

## **BROAD SPECTRUM SPF 30 FOR FACE AND BODY- 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.*

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### **Drug Facts**

Active Ingredients: Zinc Oxide - 18.6%

Purpose: Sunscreen

Uses:

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

Warnings: For external use only.

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash or irritation occurs.

Keep out of reach of children.

Directions:

- Apply generously 15 minutes before sun exposure.
- Reapply at least every 2 hours. After swimming or sweating. Immediately after towel drying.
- Children under 6 months of age: ask a doctor.

Other Information High sun protection product.

Call toll free 1-800-798-7970

Water (Aqua), Cyclopentasiloxane, Glycerin, Glyceryl Stearate, PEG-100 Stearate, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Sorbitan Stearate, Dimethicone, Triethoxysilylethyl Polydimethylsiloxyethyl Hexyl Dimethicone, Cetyl Alcohol, Polyacrylamide, C13-14 Isoparaffin, Lecithine, Imperata Cylindrica Root Extract, Xanthan Gum, Aloe Barbadensis Leaf Juice, Carica Papaya (Papaya) Fruit Extract, Phenoxyethanol, Caprylyl Glycol, Ethylhexylglycerin, Hexylene Glycol, Laureth-7, Carbomer, PEG-8, Disodium EDTA.

Made in USA

Sun Research LLC

Santa Cruz, CA

[www.burnoutsun.com](http://www.burnoutsun.com)



**BROAD SPECTRUM  
SPF 30**

*for Face & Body*

Clear Zinc Oxide  
UVA / UVB Protection

*For Sensitive Skin*

No Nanoparticles  
Fragrance-free, Paraben-free

Antioxidant rich | lightweight  
oil-free | for daily use | matte finish

net wt 2.4 oz / 68 g

**Drug Facts**

|  |                |
|--|----------------|
| <b>Active Ingredient</b>   | <b>Purpose</b> |
| Zinc Oxide (non-nano) 18.6%  | sunscreen      |
| <b>Use(s)</b>  |                |
| <ul style="list-style-type: none"> <li>Provides high protection against sunburn.</li> <li>Broad spectrum (UVA and UVB) protection.</li> <li>If used as directed with other sun protection measures, decreases the risk of skin cancer and early skin aging caused by the sun.</li> </ul>   |                |
| <b>Warnings For external use only.</b>   |                |
| When using this product  |                |
| <ul style="list-style-type: none"> <li>Keep out of eyes. Rinse with water to remove.</li> <li>Stop and ask a doctor if rash or irritation occurs.</li> </ul>   |                |
| Keep out of reach of children.   |                |
| <b>Directions</b>  |                |
| <ul style="list-style-type: none"> <li>Apply liberally 15 minutes before sun exposure</li> <li>Reapply:             <ul style="list-style-type: none"> <li>After swimming or sweating</li> <li>Immediately after towel drying</li> <li>At least every 2 hours</li> </ul> </li> <li>Children under 6 months: Ask a doctor</li> </ul>  |                |
| <b>Inactive Ingredients</b>  |                |
| Water; Cyclopentasiloxane; Cyclomethicone; Glycerin; Glyceryl Stearate; PEG 100 Stearate; Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone; Sorbitan Stearate; Dimethicone; Triethoxymethyl Polydimethylsiloxyethyl Hexyl Dimethicone; Cetyl Alcohol; Lecithin; Imperata Cylindrica (Root) Extract; Xanthan Gum; Aloe Barbadensis Leaf Juice; Carica Papaya (Papaya) Fruit Extract; Polyacrylamide; C13-14 Isoparaffin; Laureth-7; PEG-8; Carbomer; Phenoxyethanol; Caprylyl Glycol; Ethylhexylglycerin; Hexylene Glycol; Disodium EDTA. |                |
| <b>Other Information</b> High sun protection product.  |                |
| <b>Questions? Call toll free 1-800-798-7970</b>  |                |

Press center of cap to close.

Gluten-free  LDPE

Made in the U.S.A.  
Never tested on animals.  
Sun Research LLC  
Santa Cruz, CA  
www.burnoutsun.com



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**BROAD SPECTRUM SPF 30 FOR FACE AND BODY**

zinc oxide cream

| Product Information   |                   |                    |                |
|---|-------------------|--------------------|----------------|
| Product Type  | HUMAN OTC DRUG    | Item Code (Source) | NDC:62742-4116 |
| Route of Administration                                       | TOPICAL           |                    |                |
| Active Ingredient/Active Moiety                               |                   |                    |                |
| Ingredient Name   | Basis of Strength | Strength           |                |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37) | ZINC CATION       | 186 mg in 1 g      |                |
| Inactive Ingredients  |                   |                    |                |
| Ingredient Name   | Strength          |                    |                |
| WATER (UNII: 059QF0K00R)                                      |                   |                    |                |

|   |
|---|
| <b>DIMETHICONE CROSSPOLYMER (45000 MPAS AT 12 % IN CYCLOPENTASILOXANE)</b> (UNII: UF7620L1W6) |
| <b>CYCLOMETHICONE</b> (UNII: NMQ347994Z)  |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)  |
| <b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)   |
| <b>PEG-100 STEARATE</b> (UNII: YD01N1999R)  |
| <b>POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPAS)</b> (UNII: RLA2U05Z4Q)      |
| <b>SORBITAN MONOSTEARATE</b> (UNII: NVZ4I0H58X)   |
| <b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)   |
| <b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)   |
| <b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)   |
| <b>IMPERATA CYLINDRICA ROOT</b> (UNII: VYT2JA85NH)  |
| <b>POLYACRYLAMIDE (10000 MW)</b> (UNII: E2KR9C9V2I)   |
| <b>C13-14 ISOPARAFFIN</b> (UNII: E4F12ROE70)  |
| <b>CARICA PAPAYA LEAF</b> (UNII: 66J7636Z2I)  |
| <b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)  |
| <b>PEG-8 CAPRYLIC/CAPRIC GLYCERIDES</b> (UNII: 00BT03FSO2)                                    |
| <b>CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 71DD5V995L)       |
| <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)  |
| <b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)   |
| <b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)  |
| <b>HEXYLENE GLYCOL</b> (UNII: KEH0A3F75J)   |
| <b>LAURETH-7</b> (UNII: Z95S6G8201)   |
| <b>XANTHAN GUM</b> (UNII: TTV12P4NEE)   |
| <b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)  |

### Packaging

| # | Item Code        | Package Description                               | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:62742-4116-1 | 68 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 Labs Inc (926831603)

### Establishment

| Name            | Address | ID/FEI    | Business Operations     |
|-----------------|---------|-----------|-------------------------|
| Allure Labs Inc |         | 926831603 | manufacture(62742-4116) |