL-FREE- octinoxate and titanium dioxide emulsion

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 WASO COLOR-SMART DAY MOISTURIZER OIL-FREE

Drug Facts

Active ingredients	Purpose
OCTINOXATE 7.4%	Sunscreen
TITANIUM DIOXIDE 5.3%	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.

Flammable. Do not use near heat, flame, or while smoking.

Directions

For sunscreen use:

- apply liberally 15 minutes before sun exposure
- use a water resistant sunscreen if swimming or sweating
- reapply 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·CYCLOPENTASILOXANE·SD ALCOHOL 40-B GLYCERIN·METHYL METHACRYLATE CROSSPOLYMER·DIMETHICONE·PEG-10 DIMETHICONE·POLYBUTYLENE GLYCOL/PPG-9/1 COPOLYMER·LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE·POLYMETHYLSILSESQUIOXANE·TALC·ERYTHRITOL·SILICA·TREHALOSE·DISTEARDIMONIUM HECTORITE·TRIMETHYLSILOXYSILICATE·CAFFEINE·BETAINE·PEG/PPG-17/4 DIMETHYL ETHER·PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE·DIPEPTIDE-15·ERIOBOTRYA JAPONICA LEAF PROTOPLASTS·PAEONIA ALBIFLORA ROOT EXTRACT·LAMIAM ALBUM FLOWER/LEAF/STEM EXTRACT·CITRUS JUNOS SEED EXTRACT·ERIOBOTRYA JAPONICA LEAF EXTRACT·ALUMINUM HYDROXIDE·STEARIC ACID ISOSTEARIC ACID·BUTYLENE GLYCOL·TRISODIUM EDTA·POLYESTER-1 ALCOHOL·SILICA DIMETHYL SILYLATE·ALUMINA·TRIETHOXYCAPRYLYLSILANE HYDROGEN DIMETHICONE·BHT·TOCOPHEROL·PHENOXYETHANOL·BENZOIC

ACID·FRAGRANCE TITANIUM DIOXIDE IRON OXIDES MICA·

Other Information

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

Questions or Comments?

Call toll free 1-800-906-7503

PRINCIPAL DISPLAY PANEL - 50 mL Tube Carton

WASO

SHISEIDO

GINZA TOKYO

COLOR-SMART

DAY MOISTURIZER

OIL-FREE

BROAD SPECTRUM

SPF 30

SUNSCREEN

50mL NET WT. 1.9 OZ.

SHISEIDO WASO
COLOR-SMART DAY MOISTURIZER
OIL-FREE



COLOR-SMART DAY MOISTURIZER OIL-FREE. A SKIN-BRIGHTENING DAY MOISTURIZER WITH WHOLE LOQUAT LEAF CELLS. ADEPTLY CHANGES COLOR TO ENHANCE YOUR SKIN TONE. FOR A MATTE, HEALTHY-LOOKING GLOW. APPLY MORNING AFTER CLEANSER. TAKE AN APPROPRIATE AMOUNT AND SMOOTH EVENLY OVER ENTIRE FACE. SPECIALLY FORMULATED BY SHISEIDO LABORATORIES, JAPAN. FOR ALL SKIN TYPES INCLUDING SENSITIVE. NON-COMEDOGENIC. DERMATOLOGIST-TESTED. ANTI-POLLUTION.

Drug Facts

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Drug Facts (continued)

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 WATER, CYCLOPENTASILOXANE, SD ALCOHOL 40-B, GLYCERIN, METHYL METHACRYLATE, CROSPOLYMER, DIMETHICONE, PEG-10 DIMETHICONE, POLYBUTYLENE GLYCOL/PPG-9/1 COPOLYMER, LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE, POLYMETHYLSILSESQUOXANE-TALC, ERYTHRITOL, SILICA-TREHALOSE, DISTEARDIMONIUM HECTORITE, TRIMETHYLSILOXYSILICATE-CAFFEINE, BETAINES-PEG/PPG-17/4, DIMETHYL ETHER, PHYTOSTERYL OCTYLDODECYL LAUROYL GLUTAMATE, DIPEPTIDE-15, ERIOBOTRYA JAPONICA LEAF PROTOPLASTS, PAEONIA ALBIFLORA ROOT EXTRACT, LAMUM ALBUM FLOWER/LEAF/STEM EXTRACT, CITRUS JUNOS SEED EXTRACT, ERIOBOTRYA JAPONICA LEAF EXTRACT, ALUMINUM HYDROXIDE-STEARIC ACID ISOSTEARIC ACID-BUTYLENE GLYCOL-TRISODIUM EDTA-POLYESTER-1, ALCOHOL, SILICA DIMETHYL SILYLATE, ALUMINA-TRIETHOXYCARBYL SILANE, HYDROGEN DIMETHICONE 8HT, TOCOPHEROL, PHENOXYETHANOL, BENZOIC ACID, FRAGRANCE, TITANIUM DIOXIDE, IRON OXIDES, MICA.

