

SHISEIDO WASO COLOR-SMART DAY MOISTURIZER- octinoxate and titanium dioxide 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 WASO COLOR-SMART DAY MOISTURIZER

Drug Facts

Active ingredients	Purpose
OCTINOXATE 7.4%	Sunscreen
TITANIUM DIOXIDE 4.2%	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·DIMETHICONE·GLYCERIN·SD ALCOHOL 40-B·PENTAERYTHRITYL TETRAETHYLHEXANOATE·PEG-9 POLYDIMETHYLSILOXYETHYL

DIMETHICONE·TRISOSTEARIN·METHYL METHACRYLATE
CROSSPOLYMER·HYDROGENATED POLYDECENE·DIPROPYLENE
GLYCOL·DISTEARDIMONIUM HECTORITE·ERYTHRITOL·SILICA·TREHALOSE·PEG-6·PEG-
32·CAFFEINE·BETAIN·PEG/PPG-17/4 DIMETHYL ETHER·DIPEPTIDE-
15·PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE·PAEONIA ALBIFLORA ROOT
EXTRACT·LAMIUM ALBUM FLOWER/LEAF/STEM EXTRACT·DAUCUS CAROTA SATIVA
(CARROT) ROOT PROTOPLASTS·CITRUS JUNOS SEED EXTRACT·PPG-17·ALUMINUM
HYDROXIDE·STEARIC ACID·ISOSTEARIC ACID·TRISODIUM EDTA·BUTYLENE
GLYCOL·POLYESTER-1·ALCOHOL·SILICA DIMETHYL
SILYLATE·BHT·ALUMINA·TRIETHOXYCAPRYLYLSILANE·SODIUM
METABISULFITE·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

SHI SEIDO

GINZA TOKYO

COLOR-SMART

DAY MOISTURIZER

BROAD SPECTRUM

SPF 30

SUNSCREEN

50mL NET WT. 1.8 OZ.

41 X 41 X 135

1 2 3 4 5 6 7 8 9 0



Drug Facts

Active ingredients Purpose

OCTINOXATE 7.4% Sunscreen
TITANIUM DIOXIDE 4.2% ... 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

Drug Facts (continued)

Inactive ingredients

WATER-DIMETHICONE-GLYCERIN-SD ALCOHOL 40-B-PENTAERYTHRITYL-TETRAETHYLHEXANOATE-PEG-8 POLYDIMETHYLSILOXYETHYL-DIMETHICONE-TRISOSTEARIN-METHYL METHACRYLATE-CROSSPOLYMER-HYDROGENATED POLYDECENE-DIPROPYLENE GLYCOL-DISTEARDIMONIUM HECTORITE-ERYTHRITOL-SILICA-TREHALOSE-PEG-8-PEG-32-CAFFEINE-BETAINE-PEG/PPG-17/4 DIMETHYL ETHER-DIPEPTIDE-15-PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE-PAEONIA ALBIFLORA ROOT EXTRACT-LAMUN ALBUM FLOWER/LEAF/STEM EXTRACT-DAUCUS CAROTA SATIVA (CARROT) ROOT PROTOPLASTS-CITRUS JUNOS SEED EXTRACT-PPG-17-ALUMINUM HYDROXIDE-STEARIC ACID-ISOSTEARIC ACID-TRISODIUM EDTA-BUTYLENE GLYCOL-POLYESTER-1-ALCOHOL-SILICA DIMETHYL Silylate-BHT-ALUMINA-TRIETHOXYCAPRYLYLSILANE-SODIUM METABISULFITE-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 1-800-806-7503



SHISEIDO WASO
COLOR-SMART DAY MOISTURIZER



WASO
SHISEIDO
GINZA TOKYO

COLOR-SMART
DAY MOISTURIZER
BROAD SPECTRUM
SPF 30
SUNSCREEN

50mL NET WT. 1.8 OZ.

COLOR-SMART DAY MOISTURIZER. A SKIN-BRIGHTENING DAY MOISTURIZER WITH WHOLE CARROT CELLS, ADEPTLY CHANGES COLOR TO ENHANCE YOUR SKIN TONE, FOR LONG LASTING HYDRATION AND A 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.

<http://s1872.com/13862AA>
See our website for more information.

7 30852 13962 6

SHISEIDO AMERICAS CORPORATION DIST.
NEW YORK, NY 10022
MADE IN U.S.A.
GLO. 13962
www.shiseido.com

13962-41-5040
AAA

SHISEIDO WASO COLOR-SMART DAY MOISTURIZER

octinoxate and titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-342
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3955 mg in 50 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2245 mg in 50 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERIN (UNII: PDC6A3C0OX)	
PENTAERYTHRITYL TETRAETHYLHEXANOATE (UNII: XJ7052W897)	
PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: TYP81E471F)	
TRISOSTEARIN (UNII: 71503RH8KG)	
HYDROGENATED POLYDECENE (550 MW) (UNII: U333RI6EB7)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
ERYTHRITOL (UNII: RA96B954X6)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TREHALOSE (UNII: B8WCK70T7I)	
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	
CAFFEINE (UNII: 3G6A5W338E)	
BETAINE (UNII: 3SCV180C9W)	
PEG/PPG-17/4 DIMETHYL ETHER (UNII: 4ET18WJG5K)	
DIGLYCINE (UNII: 10525P22U0)	
PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE (UNII: 65954KGO9Q)	
PAEONIA LACTIFLORA ROOT (UNII: 3Z3866YW6P)	
LAMIUM ALBUM FLOWERING TOP (UNII: T95771X2XI)	
CARROT (UNII: L56Z1JK48B)	
CITRUS JUNOS SEED (UNII: UY43O1Q45N)	
PPG-17 (UNII: OV0Q322E0U)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ISO STEARIC ACID (UNII: X33R8U0062)	
EDETATE TRISODIUM (UNII: 420IP921MB)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ALCOHOL (UNII: 3K9958V90M)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	

BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
ALUMINUM OXIDE (UNII: LM26O6933)
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)
SODIUM METABISULFITE (UNII: 4VON5FNS3C)
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
BENZOIC ACID (UNII: 8SKN0B0MIM)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
MICA (UNII: V8A1AW0880)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-342-60	1 in 1 CARTON	08/01/2017	
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	08/01/2017	

Labeler - SHISEIDO AMERICAS CORPORATION (193691821)

Establishment			
Name	Address	ID/FEI	Business Operations
SHISEIDO AMERICA INC.		782677132	manufacture(58411-342) , analysis(58411-342)

Revised: 12/2018

SHISEIDO AMERICAS CORPORATION