

**BLUE LIZARD REGULAR - sunscreen lotion**  
**Crown Laboratories**

*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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**Blue Lizard Regular**

**Active Ingredients**

Octinoxate - 7.5%

Octocrylene - 2%

Oxybenzone - 3%

Zinc Oxide - 6%

**Uses**

- Helps prevent sunburn and photodamage caused by UVA/UVB exposure
- Higher SPF gives more sunburn protection
- 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**

- When using this product
- Keep out of eyes. Rinse with water to remove
- Stop use and ask a doctor if
- Rash or irritation occurs
- Do not use
- On damaged or broken skin
- If allergic to any ingredient
- If swallowed, get medical help or contact a Poison Control Center

**Directions**

- **Shake well prior to use**
- Apply liberally to dry skin 15 minutes before sun exposure
- For topical use only
- Keep out of reach of children
- Children under 6 months: ask a doctor
- **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 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 shirts, pants, hats, and sunglasses
- **Reapply to dry skin:**
- after 80 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours

### **Other Information**

- Protect the product in this container from excessive heat and direct sun
- May stain some fabrics

### **Inactive Ingredients**

Beeswax, C12-15 Alkyl Benzoate, Cetyl Dimethicone, Cetyl Dimethicone Copolyol, Diazolidinyl Urea, Disodium EDTA, Ethylhexyl Palmitate, Ethylhexyl Stearate, Ethylparaben, Fragrance, Hexyl Laurate, Hydrogenated Castor Oil, Methyl Glucose Dioleate, Methylparaben, Octododecyl Neopentanoate, PEG-7 Hydrogenated Castor Oil, Polyglyceryl-4 Isostearate, Propylene Glycol, Propylparaben, Purified Water, Sorbitan Oleate, Stearic Acid, Tocopheryl Acetate (Vitamin E), Trimethylated Silica/Dimethicone, VP Hexadecene Copolymer

### **Questions ?**

Visit [www.bluelizard.net](http://www.bluelizard.net) or call **800.877.8869**

Crown Laboratories, Inc., Johnson City, TN 37604

Patents US#6698590 & 6405867; AU#1998083259

### **Blue Lizard Regular Label**

Blue Lizard

Australian Sunscreen

Regular

Broad Spectrum SPF 30+

UVA/UVB Protection

Bottle Turns Blue in UV Light

Zinc Oxide Formula

Water Resistant (80 minutes)

Dermatologist Recommended

# BLUE LIZARD<sup>®</sup>

AUSTRALIAN SUNSCREEN



**BOTTLE TURNS BLUE IN UV LIGHT**

ZINC OXIDE | WATER RESISTANT  
FORMULA | **80 MINUTES**

**DERMATOLOGIST RECOMMENDED**

**REGULAR**

5 FL OZ (148 mL)

P6668.03

## Drug Facts

Made in USA

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Sunscreen  
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## BLUE LIZARD REGULAR

sunscreen lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0316-2010
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	76.5 mg in 1 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	20.4 mg in 1 mL
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	30.6 mg in 1 mL
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	61.2 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
YELLOW WAX (UNII: 2ZA36H0S2V)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5) (UNII: 035JKJ76MT)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)	
ETHYL PARABEN (UNII: 14255EXE39)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
METHYL GLUCOSE DIOLATE (UNII: FA9KFJ4Z6P)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
PEG-7 HYDROGENATED CASTOR OIL (UNII: WE09129TH5)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
HEXADECYL POVIDONE (4 HEXADECYL BRANCHES/REPEAT) (UNII: AG75W62QYU)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRIMETHYLSILOXYSILICATE (M/Q 0.8-1.0) (UNII: 25LXE464L2)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0316-2010-10	5 mL in 1 PACKET		
2	NDC:0316-2010-15	7.5 mL in 1 PACKET		
3	NDC:0316-2010-20	37 mL in 1 BOTTLE, PLASTIC		
4	NDC:0316-2010-30	89 mL in 1 TUBE		
5	NDC:0316-2010-40	148 mL in 1 BOTTLE, PLASTIC		
6	NDC:0316-2010-50	259 mL in 1 BOTTLE, PLASTIC		
7	NDC:0316-2010-60	3785 mL in 1 JUG		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	04/15/2001	

**Labeler** - Crown Laboratories (079035945)

**Registrant** - Crown Laboratories (079035945)

**Establishment**

Name	Address	ID/FEI	Business Operations
Crown Laboratories		079035945	manufacture(0316-2010)

Revised: 12/2014

Crown Laboratories