SHISEIDO SPORTS BB DARK- 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 SPORTS BB DARK

Drug Facts

Active ingredients	Purpose
OCTINOXATE 4.9%	Sunscreen
TITANIUM DIOXIDE 15%	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

- apply liberally 15 minutes before sun exposure
- reply
 - after 80 minutes after swimming and 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 un 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 SILICA BIS-PEG-18 METHYL ETHER DIMETHYL
SILANE ISODODECANE TRIMETHYLSILOXYSILICATE DALCOHOL 40B TRIMETHYLSILOXYSILICATE/DIMETHICONOL CROSSPOLYMER ISOPROPYL
MYRISTATE ALUMINUM HYDROXIDE PEG-9 POLYDIMETHYLSILOXYETHYL

DIMETHICONE STEARIC ACID ISOSTEARIC ACID DEXTRIN
PALMITATE DISTEARDIMONIUM HECTORITE BIS-BUTYLDIMETHICONE
POLYGLYCERYL-3 LAUROYL LYSINE PEG/PPG-14/7 DIMETHYL ETHER PCA
DIMETHICONE PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE PHYTOSTERYL
MACADAMIATE LECITHIN GLYCYRRHIZA GLABRA (LICORICE) ROOT
EXTRACT SUCROSE TETRASTEARATE

TRIACETATE POLYMETHYLSILSESQUIOXANE TALC METHYL METHACRYLATE CROSSPOLYMER ALUMINA POLYSILICONE - 2 TRIETHOXYCAPRYLYLSILANE HYDROGEN DIMETHICONE TOCOPHEROL BHT ETHYLPARABEN FRAGRANCE TITANIUM DIOXIDE IRON OXIDES MICA

Other information

- Protect this product in this container from excessive heat and direct sun.
- Avoid contact with clothing and other textiles
 - may stain.

Questions or comments?

Call toll free 1-800-906-7503

PRINCIPAL DISPLAY PANEL - 30 mL Bottle Carton

SHISEIDO GINZA TOKYO

Sports BB

50+

WetForce

Quick Dry

BROAD SPECTRUM SPF 50+

WATER RESISTANT (80 MINUTES)

SUNSCREEN

30mL 1 FL. OZ.



Sports BB



BROAD SPECTRUM SPF 50+

JEIDC GINZA TOKYO

Sports BB

WetForce **Quick Dry**

BROAD SPECTRUM SPF 50+

WATER RESISTANT (80 MINUTES)

SUNSCREEN

30mL 1 FL. OZ.

Drug Facts (continued)

Inactive ingredients

DIMETHICONE · SILICA ·

BIS PEG-18 METHYL ETHER DIMETHYL SLANE · ISODODECANE • TRIMETHYLSILOXYSILICATE • SD ALCOHOL 40-B -

TRIMETHYLSILOXYSILICATE/DIMETHICONOL

CROSSPOLYMER •

ISOPROPYL MYPISTATE - ALUMINUM HYDROXIDE -PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE + STEARIC ACID • ISOSTEARIC ACID •

DEXTRIN PALMITATE •

DISTEARDIMONIUM HECTORITE •

BIS BUTYLDIMETHICONE POLYGLYCERYL-3 + Lauroyl Lysine + Peg/PPG-14/7 dimethyl ether +

LAUROYLLYS NE - PLEGPPS-14/7 CIME IRYL EI HEH PCA DIMETHICONE PHYTOSTERYL MACADAMATE - LECTHIN GLYCYBRHIZA GLABRA (LICORICE) ROOT EXTRACT SUCROSE TETRASTEARATE TRIACETATE POLYMETHYLS LSESOUIOXANE - TALC METHYL METHACRYLATE CROSSPOLYMER - ALUMINA POLYSIUCONE 2 - TRIETHOXYCAPRYLYLS LANE HYDROGEN DIMETHOONE - TOCOPHEROL - BHT ETHYLPARABEN - PRAGRANCE - TITANIUM DIOXIDE IRON OXIDES - MICA -

Other Information

- protect this product in this container
- avoid contact with clothing and other textiles-may stain.

54.5 6 ×33×82 2 4 S တ ∞ 9

0

SHISEIDO SPORTS BB BROAD SPECTRUM SPF 50+

A BB type sunscreen ideal for outdoor scenes such as sports, featuring WetForce technology so the UV protection veil actually becomes stronger when it comes into contact with sweat and water.* Furthermore, Quick Dry technology dries your sweat quickly** to keep you looking fresh, no matter how active you have been.

