

BLUE LIZARD SENSITIVE SUNSCREEN- titanium dioxide and zinc oxide lotion

Crown Laboratories

Blue Lizard Sensitive

Active Ingredients

Titanium Dioxide 5%

Zinc Oxide 10%

Purpose

Sunscreen

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 risks 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 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
- Children under 6 months of age: 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 40 minutes of swimming or sweating

- immediately after towel drying
- at least every 2 hours

Keep out of reach of children

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?

Visit **www.bluelizardsunscreen.com** or call **800.877.8869**

Crown Laboratories, Inc., Johnson City, TN 37604

Principial Display Panel

BLUE LIZARD

AUSTRALIAN SUNSCREEN

30+

UVA/UVB PROTECTION

BROAD SPECTRUM

SPF 30+

TRUSTED BY DERMATOLOGISTS FOR OVER 20 YEARS

SENSITIVE

Mineral Sunscreen

Smart Cap TECHNOLOGY

CAP CHANGES COLOR IN HARMFUL UV LIGHT

WATER RESISTANT (40 MINUTES)

Mineral Sunscreen

Protects your skin by acting like thousands of tiny shields that reflect UV rays.

3fl oz (89ml)

P6047.14

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Drug Facts

Made in USA

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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 40 minutes of swimming or sweating
• immediately after towel drying • at least every 2 hours

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CROWN

Crown Laboratories, Inc.
Johnson City, TN 37604

BLUE LIZARD SENSITIVE SUNSCREEN

titanium dioxide and zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0316-2045
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	54 mg in 1 mL

ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)

ZINC OXIDE

108 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
METHYL GLUCOSE DIOLEATE (UNII: FA9KFJ4Z6P)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
PEG-7 HYDROGENATED CASTOR OIL (UNII: WE09129TH5)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPANEDIOL (UNII: 5965N8W85T)	
WATER (UNII: 059QF0KO0R)	
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)	
CETYL DIMETHICONE 25 (UNII: U4AS1BW4ZB)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
ALUMINUM STEARATE (UNII: U6XF9NP8HM)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5) (UNII: 035JKJ76MT)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0316-2045-10	5 mL in 1 PACKET; Type 0: Not a Combination Product	04/01/2004	
2	NDC:0316-2045-30	89 mL in 1 TUBE; Type 0: Not a Combination Product	01/03/2006	
3	NDC:0316-2045-40	148 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/08/2003	
4	NDC:0316-2045-50	259 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/03/2005	
5	NDC:0316-2045-60	3785 mL in 1 JUG; Type 0: Not a Combination Product	02/02/2004	05/31/2022
6	NDC:0316-2045-45	148 mL in 1 TUBE; Type 0: Not a Combination Product	01/02/2019	11/30/2022

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	12/08/2003	

Labeler - Crown Laboratories (079035945)

Registrant - Crown Laboratories (079035945)

Establishment

Name	Address	ID/FEI	Business Operations
Crown Laboratories		079035945	manufacture(0316-2045)

Revised: 12/2023

Crown Laboratories