

BLUE LIZARD KIDS SUNSCREEN- octocrylene 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 Kids Sunscreen

Active Ingredients

Octocrylene - 4%

Zinc Oxide - 9.7%

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 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, 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, Propanediol, 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

Blue Lizard Kids 3oz Label

BLUE LIZARD

AUSTRALIAN SUNSCREEN

30+

UVA/UVB PROTECTION

BROAD SPECTRUM

SPF 30+

No. 1 PEDIATRICIAN RECOMMENDED

mineral-based sunscreen brand

KIDS

mineral-based sunscreen

combining mineral and chemical UV protectors for water-resistant performance you can trust.

Smart Cap TECHNOLOGY

CAP TURNS BLUE INHARMFUL UV LIGHT

WATER RESISTANT (80 MINUTES)

P11469.02

BLUE LIZARD[®]

AUSTRALIAN SUNSCREEN

30⁺

UVA / UVB PROTECTION
BROAD SPECTRUM
SPF 30+

NO.1 PEDIATRICIAN
RECOMMENDED
mineral-based
sunscreen brand



KIDS

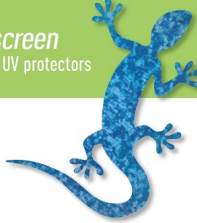
mineral-based sunscreen
combining mineral and chemical UV protectors



Smart Cap[™] TECHNOLOGY
CAP TURNS BLUE IN HARMFUL UV LIGHT

WATER RESISTANT
(80 MINUTES)

3 fl oz (89 ml)



Mineral-Based Sunscreen

Combining mineral and chemical UV protectors for water-resistant performance you can trust.

Drug Facts

Made in USA

Active Ingredients

Octocrylene 4%
Zinc Oxide 9.7%

Purpose

Sunscreen
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

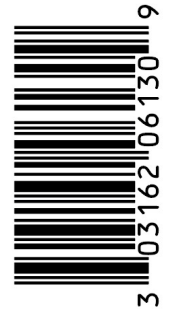
• When using this product • Keep out of eyes. Rinse with water to remove • Stop use and ask a doctor if • Rash or irritation occurs • Do not use • On damaged or broken skin • If allergic to any ingredient • If swallowed, get medical help or contact a Poison Control Center

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

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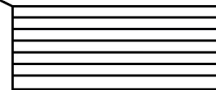
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Crown Laboratories, Inc.
Johnson City, TN 37604

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P11469.02



BLUE LIZARD KIDS SUNSCREEN

octocrylene and zinc oxide lotion

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:0316-2061

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	41.8 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	104.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CETYL DIMETHICONE 25 (UNII: U4AS1BW4ZB)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5) (UNII: 035JKJ76MT)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
TRIMETHYLSILOXYSILICATE (M/Q 0.8-1.0) (UNII: 25LXE464L2)	
HEXADECYL POVIDONE (4 HEXADECYL BRANCHES/REPEAT) (UNII: AG75W62QYU)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
METHYL GLUCOSE DIOLATE (UNII: FA9KFJ4Z6P)	
PEG-7 HYDROGENATED CASTOR OIL (UNII: WE09129TH5)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
PROPANEDIOL (UNII: 5965N8W85T)	
WATER (UNII: 059QF0KO0R)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0316-2061-10	5 mL in 1 PACKET; Type 0: Not a Combination Product	01/02/2019	
2	NDC:0316-2061-30	89 mL in 1 TUBE; Type 0: Not a Combination Product	01/02/2019	
3	NDC:0316-2061-40	1 in 1 CARTON	01/02/2019	
3		148 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
4	NDC:0316-2061-50	259 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/02/2019	
5	NDC:0316-2061-60	3785 mL in 1 JUG; Type 0: Not a Combination Product	01/02/2019	
6	NDC:0316-2061-	148 mL in 1 TUBE; Type 0: Not a Combination Product	01/02/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/02/2019	

Labeler - Crown Laboratories (079035945)**Registrant** - Crown Laboratories (079035945)**Establishment**

Name	Address	ID/FEI	Business Operations
Crown Laboratories		079035945	manufacture(0316-2061)