- Contains contouring powder to utilize the effects of light and shadow for creating a sculpted, three-dimensional look.
- Reducing the quantity of application will lower the level of sunscreen protection significantly.
 Shake well before use.

NON COMEDOGENIC. DERMATOLOGIST AND OPHTHALMOLOGIST TESTED.

- *To activate WetForce technology, expose the applied area to water or perspiration for 30 minutes.

 **in vitro test

Drug Facts

Active ingredients

Purpose Sunscreen

OCTINOXATE 4.9%TITANIUM DIOXIDE 15.0% Sunscreen

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.

SHISEIDO AMERICAS CORPORATION DIST. NEW YORK, NY 10022

Drug Facts (continued)

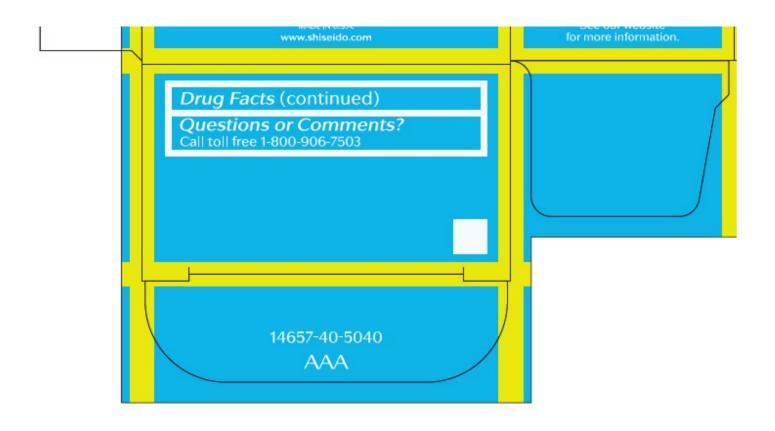
Flammable: Do not use near heat, flame, or while smoking.

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: I 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

http://s1872.com/14657AA



SHISEIDO SPORTS BB DARK

octinoxate and titanium dioxide emulsion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-536
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1.81545 g in 30 mL	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) (TITANIUM DIO XIDE - UNII:15FIX9 V2JP)	TITANIUM DIO XIDE	5.5575 g in 30 mL	

Inactive Ingredients		
Ingredient Name	Strength	
DIMETHICO NE (UNII: 92RU3N3Y1O)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
BIS-PEG-18 METHYL ETHER DIMETHYL SILANE (UNII: OEB4R3WW9C)		
ISODODECANE (UNII: A8289P68Y2)		
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)		
ALCOHOL (UNII: 3K9958V90M)		
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)		
ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0)		
PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: TYP8 1E471F)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
ISOSTEARIC ACID (UNII: X33R8U0062)		

DEXTRIN PALMITATE (CORN; 20000 MW) (UNII: 89B2BSF9I3)	
DISTEARDIMO NIUM HECTO RITE (UNII: X687XDK09L)	
LAURO YL LYSINE (UNII: 113171Q70B)	
PEG/PPG-14/7 DIMETHYL ETHER (UNII: 6 DNW9 T7YT2)	
PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE (UNII: 65954KGO9Q)	
PHYTOSTERYL MACADAMIATE (UNII: 233VSF903M)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
SUCROSE TETRASTEARATE TRIACETATE (UNII: 1K7LBQ045N)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
TALC (UNII: 7SEV7J4R1U)	
METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: EG97988M5Q)	
ALUMINUM O XIDE (UNII: LMI26 O 69 33)	
TRIETHO XYCAPRYLYLSILANE (UNII: LDC331P08E)	
HYDROGEN DIMETHICONE (13 CST) (UNII: 4QGR4P2YOI)	
.ALPHATO COPHEROL (UNII: H4N855PNZ1)	
BUTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K)	
ETHYLPARABEN (UNII: 14255EXE39)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSOFERRIC OXIDE (UNII: XM0 M87F357)	
MICA (UNII: V8A1AW0880)	

	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:58411-536-10	1 in 1 CARTON	0 3/0 1/20 19	
ı	1	30 mL 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 FINAL	part352	0 3/0 1/20 19	

Labeler - SHISEIDO AMERICAS CORPORATION (193691821)

Revised: 4/2020 SHISEIDO AMERICAS CORPORATION