

**BB CREAM SPF 20 FAIR- 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.*

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**BB Cream SPF 20 Fair**

**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 Oliviate, Polymethyl Methacrylate, Sodium Chloride, Quatemium-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 (Cl 77491, Cl 77492, Cl 77499), Titanium Dioxide (Cl 77891)

### Questions or comments?

1-855-353-7320

### Principal Display Panel - 28.5 mL Carton Label

e.l.f.

BB CREAM

SPF 20

sunscreen

fair

NET 0.96 FL. OZ. (28.5mL)





<b>BB CREAM SPF 20 FAIR</b>			
octinoxate, octisalate, oxybenzone cream			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76354-861
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>
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
<b>Inactive Ingredients</b>			
<b>Ingredient Name</b>			<b>Strength</b>

VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)
WATER (UNII: 059QF0KO0R)
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)
FERROSFERRIC 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)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
JOJOBA OIL (UNII: 724GKU717M)
CUCUMBER (UNII: YY7C30VXJT)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CYCLOMETHICONE 6 (UNII: XHK3U310BA)
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)
LEVOMENOL (UNII: 24WE03BX2T)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76354-861-01	28.5 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/07/2018	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/07/2018	

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

### Establishment

Name	Address	ID/FEI	Business Operations
Columbia Cosmetics Manufacturing, Inc.		068267863	manufacture(76354-861)

