

I CONCEAL FLAWLESS FOUNDATION BROAD SPECTRUM SPF 30 SUNSCREEN SUEDE-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:

Zinc Oxide - 8.5 %

Titanium Dioxide - 9.8%

Purpose: Sunscreen

Uses:

- Helps prevent sunburn.
- If used as directed with other sun protection measures (see Direction), decreases the risk of skin cancer and early skin aging caused by the sun.

Warning:

- For external use only.

Do not use:

- on damaged or broken skin.

When using this products:

- Keep out of eyes. If contact occurs rinse with water to remove.

Stop use and ask a doctor

- if skin irritation develops.

Keep out of reach of children:

- If swallowed, get medical help or contact a Poison Control Center right away.

Directions for Sunscreen use:

- 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 increase your risk of skin cancer and early skin aging. To decrease the 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 sleeve shirts, pants, hats and sunglasses.

Inactive Ingredients: Water/Aqua/Eau, Cyclopentasiloxane, Coconut Alkanes, Squalene, Polyglyceryl-4 Diisostearate/Polyhydroxystearate/ Sebacate, Glycerin, Silica, Cetyl PEG/PPG-10/1 Dimethicone, Hexyl Laurate, Isohexadecane, Polyglyceryl-4 Isostearate, Vinyl Dimethicone/Lauryl Dimethicone, Dimethicone, Hydroxypropylcocoate PEG-8 Dimethicone, Alumina, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Tetradecane, Mica, Cyclohexasiloxane, Magnesium Sulfate, Polyhydroxystearic Acid, Triethoxysilyethyl Polydimethylsiloxyethyl Hexyl Dimethicone, Caprylyl Glycol, Dimethicone/PEG-10/15 Crosspolymer, Ethylhexylglycerin, Hexylene Glycol, Dipotassium

Glycyrrhizate, Perflurorodecalin, Zinc PCA, Saccharomyces Lysate Extract, Centella Asiatica Extract, Leuconostoc/Radish Root Ferment Filtrate, Olea Europa (Olive) Leaf Extract, Algae Extract, Phospholipids, Artemisia Vulgaris Extract, Hyaluronic Acid, Isomalt, Cyperus Rotundus Root Extract, Lonicera Japonica (Honeysuckle) Flower Extract, Xanthium Sibiricum Fruit Extract, Dipropylene Glycol, Retinyl Palmitate, Tocopherol, Ascorbyl Palmitate, Opuntia Ficus-Indica Stem Extract, Sodium Citrate, Sodium Benzoate, Phenoxyethanol, Potassium Sorbate, Salicylic Acid, Acetyl Hexapeptide-8, Sorbic Acid, Lecithin, Vitis Vinifera (Grape) Fruit Cell Extract, Pantearythrityl Tetra-Di-T-Butyl Hydroxyhydrocinnamate, Ergothionine, [+/-: Ci 77163, Ci 77492, Ci 77491, Ci 77499, Beta-carotene].

Manufactured for:

