

KIDS BROAD SPECTRUM SPF 35- zinc oxide cream
Allure Labs Inc.

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.

Drug Facts

Active Ingredients:

Zinc Oxide 18.9%

Purpose

Sunscreen

Uses:

- Provide high protection against sunburn.
- Provide broad spectrum (UVA and UVB) protection.
- If used as directed with other sun protection measures, decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings: For external use only.

Keep out of eyes. Rinse with water to remove.

Stop and ask a doctor if rash or irritation occurs.

Keep out of reach of children.

Directions:

- Apply liberally 15 minutes before sun exposure.
- Reapply: after swimming or sweating. Immediately after towel drying. At least every 2 hours.
- Children under 6 months: Ask a doctor.

Inactive Ingredients: Caprylic/Capric Triglyceride, Water (Aqua), Glycerin, Polysorbate 60, Stearic Acid, Cetyl Alcohol, Sorbitan Stearate, Cetearyl Glucoside, Stearyl Alcohol, Polyhydroxystearic Acid, Polyglyceryl-3 Ricinoleate, Isostearic Acid, Lecithin, Phenoxyethanol, Xanthan Gum, Carageenan, Helionori, Punica Granatum (Pomegranate) Extract, Plantago Lanceolate (Plantain) Leaf Extract, Ascorbyl Palmitate (Vitamin-C), Ethylhexylglycerin.

High sun protection product.

Questions? Call toll free 1-800-798-7970

Sun Research LLC

Santa Cruz, CA

www.burnoutsun.com



BurnOut® KIDS

**BROAD SPECTRUM
SPF 35**

No chemical sunscreens

Petroleum-free,
Paraben-free, Biodegradable,
No Nanoparticles

Recommended by
Pediatricians and
Dermatologists

for Sensitive Skin

Rich in Antioxidants, Enriched with
Helionori, Pomegranate, and Plantain

Drug Facts

Active Ingredient **Purpose**
Zinc Oxide (non-nano) 18.9% sunscreen

Use(s)

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- Provides broad spectrum (UVA and UVB) protection.
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Other Information

High sun protection product.

Questions? Call toll free 1-800-798-7970

Press center of cap to close.

3.4 oz.

Gluten-free

Made in the U.S.A.

Never tested on animals.

Sun Research LLC

Santa Cruz, CA

www.burnoutsun.com



KIDS BROAD SPECTRUM SPF 35

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62742-4114
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	189 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
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PLANTAGO LANCEOLATA LEAF (UNII: 2YWL9J7EE8)
ASCORBYL PALMITATE (UNII: QN83US2B0N)
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
GLYCERIN (UNII: PDC6A3C0OX)
PORPHYRA UMBILICALIS (UNII: 14AN0J70WO)
CARRAGEENAN (UNII: 5C69YCD2YJ)
WATER (UNII: 059QF0K00R)
STEARYL ALCOHOL (UNII: 2KR89I4HIY)
POLYHYDROXYSTEARIC ACID STEARATE (UNII: 8KQ7I65XZE)
ISOSTEARIC ACID (UNII: X33R8U0062)
PUNICA GRANATUM ROOT BARK (UNII: CLV24I3T1D)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
POLYSORBATE 60 (UNII: CAL22UVI4M)
STEARIC ACID (UNII: 4ELV7Z65AP)
CETYL ALCOHOL (UNII: 936JST6JCN)
POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
XANTHAN GUM (UNII: TTV12P4NEE)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62742-4114-1	96 g in 1 TUBE; Type 0: Not a Combination Product	12/04/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/04/2017	

Labeler - Allure Labs Inc. (926831603)

Registrant - Allure Lab Inc (926831603)

Establishment

Name	Address	ID/FEI	Business Operations
Allure Labs		926831603	manufacture(62742-4114)