

ELF BROAD SPECTRUM SPF 20 SUNSCREEN DARK BB CREAM- octinoxate cream
J. A. Cosmetics U.S. 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.

Drug Fact

Active Ingredient:

OCTINOXATE: 7.5%

OCTISALATE: 5.0%

OXYBENONE: 4.0%

Purpose:

Sunscreen

Uses:

Help prevent sunburn

If used as directed with other sun protection measures, decreases the risk of skin cancer and early skin aging caused by the sun

Warning:

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 swallowed, get medical help or contact a poison control center immediately

Directions:

For sunscreen use:

Apply generously 15 min before sun exposure. Reapply every two hours.

Use a water resistant sunscreen if swimming or sweating

Sun Protection Measures:

Spending time in sun increases your risk of skin cancer or early skin aging. To decrease the risk, regularly use a sunscreen with broad spectrum SPF value of 15 or higher and other sun protection measures including

- Limit time in the sun, especially from 10 am to 2 pm
- Wear long sleeved shirts, pants, hats, and sunglasses.
- Children under six months of age: ask a doctor

Inactive Ingredient:

Water, Glycerin, Propylene Glycol, C12-15 Akyl Benzoate, Titanium Dioxide, Cetyl PEG/PPG-10/1 Dimethicone, Cyclohexasiloxane, Cyclopentasiloxane, Sorbitan Oliviate, Polymethyl Methacrylate,

Sodium Chloride, Quaternium-18, Bentonite, Triethoxycaprylsilane, Dimethicone, Zinc Stearate, Talc, VP/Hexadecene Copolymer, Bisabolol, Tocopheryl Acetate, Simmondsia Chinensis (Jojoba) Seed Oil, Aloe Barbadensis Leaf Extract, Cucumis Sativus (Cucumber) Fruit Extract, Mica, Silica, Phenoxyethanol, Ethylhexylglycerin, Methylisothiazolinone, Fragrance

May contain:

Iron Oxides (CI 77491, CI 77492, CI 77499)



PMS 4705C

99238

BB Cream

Broad Spectrum SPF 20 Sunscreen

Infused with Vitamin E, Jojoba, Aloe, and Cucumber to help hydrate and nourish the skin.

The smoothing formula helps minimize fine lines and provides a natural tint of color for seamless coverage.

DIRECTIONS: Apply a thin, even layer all over the skin with a brush, sponge, or fingertips and blend in. Wear alone or under foundation.

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Drug Facts

Active ingredients	Purpose
Octinoxate 7.5%	Sunscreen
Octisalate 5%	
Oxybenzone 4%	

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 swallowed, get medical help or contact a Poison Control Center right away.

Directions

For sunscreen use: • Apply liberally 15 minutes before sun exposure • Reapply at least every 2 hours • Use a water resistant sunscreen if swimming or sweating **Sun Protection Measures:** Spending time in the sun increases your risk of sun cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value 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-sleeved shirt, pants, hats and sunglasses • children under 6 months of age: Ask doctor.

Other information

- Protect the product in this container from excessive heat and direct sunlight

Inactive ingredients

Water (Aqua), Glycerin, Propylene Glycol, C12-15 Alkyl Benzoate, Titanium Dioxide, Cetyl PEG/PPG-10/1 Dimethicone, Cyclohexasiloxane, Cyclopentasiloxane, Sorbitan Olivatate, Polymethyl Methacrylate, Sodium Chloride, Quaternium-18 Bentonite, Triethoxycaprylsilane, Dimethicone, Zinc Stearate, Talc, Vp / Hexadecene Copolymer, Bisabolol, Tocopheryl Acetate



CLEAR ACETATE WINDOW

Broad Spectrum
SPF 20 Sunscreen
BB Cream

Dark

Drug Facts (cont.)

Leaf Extract, Cucumis Sativus (Cucumber) Fruit Extract, Mica, Silica, Phenoxyethanol, Ethylhexylglycerin, Methylisothiazolinone, Fragrance (Parfum) **May Contain:** Iron Oxides (CI 77491, CI 77492, CI 77499)

Questions or comments

1-800-451-2222

Net 60g (2.1 oz) (205.5g)



ELF BROAD SPECTRUM SPF 20 SUNSCREEN DARK BB CREAM

octinoxate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76354-614
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	4 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MICA (UNII: V8A1AW0880)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
SODIUM CHLORATE (UNII: T95DR77GMR)	
QUATERNIUM-18 (UNII: O7757NO1VL)	
BENTONITE (UNII: A3N5ZCN45C)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ZINC STEARATE (UNII: H92E6QA4FV)	

TALC (UNII: 7SEV7J4R1U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALOE ANDONGENSIS LEAF (UNII: N1P4NU25EJ)	
JOJOBA OIL (UNII: 724GKU717M)	
CUCUMBER FRUIT OIL (UNII: R81Y52NPCT)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76354-614-01	28.5 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 not final	part352	10/10/2015	

Labeler - J. A. Cosmetics U.S. INC (186705047)

Registrant - Hangzhou Facecare Cosmetics Co., Ltd. (545341856)

Establishment

Name	Address	ID/FEI	Business Operations
Hangzhou Facecare Cosmetics Co., Ltd.		545341856	manufacture(76354-614)

Revised: 10/2015

J. A. Cosmetics U.S. INC