Other Information

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WASO
SHISEIDO
GINZA TOKYO

COLOR-SMART
DAY MOISTURIZER
OIL-FREE
BROAD SPECTRUM
SPF 30
SUNSCREEN

50mL NET WT. 1.9 OZ.

<http://1802.com/3963AA>
See our website for more information

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SHISEIDO AMERICAS CORPORATION DIST.
NEW YORK, NY 10017
MADE IN U.S.A.
G.L.O. 13963
www.shiseido.com

13963-42-5040
AAB

41 X 41 X 135

NS 1 2 3 4 5 6 7 8 9 0



SHISEIDO WASO COLOR-SMART DAY MOISTURIZER OIL-FREE

octinoxate and titanium dioxide emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-457
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Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	4177 mg in 50 mL	
	TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2992 mg in 50 mL	
Inactive Ingredients				
	Ingredient Name	Strength		
	WATER (UNII: 059QF0KO0R)			
	CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)			
	GLYCERIN (UNII: PDC6A3C0OX)			
	METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: 657L0NC5MT)			
	DIMETHICONE (UNII: 92RU3N3Y1O)			
	PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)			
	LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)			
	POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)			
	TALC (UNII: 7SEV7J4R1U)			
	ERYTHRITOL (UNII: RA96B954X6)			
	SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
	TREHALOSE (UNII: B8WCK70T7I)			
	DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)			
	TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)			
	CAFFEINE (UNII: 3G6A5W338E)			
	BETAINE (UNII: 3SCV180C9W)			
	PEG/PPG-17/4 DIMETHYL ETHER (UNII: 4ET18WJG5K)			
	PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE (UNII: 65954KGO9Q)			
	DIGLYCINE (UNII: 10525P22U0)			
	PAEONIA LACTIFLORA ROOT (UNII: 3Z3866YW6P)			
	LAMIUM ALBUM FLOWERING TOP (UNII: T95771X2XI)			
	CITRUS JUNOS SEED (UNII: UY43O1Q45N)			
	ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)			
	STEARIC ACID (UNII: 4ELV7Z65AP)			
	ISOSTEARIC ACID (UNII: X33R8U0062)			
	BUTYLENE GLYCOL (UNII: 3XUS85K0RA)			
	EDETATE TRISODIUM (UNII: 420IP921MB)			
	ALCOHOL (UNII: 3K9958V90M)			
	SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)			
	ALUMINUM OXIDE (UNII: LMI26O6933)			
	TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)			
	HYDROGEN DIMETHICONE (13 CST) (UNII: 4QGR4P2YOI)			
	BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)			
	.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)			
	PHENOXYETHANOL (UNII: HIE492ZZ3T)			
	BENZOIC ACID (UNII: 8SKN0B0MIM)			
	FERRIC OXIDE RED (UNII: 1K09F3G675)			
	FERRIC OXIDE YELLOW (UNII: EX438O2MRT)			
	FERROSFERRIC OXIDE (UNII: XM0M87F357)			
	MICA (UNII: V8A1AW0880)			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-457-60	1 in 1 CARTON	02/01/2019	
1		50 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	02/01/2019	

Labeler - SHISEIDO AMERICAS CORPORATION (193691821)

Establishment

Name	Address	ID/FEI	Business Operations
SHISEIDO AMERICA INC.		782677132	MANUFACTURE(58411-457) , ANALYSIS(58411-457)

Revised: 11/2018

SHISEIDO AMERICAS CORPORATION