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.

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, BHT, Cetyl Dimethicone, Cetyl PEG/PPG 10/1 Dimethicone, Diazolidinyl Urea, Dimethicone, Disodium EDTA, Ethylhexyl Palmitate, Ethylhexyl Stearate, Ethylparaben, Fragrance, Hexyl Laurate, Hydrogenated Castor Oil, Methyl Glucose Dioleate, Methylparaben, Octyldodecyl Neopentanoate, PEG-7 Hydrogenated Castor Oil, Polyglyceryl-4 Isostearate, Propylene Glycol, Propylparaben, Purified Water, Sorbitan Oleate, Stearic Acid, Tocopheryl Acetate (Vitamin E), Triethoxycaprylylsilane, Trimethylsiloxysilicate, VP Hexadecene Copolymer

Questions ?

Visit **www.bluelizard.net** or call **800.877.8869**

Crown Laboratories, Inc., Johnson City, TN 37604

Patent: US#6698590

Blue Lizard Regular Label

Blue Lizard

Australian Sunscreen

UVA/UVB Protection

Broad Spectrum SPF 30+

Trusted by Dermatologist for over 20 years

REGULAR

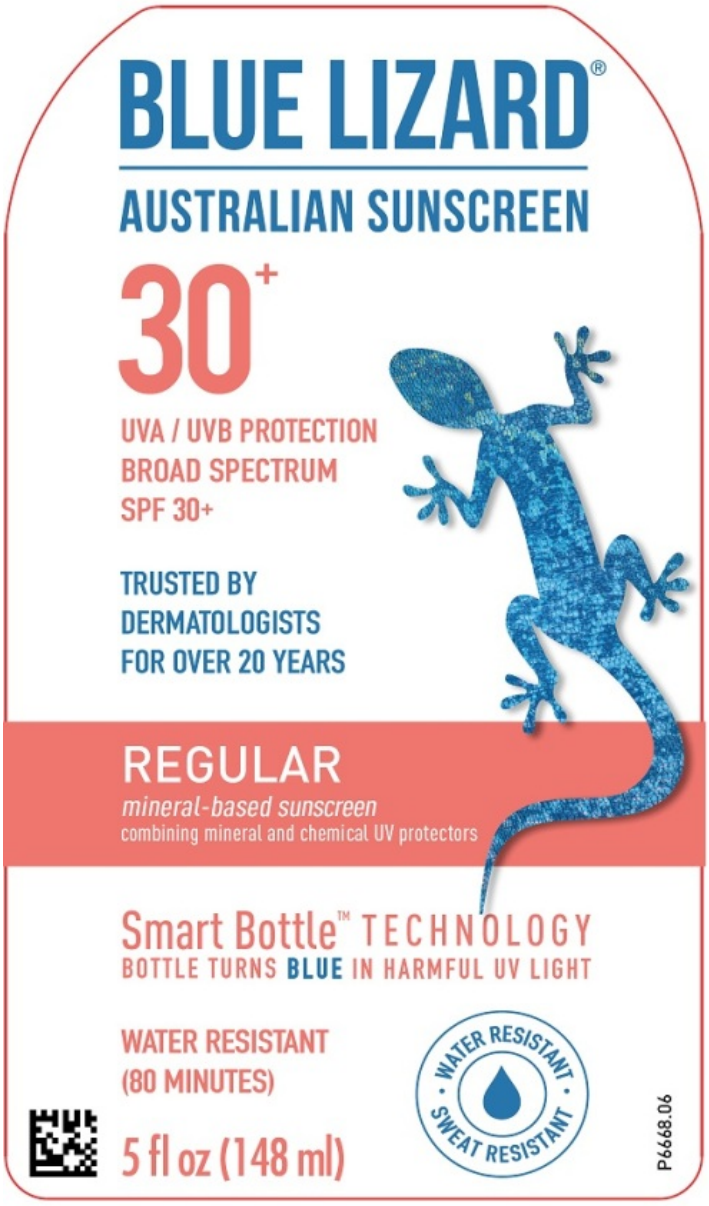
mineral-based sunscreen

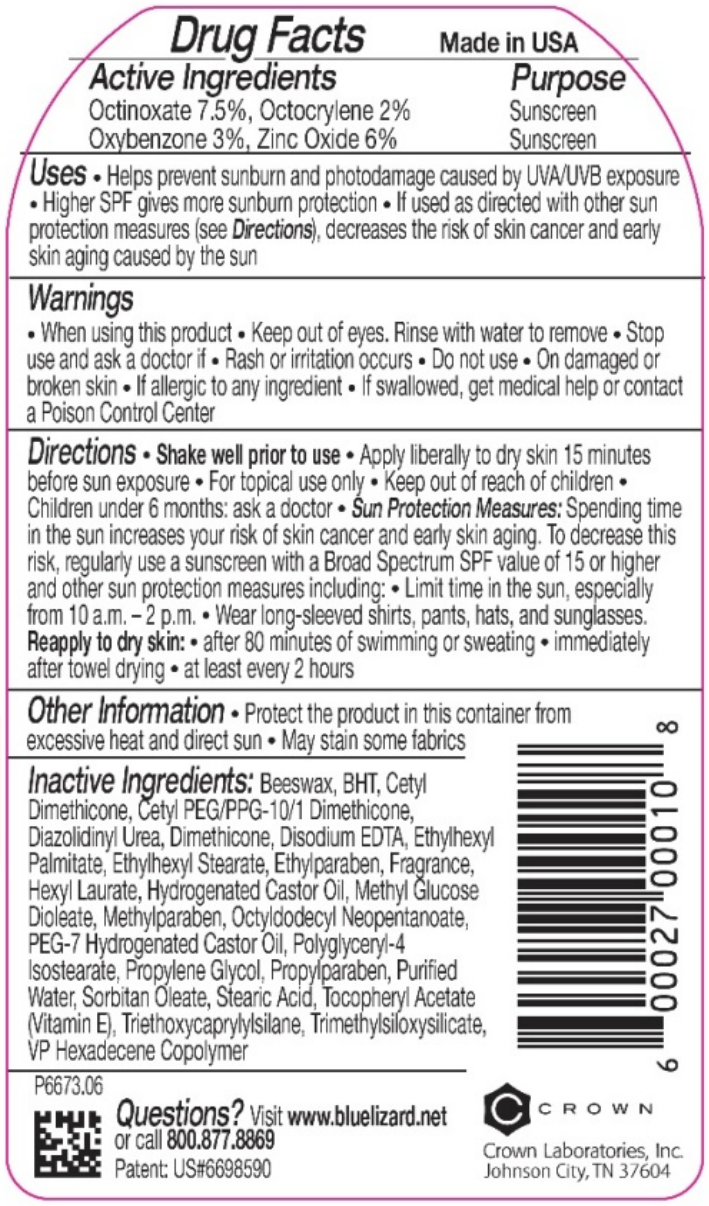
combining mineral and chemical UV protectors

Smart Bottle Technology

Bottle Turns Blue in UV Light

Water Resistant (80 minutes)





BLUE LIZARD REGULAR

sunscreen lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0316-2010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	76.5 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	20.4 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	30.6 mg in 1 mL
ZINC OXIDE (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)	
ETHYLPARABEN (UNII: 14255EXE39)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
METHYL GLUCOSE DIOLEATE (UNII: FA9KFJ4Z6P)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
PEG-7 HYDROGENATED CASTOR OIL (UNII: WE09129TH5)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
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)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0316-2010-10	5 mL in 1 PACKET; Type 0: Not a Combination Product	10/01/2002	09/30/2010
2	NDC:0316-2010-30	89 mL in 1 TUBE; Type 0: Not a Combination Product	01/03/2006	05/31/2014
3	NDC:0316-2010-40	148 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/15/2001	06/30/2022
4	NDC:0316-2010-50	259 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/15/2001	04/30/2022
5	NDC:0316-2010-60	3785 mL in 1 JUG; Type 0: Not a Combination Product	02/02/2004	04/30/2022

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	04/15/2001	06/30/2022

Labeler - Crown Laboratories (079035945)

Registrant - Crown Laboratories (079035945)

Establishment

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

Revised: 10/2021 Crown Laboratories