

PROTECTIF DEEP TINT- zinc oxide and titanium dioxide cream

Allure Labs

Drug Facts

Active Ingredients:

Zinc Oxide 8.6%,

Titanium Dioxide 6.5%

Purpose: Sun Protectant

Uses: Broad spectrum (Sun Protection Factor 50 /SPF 50).

Warning: For external use only.

Do not use on damaged or broken skin.

When using this product, avoid contact with the eyes. If contact occurs, rinse thoroughly with water.

Discontinue use if rash or irritation develops or lasts. If irritation persists, consult a doctor.

Keep out of reach of Children - if swallowed get medical help or contact Poison Control Center right away.

Directions: Adults and Children over 6 months of age: Apply generously and evenly 15 minutes before sun exposure. Reapply at least every 2 hours. 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 take other sun protection measures including limiting time in the sun, especially from 10 a.m. - 2 p.m., and wearing long-sleeve shirts, pants, hats and sunglasses.

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Inactive Ingredients: Water (Aqua), Cyclopentasiloxane, C12-15 Alkyl Benzoate, Dimethicone, Cyclotetrasiloxane, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Polysilicone-31, Glycerin, Aluminum Hydroxide, Stearic Acid, Dimethicone/PEG-10/15 Crosspolymer, Pyrus Malus (Apple) Fruit Extract, Sodium Chloride, Dipropylene Glycol, Sodium Citrate, Tocopherol, Dimethicone/Polyglycerin-3 Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Tocopheryl Acetate, PEG/PPG-18/18 Dimethicone, Polyglyceryl-4 Isostearate, Cetyl PEG/PPG-10/1 Dimethicone, Hexyl Laurate, Pentaerythrityl Tetra-di-tbutyl Hydroxyhydrocinnamate, Cetearyl Oliviate, Sorbitan Oliviate, Benzoic Acid, Ethylhexyl Palmitate, Silica Dimethyl Silylate, Butylene Glycol, Pentylene Glycol, Sodium Hyaluronate, Cyclohexasiloxane, PEG-8, Ascorbyl Palmitate, Ascorbic Acid, Triethoxysilylethyl Polydimethylsiloxyethyl Hexyl Dimethicone, Sodium Ferrocyanide Decahydrate, Hydroxytyrosol, Polygonum Aviculare Extract, Sodium Benzoate, Potassium Sorbate, Alcohol, Lecithin, Ectoin, Cyclotetrapeptide-24

Aminocyclohexane Carboxylate, Carbomer, Polysorbate 20, Palmitoyl Tripeptide-1, Palmitoyl Tetrapeptide-7, Vitis Vinifera (Grape) Fruit Cell Extract, Isomalt, Camellia Sinensis Leaf Extract, Coffea Arabica (Coffee) Seed Extract, Citric Acid, Phenoxyethanol, Caprylyl Glycol, Ethylhexylglycerin, Hexylene Glycol, Triethoxycaprylylsilane, Iron Oxides (CI 77491, CI 77492, CI 77499)

Protectif™

SPF 50+ FPS

BROAD SPECTRUM SUNSCREEN
CRÈME SOLAIRE À LARGE SPECTRE

MINERAL REPAIR
WITH GMA7™

RÉPARATION MINÉRALE
AVEC GMA7™

DEEP TINT
UVA/UVB PROTECTION

3.4 FL. OZ e 100 mL

Drug Facts / Info-médicament

| | |
|--|---|
| Active Ingredients Ingredients Médicinaux Zinc Oxide 8.6% Titanium Dioxide 6.5% | Purpose Objectif Sun Protectant / Écran Solaire Sun Protectant / Écran Solaire |
|--|---|

Uses: Broad spectrum (Sun Protection Factor 50 / SPF 50). **Directions:** Adults and Children over 6 months of age: Apply generously and evenly 15 minutes before sun exposure. Reapply at least every 2 hours. **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 take other sun protection measures including limiting time in the sun, especially from 10 a.m. – 2 p.m., and wearing long-sleeve shirts, pants, hats and sunglasses. / **Utilisations:** Large Spectre (Facteur de Protection Solaire / FPS 50). **D'emploi:** Adultes et enfants de plus de 6 mois : Appliquez abondamment et uniformément 15 minutes avant d'exposition au soleil.

Warnings: For external use only. Do not use on damaged or broken skin. When using this product, avoid contact with the eyes. If contact occurs, rinse thoroughly with water. Discontinue use if rash or irritation develops or lasts. If irritation persists, consult a doctor. Keep out of reach of children – if swallowed get medical help or contact Poison Control Center right away. **Mises en garde:** Pour usage externe seulement. Ne pas utiliser sur la peau endommagée ou cassée. Lors de l'utilisation de ce produit – éviter le contact avec les yeux. En cas de contact, rincer abondamment à l'eau. Cesser d'utiliser – le produit si une éruption cutanée ou une irritation se manifeste ou persiste. Si l'irritation persiste, consulter un médecin. En cas d'ingestion – consulter un médecin ou contacter un centre antipoison immédiatement.

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Questions or Comments: Call toll free 1-855-968-3600

Protectif™

SPF 50+ FPS

BROAD SPECTRUM SUNSCREEN
CRÈME SOLAIRE À LARGE SPECTRE

MINERAL REPAIR
WITH GMA7™

RÉPARATION MINÉRALE
AVEC GMA7™

DEEP TINT
UVA/UVB PROTECTION

3.4 FL. OZ e 100 mL

Daily Protection Against UV Rays
Safeguard your skin from the sun with daily UV protection and skin nourishment. Natural minerals Zinc Oxide and Titanium Dioxide form a sun protective shield. Powerful extracts of Olive, Coffee Seed and Green Tea restoratively beautify the skin and help prevent UV damage. Our expert formulation is non-greasy, scent-free, and provides a make-up-friendly matte finish.

