

**BENEFIANCE PROTECTIVE HAND REVITALIZER- octinoxate cream
SHISEIDO AMERICA INC.**

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.

BENEFIANCE PROTECTIVE HAND REVITALIZER

Drug Facts

Active ingredient

OCTINOXATE 7.4%

Purpose

Sunscreen

Use

- helps prevent sunburn

Warnings

Skin Cancer/Skin Aging Alert

Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, not skin cancer or early skin aging.

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
- use a water resistant sunscreen if swimming or sweating
- reapply at least every 2 hours
- children under 6 months: Ask a doctor

Inactive Ingredients

WATER, DIPROPYLENE GLYCOL, DIMETHICONE, BUTYLENE GLYCOL, DIPHENYLSILOXY PHENYL TRIMETHICONE, STEARYL ALCOHOL, HYDROGENATED PALM OIL, PEG-5 GLYCERYL STEARATE, BENTONITE, GLYCERIN, SQUALANE, TRANEXAMIC ACID, TRIMETHYLSILOXYSILICATE, XANTHAN GUM, PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE, TOCOPHERYL ACETATE, POTASSIUM ASCORBYL TOCOPHERYL PHOSPHATE, MAGNESIUM ASCORBYL PHOSPHATE, SODIUM HYALURONATE,

SAXIFRAGA SARMENTOSA EXTRACT, STEARIC ACID, ISOSTEARIC ACID, BEHENIC ACID, CYCLOMETHICONE, TRISODIUM EDTA, SODIUM CITRATE, POTASSIUM HYDROXIDE, ALCOHOL, BHT, TOCOPHEROL, PHENOXYETHANOL, ETHYLPARABEN, BUTYLPARABEN, FRAGRANCE, IRON OXIDES,

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 - 75g Tube Carton

SHISEIDO

Shiseido

Benefiance

Protective

Hand Revitalizer (Cream)

SPF 10

SUNSCREEN

75g NET WT. 2.6 OZ.

Protective
Hand Revitalizer (Cream)

SHISEIDO

**Shiseido
Benefiance**

Protective
Hand Revitalizer (Cream)
SPF 10

SUNSCREEN

75g NET WT. 2.6 OZ.

SHISEIDO
BENEFIANCE
PROTECTIVE HAND REVITALIZER
SPF 10

Total luxury for the skin.

A concentrated cream that effectively protects the entire hand against roughness and chapping while promoting a healthy skin clarity.

- Retexturizes skin with TRA Revitalizer, an exclusive Shiseido ingredient that helps promote smoothness and resilience.
- Developed with a highly effective combination of botanical extract and Vitamin C derivative to enhance skin clarity and tone.
- Allergy tested by dermatologists.
(Formulated to minimize the risk of allergy.)

SPECIALLY FORMULATED BY SHISEIDO LABORATORIES, JAPAN.

Drug Facts

Active ingredient	Purpose
OCTINOXATE 7.4%	Sunscreen

Drug Facts
(continued)

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64X47X148

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SHISEIDO AMERICA INC.
NEW YORK, N.Y. 10022
MADE IN U.S.A.
SHISEIDO DIST.
NEW YORK · PARIS · MILANO
GLO. 18012

GLYCERIN · DIMETHYLGLYCERIN · TRIQUIDRUM EDTA ·
SODIUM CITRATE · POTASSIUM HYDROXIDE ·
ALCOHOL · BHT · TOCOPHEROL ·
PHENOXYETHANOL · ETHYLPARABEN ·
BUTYLPARABEN · FRAGRANCE · IRON OXIDES ·

Other Information

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Questions or Comments?

Call toll free 1-800-906-7503

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18012-4-5043

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BENEFIANCE PROTECTIVE HAND REVITALIZER

octinoxate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52686-106
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	5550 mg in 75 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
DIPHENYLSILOXY PHENYL TRIMETHICONE (UNII: I445L28B12)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
HYDROGENATED PALM OIL (UNII: 257THB963H)	
PEG-5 GLYCERYL STEARATE (UNII: 8CAC4NQ872)	
BENTONITE (UNII: A3N5ZCN45C)	
GLYCERIN (UNII: PDC6A3C0OX)	
SQUALANE (UNII: GW89575KF9)	
TRANEXAMIC ACID (UNII: 6T84R30KC1)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
XANTHAN GUM (UNII: TTV12P4NEE)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
POTASSIUM ASCORBYL TOCOPHERYL PHOSPHATE (UNII: 61R4GJ48ER)	
MAGNESIUM ASCORBYL PHOSPHATE (UNII: 0R822556M5)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
SAXIFRAGA STOLONIFERA LEAF (UNII: O3TMV4903H)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
BEHENIC ACID (UNII: H390488X0A)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
EDETATE TRISODIUM (UNII: 420IP921MB)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
ALCOHOL (UNII: 3K9958V90M)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
TOCOPHEROL (UNII: R0ZB2556P8)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLPARABEN (UNII: 14255EXE39)	
BUTYLPARABEN (UNII: 3QPII03FV8)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52686-106-60	1 in 1 CARTON		
1		75 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	10/01/2012	

Labeler - SHISEIDO AMERICA INC. (782677132)

Establishment

Name	Address	ID/FEI	Business Operations
SHISEIDO AMERICA INC.		782677132	MANUFACTURE(52686-106) , ANALYSIS(52686-106)

Establishment

Name	Address	ID/FEI	Business Operations
Davlyn Industries Inc		624436254	MANUFACTURE(52686-106)

Revised: 9/2012

SHISEIDO AMERICA INC.