## BLUE LIZARD BABY SPF 50 SUNSCREEN- titanium dioxide and zinc oxide lotion Crown Laboratories

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#### Blue Lizard Baby SPF 50 Sunscreen

#### **Active Ingredients**

Titanium Dioxide 8% 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: 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

#### 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

#### **Blue Lizard Baby 3oz Tube**

**BLUE LIZARD** 

**AUSTRALIAN SUNSCREEN** 

50 +

**UVA/UVB PROTECTION** 

**BROAD SPECTRUM SPF 50+** 

No. 1 PEDIATRICIAN RECOMMENDED

mineral-based sunscreen brand

**BABY** 

mineral sunscreen

Smart Cap TECHNOLOGY

CAP CHANGES COLOR IN HARMFUL UV LIGHT

WATER RESISTANT (80 MINUTES)

3fl oz (89ml)

Mineral Sunscreen

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

P11642.01

# BLUE LIZARD® AUSTRALIAN SUNSCREEN



#### **BABY**

mineral sunscreen

Smart Cap™ TECHNOLOGY
CAP CHANGES COLOR IN HARMFUL UV LIGHT

WATER RESISTANT (80 MINUTES)

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#### **Mineral Sunscreen**

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

Drug Facts	Made in USA	
Active Ingredients	Purpose	
Titanium Dioxide 8%	Sunscreen	
Zinc Oxide 10%	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 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: 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

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Crown Laboratories, Inc. Johnson City, TN 37604

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#### **BLUE LIZARD BABY SPF 50 SUNSCREEN**

titanium dioxide and zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0316-2036
Route of Administration	TOPICAL		

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

Inactive Ingredients	Chua e culle
Ingredient Name	Strength
ALUMINUM OXIDE (UNII: LMI2606933)	
ALUMINUM STEARATE (UNII: U6XF9NP8HM)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5) (UNII: 035JKJ76MT)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
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: 1670DAL4SZ)	
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: 4ELV7Z 65AP)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
DIMETHICONE (UNII: 92RU3N3Y10)	
TRIMETHYLSILOXYSILICATE (M/Q 0.8-1.0) (UNII: 25LXE464L2)	
HEXADECYL POVIDONE (4 HEXADECYL BRANCHES/REPEAT) (UNII: AG75W62QYU)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
CETYL DIMETHICONE 25 (UNII: U4AS1BW4ZB)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0316- 2036-30	89 mL in 1 TUBE; Type 0: Not a Combination Product	02/17/2020	
2	NDC:0316- 2036-40	148 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/29/2020	
3	NDC:0316- 2036-50	259 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/24/2020	
4	NDC:0316- 2036-10	5 mL in 1 PACKET; Type 0: Not a Combination Product	03/02/2020	
5	NDC:0316- 2036-45	148 mL in 1 TUBE; Type 0: Not a Combination Product	02/17/2020	02/17/2020
6	NDC:0316- 2036-46	148 mL in 1 TUBE; Type 0: Not a Combination Product	02/17/2020	

Marketing Information			
Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
OTC Monograph Drug	M020	01/29/2020	

### Labeler - Crown Laboratories (079035945)

Establishment			
Name	Address	ID/FEI	Business Operations
Crown Laboratories		079035945	manufacture(0316-2036)

Revised: 12/2023 Crown Laboratories