

PREVENTION DAILY TINTED MOISTURIZER SPF 30- zinc oxide and titanium dioxide 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

Titanium Dioxide 4.7%

Zinc Oxide 6.0%

Purpose

Sunscreen

Indication and usage

Helps prevent sunburn • 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

For external use only

Do not use on damaged or broken skin

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

Stop use and ask a doctor if rash occurs

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

apply generously 15 minutes before sun exposure

children under 6 months of age: Ask a doctor

reapply at least every 2 hours

use a water resistant sunscreen if swimming or sweating

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

protect the product in this container from excessive heat and direct sun

Inactive ingredients AQUA/WATER/EAU, CYCLOPENTASILOXANE, C12-15 ALKYL BENZOATE, DIMETHICONE, GLYCERIN, CYCLOHEXASILOXANE, POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE, DIMETHICONE/PEG-10/15


CROSSPOLYMER, ALUMINUM HYDROXIDE, HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL, STEARIC ACID, SODIUM CHLORIDE, CETYL PEG/PPG-10/1 DIMETHICONE, HEXYL LAURATE, POLYGLYCERYL-4 ISOSTEARATE, PHENOXYETHANOL, DIMETHICONE/POLYGLYCERIN-3 CROSSPOLYMER, CITRUS AURANTIUM DULCIS (ORANGE) PEEL OIL, IRON OXIDES (CI 77492), LIMONENE, CAPRYLYL GLYCOL, CETEARYL OLIVATE, TRIETHOXYSILYLETHYL POLYDIMETHYLSILOXYETHYL HEXYL DIMETHICONE, SORBITAN OLIVATE, DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER, ETHYLHEXYLGLYCERIN, HEXYLENE GLYCOL, CITRUS NOBILIS (MANDARIN ORANGE) PEEL OIL, TOCOPHERYL ACETATE, IRON OXIDES (CI 77491), CAMELLIA SINENSIS LEAF EXTRACT, IRON OXIDES (CI 77499), BENZOIC ACID, DIPROPYLENE GLYCOL, TITANIUM DIOXIDE (CI 77891), ARTEMISIA VULGARIS EXTRACT, LAMINARIA DIGITATA EXTRACT, VANILLA PLANIFOLIA FRUIT EXTRACT, TRIETHOXYCAPRYLYLSILANE, SODIUM CITRATE, GLUCOSE, HYDROLYZED PEA PROTEIN, TOCOPHEROL, BAROSMA BETULINA LEAF OIL, TETRAHEXYLDECYL ASCORBATE, ALUMINA, MAGNESIUM OXIDE, SODIUM SUCCINATE, POTASSIUM SORBATE, SODIUM BENZOATE, LECITHIN, PENTAERYTHRITYL TETRA-DI-T-BUTYL HYDROXYHYDROCINNAMATE, SODIUM FERROCYANIDE, ARABIDOPSIS THALIANA EXTRACT, MICROCOCCUS LYSATE, PLANKTON EXTRACT, ERGOTHIONEINE.

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- Helps to blur the look of imperfections and even out skin tone
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Multi-action daily sunscreen
to fight environmental
skin stressors.



Smooth blending,
moisturizing formula defends
against dryness and other
signs of premature aging

| Drug Facts | |
|---|-----------|
| Active ingredients | Purpose |
| Titanium Dioxide 4.7% | Sunscreen |
| Zinc Oxide 6.0% | Sunscreen |
| Uses • helps prevent sunburn • 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 • For external use only • Do not use on damaged or broken skin • When using this product keep out of eyes. Rinse with water to remove. • Stop use and ask a doctor if rash occurs. • Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. | |
| Directions • apply generously 15 minutes before sun exposure • children under 6 months of age: Ask a doctor • reapply at least every 2 hours • use a water resistant sunscreen if swimming or sweating • 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 | |
| Other information • protect the product in this container from excessive heat and direct sun | |
| Inactive ingredients AQUAWATEREAL, CYCLOPENTASILOXANE, C12-15 ALKYL BENZOATE, DIMETHICONE, GLYCERIN, CYCLOHEXASILOXANE, POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE, DIMETHICONE/PEG-10/15 CROSSPOLYMER, ALUMINUM HYDROXIDE, HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL, STEARIC ACID, SODIUM CHLORIDE, CETYL PEG/PPG-10/1 DIMETHICONE, HEXYL LAURATE, POLYGLYCERYL-4 ISOSTEARATE, PHENOXYETHANOL, DIMETHICONE/POLYGLYCERIN-3 CROSSPOLYMER, CITRUS AURANTIUM DULCIS (ORANGE) PEEL OIL, IRON OXIDES (CI 77492), LIMONENE, CAPRYLYL GLYCOL, CETEARYL OLIVATE, TRIETHOXYSILYLETHYL POLYDIMETHYLSILOXYETHYL HEXYL DIMETHICONE, SORBITAN OLIVATE, DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER, ETHYLHEXYLGLYCERIN, HEXYLENE GLYCOL, CITRUS NOBILIS (MANDARIN ORANGE) PEEL OIL, TOCOPHERYL ACETATE, IRON OXIDES (CI 77491), CAMELLIA SINENSIS LEAF EXTRACT, IRON OXIDES (CI 77499), BENZOIC ACID, DIPROPYLENE GLYCOL, TITANIUM DIOXIDE (CI 77891), ARTEMISIA VULGARIS EXTRACT, LAMINARIA DIGITATA EXTRACT, VANILLA PLANIFOLIA FRUIT EXTRACT, TRIETHOXYCAPRYLYLSILANE, SODIUM CITRATE, GLUCOSE, HYDROLYZED PEA PROTEIN, TOCOPHEROL, BAROSMA BETULINA LEAF OIL, TETRAHEXYLDECYL ASCORBATE, ALUMINA, MAGNESIUM OXIDE, SODIUM SUCCINATE, POTASSIUM SORBATE, SODIUM BENZOATE, LECITHIN, PENTAERYTHRITYL TETRA-DI-T-BUTYL HYDROXYHYDROCINNAMATE, SODIUM FERROCYANIDE, ARABIDOPSIS THALIANA EXTRACT, MICROCOCCUS LYSATE, PLANKTON EXTRACT, ERGOTHIONEINE. | |
| Questions? call 800-736-7546 | |

