

BB CREAM SPF 20 BEIGE- octinoxate, octisalate, oxybenzone 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.

BB Cream SPF 20 Beige

Drug Facts

Active ingredients

Octinoxate 6.0%

Octisalate 4.0%

Oxybenzone 3.5%

Purpose

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 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.

Inactive ingredients

Water (Aqua), Glycerin, Propylene Glycol, C12-15 Alkyl Benzoate, Cetyl PEG/PPG-10/1 Dimethicone, Cyclopentasiloxane, Cyclohexasiloxane, Sorbitan Olivatate, Polymethyl Methacrylate, Sodium Chloride, Quaternium-18 Bentonite, Quartz, Triethoxycaprylylsilane, Zinc Stearate, Talc, Vp/Hexadecene Copolymer, Bisabolol, Tocopheryl Acetate (Ve), Simmondsia Chinensis (Jojoba) Seed Oil, Aloe Barbadensis Leaf Extract, Cucumis Sativus (Cucumber) Fruit Extract, Mica, Silica, Butylene Glycol, Phenoxyethanol, Ethylhexylglycerin, Caprylyl Glycol, Fragrance (Parfum) May Contain: Iron Oxides (CI 77491, CI 77492, CI 77499), Titanium Dioxide (CI 77891)

Questions or comments?

1-855-353-7320

Principal Display Panel - 28.5 mL Carton Label

e.l.f.

BB CREAM

SPF 20

sunscreen

BEIGE

NET 0.96 FL. OZ. (28.5mL)





BB CREAM SPF 20 BEIGE			
octinoxate, octisalate, oxybenzone cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76354-863
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)		OCTINOXATE	60 mg in 1 mL
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)		OXYBENZONE	35 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)		OCTISALATE	40 mg in 1 mL
Inactive Ingredients			
Ingredient Name			Strength

FERROSO FERRIC OXIDE (UNII: XM0M87F357)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)
SORBITAN OLIVATE (UNII: MDL271E3GR)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
BENTOQUATAM (UNII: 7F465U79Q1)
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)
ZINC STEARATE (UNII: H92E6QA4FV)
TALC (UNII: 7SEV7J4R1U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
JOJOBA OIL (UNII: 724GKU717M)
CUCUMBER (UNII: YY7C30VXJT)
WATER (UNII: 059QF0K00R)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
MICA (UNII: V8A1AW0880)
GLYCERIN (UNII: PDC6A3C0OX)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
CYCLOMETHICONE 6 (UNII: XHK3U310BA)
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)
VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)
LEVOMENOL (UNII: 24WE03BX2T)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
ALOE VERA LEAF (UNII: ZY81Z83H0X)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76354-863-01	28.5 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/26/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/26/2018	

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

Establishment

Name	Address	ID/FEI	Business Operations
Columbia Cosmetics Manufacturing, Inc.		068267863	manufacture(76354-863)

