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

Shis eido Benefiance

Protective Hand Revitalizer (Cream) SPF 10 SUNSCREEN

75g NET WT. 2.6 OZ.

	Protective Hand Revitalizer (Cream)	
OHIDO Hand	Shiseido Benefiance Protective I Revitalizer (Cream) SPF 10	

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 OCTINOXATE 7.4%

Purpose Sunscreen

(continued)

Directions

For sunscreen use:

- apply liberally 15 minutes before sun
- use a water resistant sunscreen if swimming or sweating
- reapply at least every 2 hours
- children under 6 months: Ask a doctor

Inactive ingredients

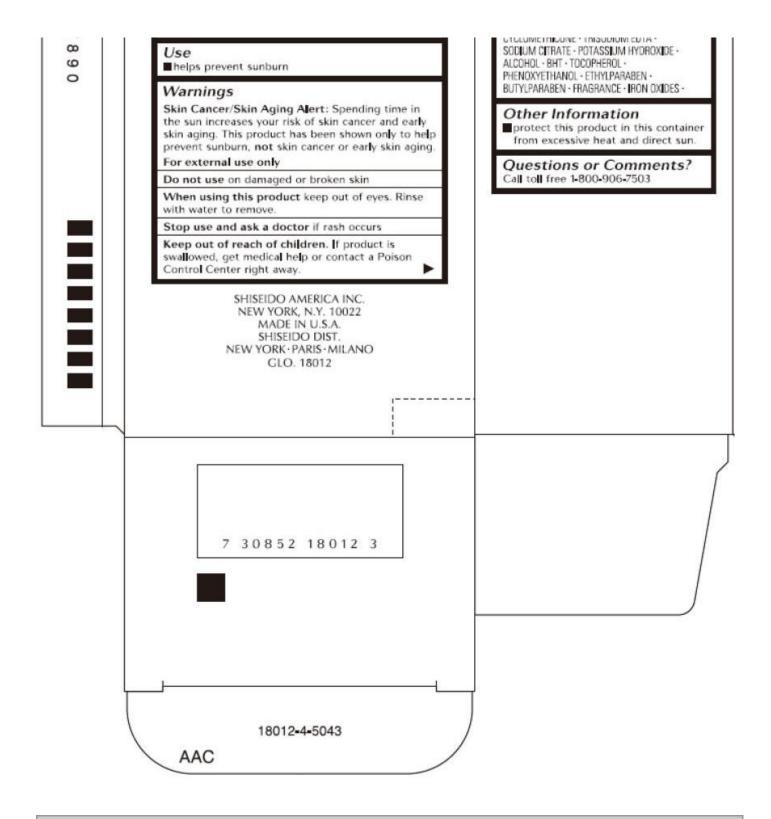
WATER - DIPROPYLENE GLYCOL - DIMETHICONE -BUTYLENE GLYCOL ·

DIPHENYLSILOXY PHENYL TRIMETHICONE -STEARYL ALCOHOL - HYDROGENATED PALM OIL -PEG-5 GLYCERYL STEARATE · BENTONITE · GLYCERIN · SQUALANE · TRANEXAMIC ACID · TRIMETHYLS LOXYS LICATE - XANTHAN GUM -PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE -

TOCOPHERYL ACETATE ·

POTASSIUM ASCORBYL TOCOPHERYL PHOSPHATE -MAGNES UM ASCORBYL PHOSPHATE -SODIUM HYALURONATE ·

SAXIFRAGA SARMENTOSA EXTRACT -STEARIC ACID - ISOSTEARIC ACID - BEHENIC ACID -EVELOMETHICANE, TOLOGRAPHIA COTA :



BENEFIANCE PROTECTIVE HAND REVITALIZER

octinoxate cream

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

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTINOXATE (OCTINOXATE)	OCTINOXATE	5550 mg in 75 g	

Ingredient Name TER PROPYLENE GLYCOL METHICONE TYLENE GLYCOL PHENYLSILOXY PHENYL TRIMETHICONE EARYL ALCOHOL DRO GENATED PALM O IL G-5 GLYCERYL STEARATE NTONITE YCERIN UALANE ANEXAMIC ACID IMETHYLSILOXYSILICATE (M/Q 0.6-0.8)	Strength			
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ANEXAMIC ACID IMETHYLSILO XYSILICATE (M/Q 0.6-0.8)				
IMETHYLSILOXYSILICATE (M/Q 0.6-0.8)				
NTHAN GUM				
PHATO COPHEROL ACETATE				
POTASSIUM ASCORBYL TOCOPHERYL PHOSPHATE				
GNESIUM ASCORBYL PHOSPHATE				
ALURO NATE SO DIUM				
XIFRAGA STOLONIFERA LEAF				
EARIC ACID				
STEARIC ACID				
HENIC ACID				
CLOMETHICONE				
ETATE TRISODIUM				
DIUM CITRATE				
TASSIUM HYDRO XIDE				
СОНОГ				
TYLATED HYDRO XYTO LUENE				
COPHEROL				
ENO XYETHANO L				
HYLPARABEN				
TYLPARABEN				
RRIC OXIDE RED				
RRIC OXIDE YELLOW				

1 4611481118	Packaging				
# Item Co	de Package Descrij	otion 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.