PREVENTION DAILY TINTED MOISTURIZER SPF 30
zinc oxide and titanium dioxide cream

Product Information

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|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:62742-4221 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|-----------------|
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE | 4.7 g in 100 g |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE | 6 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|-----------------|
| CYCLOMETHICONE 6 (UNII: XHK3U310BA) | |
| DIMETHICONE/POLYGLYCERIN-3 CROSSPOLYMER (UNII: 2P2G24V6T9) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA) | |
| POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| ORANGE OIL (UNII: AKN3KSD11B) | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | |
| BENZOIC ACID (UNII: 8SKN0B0MIM) | |
| TOCOPHEROL (UNII: R0ZB2556P8) | |
| AGATHOSMA BETULINA LEAF OIL (UNII: KOS935A04V) | |
| MAGNESIUM OXIDE (UNII: 3A3U0GI71G) | |
| SODIUM SUCCINATE ANHYDROUS (UNII: V8ZGC8ISR3) | |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS) | |
| SODIUM FERROCYANIDE (UNII: 5HT6X21AID) | |
| WATER (UNII: 059QF0KO0R) | |
| CYCLOMETHICONE 5 (UNII: 0THT5PCI0R) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPA.S) (UNII: RLA2U05Z4Q) | |
| ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) | |
| MANDARIN OIL (UNII: NJO720F72R) | |
| TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ) | |
| PEA PROTEIN (UNII: 7Q50F46595) | |
| FERROSO FERRIC OXIDE (UNII: XM0M87F357) | |
| LECITHIN, SOYBEAN (UNII: 1DI56QDM62) | |
| ERGOThIONEINE (UNII: BDZ3DQM98W) | |
| GREEN TEA LEAF (UNII: W2ZU1RY8B0) | |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | |
| SORBITAN OLIVATE (UNII: MDL271E3GR) | |
| ALUMINUM OXIDE (UNII: LMI26O6933) | |
| DIMETHICONE/PEG-10/15 CROSSPOLYMER (UNII: 21AS8B1BSS) | |
| SUNFLOWER OIL (UNII: 3W1JG795YI) | |

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| HEXYL LAURATE (UNII: 4CG9F9W01Q) |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) |
| HEXYLENE GLYCOL (UNII: KEH0A3F75J) |
| ARTEMISIA VULGARIS ROOT (UNII: 32MP823R8S) |
| LAMINARIA DIGITATA (UNII: 15E7C67EE8) |
| SODIUM CITRATE (UNII: 1Q73Q2JULR) |
| DIMETHICONE (UNII: 92RU3N3Y1O) |
| ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ) |
| FERRIC OXIDE YELLOW (UNII: EX438O2MRT) |
| LIMONENE, (+)- (UNII: GFD7C86Q1W) |
| ARABIDOPSIS THALIANA (UNII: AI3L60HQ81) |
| MICROCOCCUS LUTEUS (UNII: LV6L29Z6AX) |
| TRIETHOXSILYLETHYL POLYDIMETHYLSILOXYETHYL HEXYL DIMETHICONE (UNII: X75PL53TZJ) |
| DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5) |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) |
| DIPROPYLENE GLYCOL (UNII: E107L85C40) |
| CETEARYL OLIVATE (UNII: 58B69Q84JO) |
| VANILLA (UNII: Q74T35078H) |
| TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E) |
| ANHYDROUS DEXTROSE (UNII: 5SL0G7R0OK) |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:62742-4221-1 | 7 g in 1 TUBE; Type 0: Not a Combination Product | 11/15/2022 | |
| 2 | NDC:62742-4221-3 | 1 in 1 CARTON | 11/15/2022 | |
| 2 | NDC:62742-4221-2 | 91 g in 1 TUBE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | M020 | 11/15/2022 | |

Labeler - Allure Labs Inc (926831603)

Registrant - Allure Labs Inc (926831603)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------|---------|-----------|-------------------------|
| Allure Labs Inc | | 926831603 | manufacture(62742-4221) |