

**BEAUTIPHARM EYE CARE BALM SPF 10- sunscreen cream**  
**Linde Eckstein GmbH + Co. KG**

*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.*

**Beautipharm® Eye Care Balm**

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SPF 10

1 OZ. NET.WT. – 30 ml

Art. 03190

MADE IN GERMANY

Augencreme - Eye Cream – Oogcrème – Crema occhi – Crema Para Ojos

Ingredients: Aqua (Water), Ethylhexyl Methoxycinnamate, Octocrylene, Caprylic/Capric Triglyceride, Polysorbate 60, Theobroma Cacao (Cocoa) Seed Butter, Sorbitan Stearate, Steareth-7, Stearyl Alcohol, Glycerin, Benzyl Alcohol, Cetyl Hydroxyethylcellulose, Opuntia Ficus-Indica (Cactus) Flower Extract, Sodium Carbomer, Bisabolol, Tocopheryl Acetate, Vaccinium Myrtillus (Bilberry) Fruit Extract, Sodium Hyaluronate, Dehydroacetic Acid, Diazolidinyl Urea, Saccharum Officinarum (Sugar Cane) Extract, Allantoin, Citrus Aurantium Dulcis (Orange) Fruit Extract, Citrus Limon (Lemon) Fruit Extract, Lactic Acid, Retinyl Palmitate, Acer Saccharum (Sugar Maple) Extract, Potassium Sorbate, Sodium Benzoate.

NL-Cosinta, Bleiswijk

KosmEck Italia – Bosisio Parini (LC)

CH-Intercosina AG, Aarberg

Eckstein Biokosmetik USA

Carlsbad, CA 92010

LINDE ECKSTEIN GMBH+CO.KG

90522 OBERASBACH · GERMANY

***Drug Facts***

***Active Ingredients***

Octocrylene 4%

Octyl methoxycinnamate 4%

***Purpose***

Sunscreen

***Uses***

- Helps prevent sunburn

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

***Directions***

- Apply liberally 15 minutes before sun exposure
- Reapply:
- after 40 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours

***Sun Protection Measures.***

Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF 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-sleeve shirts, pants, hats and sunglasses
- children under 6 months: ask a doctor

***Inactive ingredients***

Acer Saccharum (Sugar Maple) Extract, Allantoin, Aqua (Water), Benzyl Alcohol, Bisabolol, Caprylic/Capric Triglyceride, Cetyl Hydroxyethylcellulose, Citrus Aurantium Dulcis (Orange) Fruit Extract, Citrus Limon (Lemon) Fruit Extract, Dehydroacetic Acid, Diazolidinyl Urea, Glycerin, Lactic

Acid, Opuntia Ficus-Indica (Cactus) Flower Extract, Polysorbate 60, Potassium Sorbate, Retinyl Palmitate, Saccharum Officinarum (Sugar Cane) Extract, Sodium Benzoate, Sodium Carbomer, Sodium Hyaluronate, Sorbitan Stearate, Steareth-7, Stearyl Alcohol, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Vaccinium Myrtillus (Bilberry) Fruit Extract.

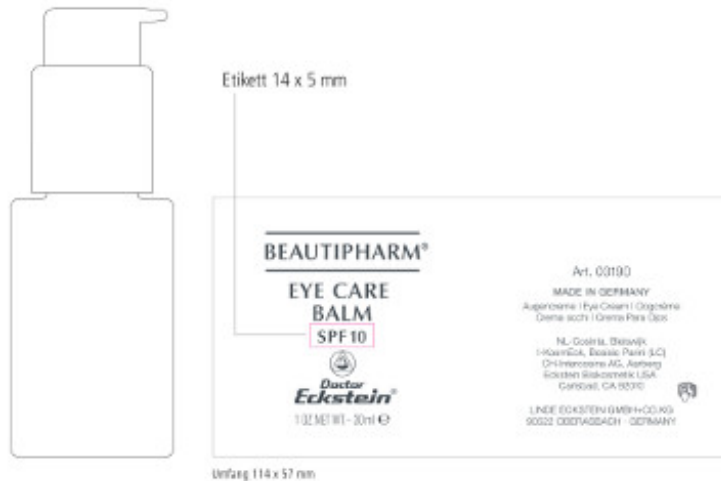
**Other information**

- protect this product from excessive heat and direct sun

**Questions or comments?**

Call toll free +888 345 1950

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<b>BEAUTIPHARM EYE CARE BALM SPF 10</b>			
sunscreen cream			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:6889-0319
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	1.33 g in 30 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1.33 g in 30 mL

**Inactive Ingredients**

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	9.335 g in 30 mL
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	3.33 g in 30 mL
POLYSORBATE 60 (UNII: CAL22UVI4M)	3.33 g in 30 mL
COCOA BUTTER (UNII: 512OYT1CRR)	3.33 g in 30 mL
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	3.33 g in 30 mL
STEARETH-7 (UNII: 820H8P0BYX)	1 g in 30 mL
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	1 g in 30 mL
GLYCERIN (UNII: PDC6A3C0OX)	1 g in 30 mL
BENZYL ALCOHOL (UNII: LKG8494WBH)	0.3 g in 30 mL
CETYL HYDROXYETHYLCELLULOSE (350000 MW) (UNII: T7SWE4S2TT)	0.3 g in 30 mL
OPUNTIA FICUS-INDICA FLOWER (UNII: 83YSP51SMA)	0.3 g in 30 mL
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	0.16 g in 30 mL
LEVOMENOL (UNII: 24WE03BX2T)	0.1 g in 30 mL
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	0.1 g in 30 mL
BILBERRY (UNII: 9P2U39H18W)	0.1 g in 30 mL
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	0.1 g in 30 mL
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	0.09 g in 30 mL
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	0.03 g in 30 mL
SUGARCANE (UNII: 81H2R5AOH3)	0.03 g in 30 mL
ALLANTOIN (UNII: 344S277G0Z)	0.03 g in 30 mL
ORANGE (UNII: 5EVU04N5QU)	0.01 g in 30 mL
LEMON (UNII: 24RS0A988O)	0.01 g in 30 mL
LACTIC ACID (UNII: 33X04XA5AT)	0.01 g in 30 mL
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	0.01 g in 30 mL
ACER SACCHARUM BARK/SAP (UNII: Z120VL0KAC)	0.003 g in 30 mL
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	0.001 g in 30 mL
SODIUM BENZOATE (UNII: OJ245FE5EU)	0.001 g in 30 mL

**Product Characteristics**

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC 6880 0310			

1	NDC:6889-0319-02	1 in 1 BOX	11/24/2016	
1	NDC:6889-0319-01	30 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	06/30/2014	

**Labeler** - Linde Eckstein GmbH + Co. KG (316104744)

**Registrant** - Linde Eckstein GmbH + Co. KG (316104744)

### Establishment

Name	Address	ID/FEI	Business Operations
Linde Eckstein GmbH + Co. KG		316104744	manufacture(6889-0319)

Revised: 10/2016

Linde Eckstein GmbH + Co. KG