

**BLUE LIZARD SENSITIVE SPF 50 SUNSCREEN- titanium dioxide and zinc oxide lotion**  
**Crown Laboratories**

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**Blue Lizard Sensitive SPF 50 Sunscreen**

***Active ingredients***

Titanium Dioxide 8%

Zinc Oxide 10%

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

***Directions***

- shake well prior to use
- Apply liberally 15 minutes before sun exposure
- 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:
  - 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***

Alumina, Aluminum Stearate, Beeswax, C12-15 Alkyl Benzoate, Caprylyl Glycol, Cetyl Dimethicone, Cetyl PEG/PPG-10/1 Dimethicone, Chlorphenesin, Dimethicone, Disodium EDTA, Ethylhexyl Palmitate, Ethylhexyl Stearate, Hexyl Laurate, Hydrogenated Castor Oil, Methyl Glucose Dioleate, Octyldodecyl Neopentanoate, PEG-7 Hydrogenated Castor Oil, Phenoxyethanol, Polyglyceryl-4 Isostearate, Polyhydroxystearic Acid, Propanediol, Purified Water, Sorbitan Oleate, Stearic Acid, Tocopheryl Acetate (Vitamin E), Triethoxycaprylylsilane, Trimethylsiloxysilicate, VP Hexadecene Copolymer

### ***Questions?***

Call **800.877.8869** or visit [www.bluelizardsunscreen.com](http://www.bluelizardsunscreen.com)

Crown Laboratories, Inc., Johnson City, TN 37604

### **Blue Lizard Sensitive 3oz Tube**

BLUE LIZARD

AUSTRALIAN SUNSCREEN

50+

UVA/UVB PROTECTION

BROAD SPECTRUM SPF 50+

TRUSTED BY DERMATOLOGISTS FOR OVER 20 YEARS

SENSITIVE

mineral sunscreen

Smart Cap TECHNOLOGY

CAP CHANGES COLOR IN HARMFUL UV LIGHT

WATER RESISTANT (80 MINUTES)

3fl oz (89ml)

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| Drug Facts  |  |
|---|--|
| <b>Active ingredients</b><br>Titanium Dioxide 8%<br>Zinc Oxide 10%  | <b>Purpose</b><br>Sunscreen<br>Sunscreen |
| <b>Uses</b> • helps prevent sunburn   |  |
| <b>Warnings</b><br><b>For external use only</b><br><b>Do not use</b> • on damaged or broken skin<br><b>When using this product</b> • keep out of eyes. Rinse with water to remove<br><b>Stop use and ask a doctor if</b> • rash occurs<br><b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away  |  |
| <b>Directions</b> • shake well prior to use • apply liberally 15 minutes before sun exposure • children under 6 months of age: Ask a doctor • <b>Sun Protection Measures.</b> 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: • after 80 minutes of swimming or sweating • immediately after towel drying • at least every 2 hours |  |
| <b>Other information</b> • protect the product in this container from excessive heat and direct sun • may stain some fabrics  |  |
| <b>Inactive ingredients</b> Alumina, Aluminum Stearate, Beeswax, C12-15 Alkyl Benzoate, Caprylyl Glycol, Cetyl Dimethicone, Cetyl PEG/PPG-10/1 Dimethicone, Chlorphenesin, Dimethicone, Disodium EDTA, Ethylhexyl Palmitate, Ethylhexyl Stearate, Hexyl Laurate, Hydrogenated Castor Oil, Methyl Glucose Dioleate, Octyldodecyl Neopentanoate, PEG-7 Hydrogenated Castor Oil, Phenoxylethanol, Polyglyceryl-4 Isostearate, Polyhydroxystearic Acid, Propanediol, Purified Water, Sorbitan Oleate, Stearic Acid, Tocopheryl Acetate (Vitamin E), Triethoxycaprylylsilane, Trimethylsiloxysilicate, VP Hexadecene Copolymer                       |  |
| <b>Questions?</b> call 800.877.8869 or visit <a href="http://www.bluelizardsunscreen.com">www.bluelizardsunscreen.com</a>   |  |



Distributed by:  
Crown Laboratories, Inc.  
Johnson City, TN 37604  
P11661.03

### BLUE LIZARD SENSITIVE SPF 50 SUNSCREEN

titanium dioxide and zinc oxide lotion

#### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:0316-2046 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

#### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength        |
|---|-------------------|-----------------|
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE  | 89.6 mg in 1 mL |
| <b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)             | ZINC OXIDE        | 112 mg in 1 mL  |

#### Inactive Ingredients

| Ingredient Name | Strength |
|-----------------|----------|
|                 |          |

|  |
|--|
| <b>PEG-7 HYDROGENATED CASTOR OIL</b> (UNII: WE09129TH5)                    |
| <b>POLYGLYCERYL-4 ISOSTEARATE</b> (UNII: 820DPX33S7)                       |
| <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)                                   |
| <b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)                                     |
| <b>PROPANEDIOL</b> (UNII: 5965N8W85T)                                      |
| <b>WATER</b> (UNII: 059QF0K00R)  |
| <b>SORBITAN MONOOLEATE</b> (UNII: 06XEA2VD56)                              |
| <b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)                       |
| <b>HEXADECYL POVIDONE (4 HEXADECYL BRANCHES/REPEAT)</b> (UNII: AG75W62QYU) |
| <b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)                                      |
| <b>TRIMETHYLSILOXYSILICATE (M/Q 0.8-1.0)</b> (UNII: 25LXE464L2)            |
| <b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)                |
| <b>CETYL DIMETHICONE 25</b> (UNII: U4AS1BW4ZB)                             |
| <b>ALUMINUM STEARATE</b> (UNII: U6XF9NP8HM)                                |
| <b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)                          |
| <b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)                             |
| <b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)                                   |
| <b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)                                       |
| <b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)                          |
| <b>CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5)</b> (UNII: 035JKJ76MT)           |
| <b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)                                 |
| <b>ETHYLHEXYL STEARATE</b> (UNII: EG3PA2K3K5)                              |
| <b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)                                  |
| <b>HEXYL LAURATE</b> (UNII: 4CG9F9W01Q)                                    |
| <b>HYDROGENATED CASTOR OIL</b> (UNII: ZF94AP8MEY)                          |
| <b>METHYL GLUCOSE DIOLATE</b> (UNII: FA9KFJ4Z6P)                           |
| <b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)                                    |
| <b>OCTYLDODECYL NEOPENTANOATE</b> (UNII: X8725R883T)                       |

## Packaging

| # | Item Code        | Package Description  | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0316-2046-10 | 5 mL in 1 PACKET; Type 0: Not a Combination Product            | 03/02/2020           |                    |
| 2 | NDC:0316-2046-30 | 89 mL in 1 TUBE; Type 0: Not a Combination Product             | 02/17/2020           |                    |
| 3 | NDC:0316-2046-40 | 148 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 01/29/2020           |                    |
| 4 | NDC:0316-2046-50 | 259 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 02/24/2020           |                    |
| 5 | NDC:0316-2046-45 | 148 mL in 1 TUBE; Type 0: Not a Combination Product            | 02/17/2020           |                    |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M020                                     | 01/29/2020           |                    |

**Labeler** - Crown Laboratories (079035945)

## Establishment

| Name               | Address | ID/FEI    | Business Operations    |
|--------------------|---------|-----------|------------------------|
| Crown Laboratories |         | 079035945 | manufacture(0316-2046) |

Revised: 12/2023

Crown Laboratories