BLUE LIZARD BABY SPF 50 SUNSCREEN- titanium dioxide and zinc oxide 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.

Blue Lizard Baby SPF 50 Sunscreen

Active Ingredients

Titanium Dioxide - 8%

Zinc Oxide - 10%

Purpose

Sunscreen

Drug Facts - 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

• 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

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+

PEDIATRICIAN RECOMMENDED

mineral-based

sunscreen brand

BABY

Mineral Sunscreen

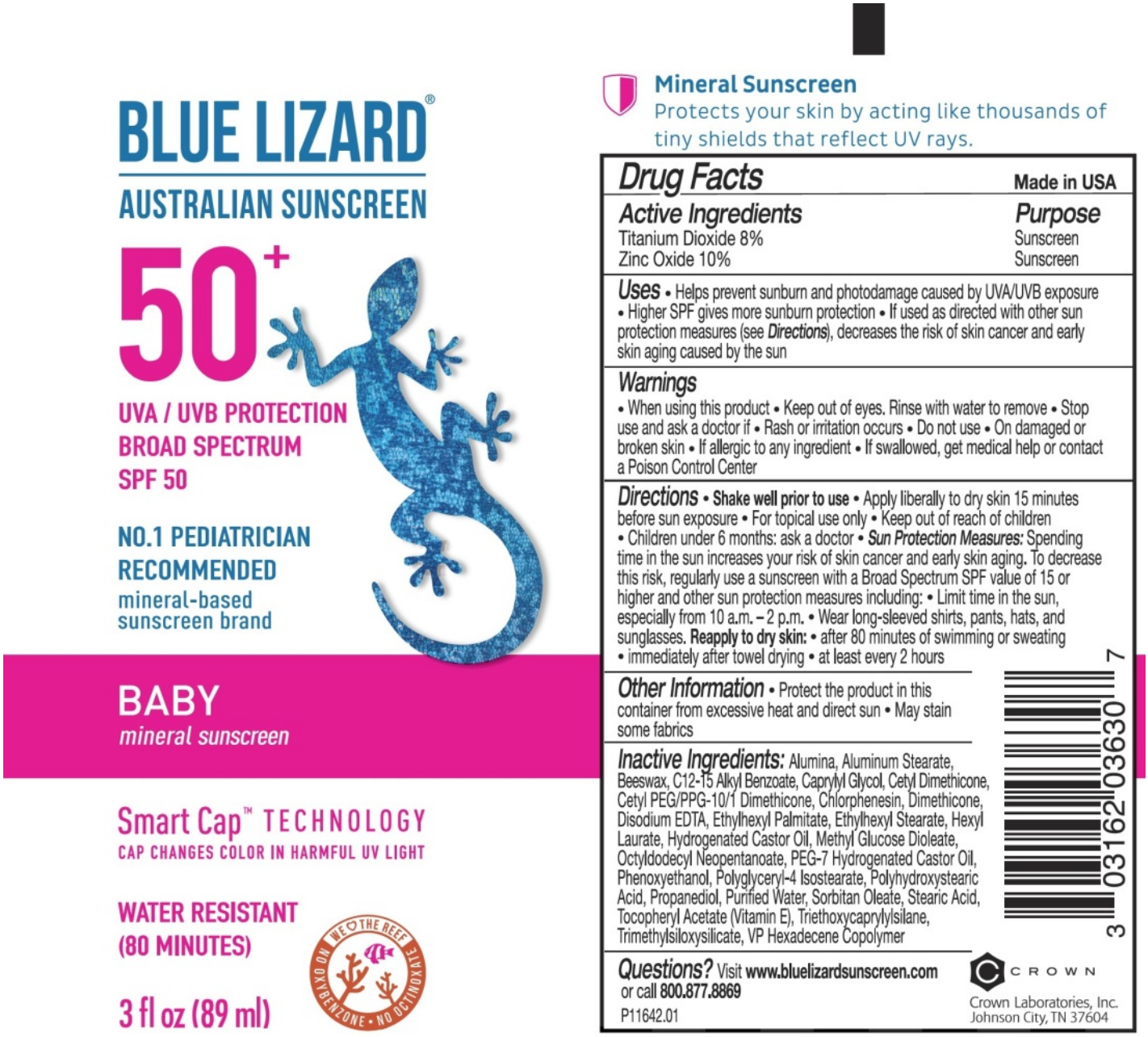
Protects your skin by acting like thousands of tiny shields that reflect UV rays.

Smart Cap TECHNOLOGY

CAP CHANGES COLOR IN HARMFUL UV LIGHT

WATER RESISTANT (80 MINUTES)

P11642.01



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	**Basis of Strength**	**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

Ingredient Name	Strength
ALUMINUM OXIDE (UNII: LMI26O6933)	
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: 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)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
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 Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/29/2020	

Labeler - Crown Laboratories (079035945)

Establishment

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

Revised: 10/2021 Crown Laboratories