Skin and coral reef friendly.

Protection quotidienne contre les rayons UV
Protégez votre peau du soleil avec une protection UV quotidienne et un soin nourrissant pour la peau. Les minéraux naturels de l'oxyde de zinc et du dioxyde de titane forment un écran de protection solaire. Des extraits puissants d'olive, de graine de café et de thé vert embellissent la peau de manière réparatrice et aident à prévenir les dommages causés par les rayons UV. Notre formulation experte est non grasse, sans parfum et offre une finition mate idéale pour le maquillage.

Sans danger pour la peau et les récifs coralliens.

NPN 80120154

DERMA RESEARCH GROUP
33 Farley Drive, Guelph
ON N1L0B7
Made in USA
Fabrique en USA
sajicskin.com

| PROTECTIF DEEP TINT | | | |
|--|--------------------------|---------------------------|-----------------|
| zinc oxide and titanium dioxide cream | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:62742-4261 |
| Route of Administration | TOPICAL | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | Basis of Strength | Strength | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE | 6.5 g in 100 g | |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE | 8.6 g in 100 g | |
| Inactive Ingredients | | | |
| Ingredient Name | | | Strength |
| VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR) | | | |

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| POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) | |
| ASCORBYL PALMITATE (UNII: QN83US2B0N) | |
| ALCOHOL (UNII: 3K9958V90M) | |
| CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) | |
| TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E) | |
| FERRIC OXIDE YELLOW (UNII: EX438O2MRT) | |
| PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS) | |
| CETEARYL OLIVATE (UNII: 58B69Q84JO) | |
| ETHYLHEXYL PALMITATE (UNII: 2865993309) | |
| HYDROXYTYROSOL (UNII: QEU0NE4O90) | |
| PALMITOYL TRIPEPTIDE-1 (UNII: RV743D216M) | |
| ISOMALT (UNII: S870P55O2W) | |
| FERROSFERRIC OXIDE (UNII: XM0M87F357) | |
| ARABICA COFFEE BEAN (UNII: 3SW678MX72) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| BENZOIC ACID (UNII: 8SKN0B0MIM) | |
| PENTYLENE GLYCOL (UNII: 50C1307PZG) | |
| CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| HEXYL LAURATE (UNII: 4CG9F9W01Q) | |
| POLYGONUM AVICULARE TOP (UNII: ZCD6009IUF) | |
| ECTOINE (UNII: 7GXZ3858RY) | |
| POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7) | |
| HYALURONATE SODIUM (UNII: YSE9PPT4TH) | |
| GREEN TEA LEAF (UNII: W2ZU1RY8B0) | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | |
| CYCLOMETHICONE 5 (UNII: 0THT5PCI0R) | |
| ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ) | |
| SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W) | |
| SODIUM FERROCYANIDE DECAHYDRATE (UNII: CG0CLR485X) | |
| POLYSORBATE 20 (UNII: 7T1F30V5YH) | |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | |
| POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPA.S) (UNII: RLA2U05Z4Q) | |
| DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| DIMETHICONE/POLYGLYCERIN-3 CROSSPOLYMER (UNII: 2P2G24V6T9) | |
| HEXYLENE GLYCOL (UNII: KEH0A3F75J) | |
| DIMETHICONE/PEG-10/15 CROSSPOLYMER (UNII: 21AS8B1BSS) | |
| APPLE (UNII: B423VGH5S9) | |
| PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794) | |
| DIPROPYLENE GLYCOL (UNII: E107L85C40) | |
| TOCOPHEROL (UNII: R0ZB2556P8) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| PALMITOYL TETRAPEPTIDE-7 (UNII: Q41S464P1R) | |
| WINE GRAPE (UNII: 3GOV20705G) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| LECITHIN, SOYBEAN (UNII: 1DI56QDM62) | |
| ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) | |

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| SODIUM CITRATE (UNII: 1Q73Q2JULR) |
| DIMETHICONE (UNII: 92RU3N3Y1O) |
| WATER (UNII: 059QF0KO0R) |
| CYCLOMETHICONE 4 (UNII: CZ227117JE) |
| CYCLOMETHICONE 6 (UNII: XHK3U310BA) |
| SORBITAN OLIVATE (UNII: MDL271E3GR) |
| TRIETHOXSILYLETHYL POLYDIMETHYLSILOXYETHYL HEXYL DIMETHICONE (UNII: X75PL53TZJ) |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) |
| ASCORBIC ACID (UNII: PQ6CK8PD0R) |
| CYCLOTETRAPEPTIDE-24 AMINOCYCLOHEXANE CARBOXYLATE (UNII: NR327745KQ) |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:62742-4261-2 | 1 in 1 CARTON | 05/09/2024 | |
| 1 | NDC:62742-4261-1 | 100 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | | |
| 2 | NDC:62742-4261-4 | 1 in 1 CARTON | 05/09/2024 | |
| 2 | NDC:62742-4261-3 | 30 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M020 | 05/09/2024 | |

Labeler - Allure Labs (926831603)

Registrant - Allure Labs (926831603)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------|---------|-----------|-------------------------|
| Allure Labs | | 926831603 | manufacture(62742-4261) |