IMAGE Skincare, Lantana, FL 33462 USA

Manufactured in USA from globally

sourced ingredients and components

www.ImageSkincare.com

<p>Drug Facts (continued)</p> <p>Other Information</p> <ul style="list-style-type: none"> Protect the product in this container from excessive heat and direct sun. <p>Inactive Ingredients</p> <p>Water/Aqua/Eau, Cyclopentasiloxane, Coconut Alkanes, Squalane, Polyglyceryl-4 Disostearate/Polyhydroxystearate/Sebacate, Glycerin, Silica, Cetyl PEG/PPG-10/1 Dimethicone, Hexyl Laurate, Isohexadecane, Polyglyceryl-4 Isostearate, Vinyl Dimethicone/Lauryl Dimethicone Crosspolymer, Hydrogen Dimethicone, Hydroxypropylcoate PEG-8 Dimethicone, Dimethicone, Alumina, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Tetradecane, Mica, Cyclohexasiloxane, Magnesium Sulfate, Polyhydroxystearic Acid, Triethoxysilyethyl Polydimethylsiloxyethyl Hexyl Dimethicone, Caprylyl Glycol, Dimethicone/PEG-10/15 Crosspolymer, Ethylhexylglycerin, Hexylene Glycol, Dipotassium Glycyrrhizate, Perflurorodecalin, Zinc PCA, Saccharomyces Lysate Extract, Centella Asiatica Extract, Leuconostoc/Radish Root Ferment Filtrate, Olea Europa (Olive) Leaf Extract, Algae Extract, Phospholipids, Artemisia Vulgaris Extract, Hyaluronic Acid, Isomalt, Cyperus Rotundus Root Extract, Lonicera Japonica (Honeysuckle) Flower Extract, Xanthium Sibiricum Fruit Extract, Dipropylene Glycol, Retinyl Palmitate, Tocopherol, Ascorbyl Palmitate, Opuntia Ficus-Indica Stem Extract, Sodium Citrate, Sodium Benzoate, Phenoxyethanol, Potassium Sorbate, Salicylic Acid, Acetyl Hexapeptide-8, Sorbic Acid, Lecithin, Vitis Vinifera (Grape) Fruit Cell Extract, Pentaerythrityl Tetra-Di-T-Butyl Hydroxyhydrocinnamate, Ergothionine, [+/-: Ci 77163, Ci 77492, Ci 77491, Ci 77499, Beta-carotene]</p> <p>Questions Call 800-796-7546</p> <p>Manufactured for IMAGE Skincare, Lantana, FL 33462 USA Manufactured in USA from globally sourced ingredients and components www.ImageSkincare.com</p> <p>12M</p> <p>IBSU-BOX-001-US</p>	<p style="text-align: center;">I</p> <p style="text-align: center;">IMAGE SKINCARE</p> <p style="text-align: center;">I CONCEAL</p> <p style="text-align: center;">flawless foundation fond de teint impeccable</p> <p style="text-align: center;">broad spectrum SPF 30 sunscreen écran solaire à large spectre FPS 30</p> <p style="text-align: center;">SUEDE</p> <p style="text-align: center;">1 oz / 28 g</p>	<p style="text-align: center;">Protect and perfect for flawless skin</p> <ul style="list-style-type: none"> All-mineral, broad-spectrum UVA and UVB protection with zinc oxide and titanium dioxide Mineral pigments blend seamlessly to provide a full-coverage finish Plant stem cells, antioxidants and skin-conditioning botanicals nourish the skin Covers the appearance of redness after cosmetic procedures Minimizes the look of pores and imperfections <p style="text-align: center;">DIRECTIONS: Apply desired amount to face and neck and blend.</p> <p style="text-align: center;">Get to know I BEAUTY at www.imageskincare.com</p> <p style="text-align: center;">I BEAUTY</p>	<p style="text-align: center;">Physician formulated Oxybenzone free Paraben free</p> <p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active Ingredients</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Titanium Dioxide 9.8%</td> <td>Sunscreen</td> </tr> <tr> <td>Zinc Oxide 8.5%</td> <td>Sunscreen</td> </tr> </tbody> </table> <p>Uses</p> <ul style="list-style-type: none"> 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. <p>Warnings</p> <ul style="list-style-type: none"> For external use only. <p>Do not use</p> <ul style="list-style-type: none"> On damaged or broken skin <p>When using this product</p> <ul style="list-style-type: none"> Keep out of eyes. If contact occurs rinse with water to remove. <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> skin irritation develops. <p>Keep out of reach of children.</p> <ul style="list-style-type: none"> If swallowed, get medical help or contact a Poison Control Center right away. <p>Directions For Sunscreen Use</p> <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> limit time in the sun, especially from 10 a.m.-2 p.m. wear long-sleeved shirts, pants, hats and sunglasses. 	Active Ingredients	Purpose	Titanium Dioxide 9.8%	Sunscreen	Zinc Oxide 8.5%	Sunscreen
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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62742-4175
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	85 mg in 1 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	98 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
COCONUT ALKANES (UNII: 1E5KJY107T)	
SQUALANE (UNII: GW89575KF9)	
GLYCERIN (UNII: PDC6A3C0OX)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
HYDROGEN DIMETHICONE (13 CST) (UNII: 4QGR4P2YOI)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ALUMINUM OXIDE (UNII: LM26O6933)	
POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPAS) (UNII: RLA2U05Z4Q)	
TETRADECANE (UNII: 03LY784Y58)	
MICA (UNII: V8A1AW0880)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
GLYCERYRRHIZINATE DIPO TASSIUM (UNII: CA2Y0FE3FX)	
PERFLUNAFENE (UNII: 54A06VV62N)	
ZINC PIDOLATE (UNII: C32PQ86DH4)	
SACCHAROMYCES LYSATE (UNII: R85W246Z1C)	
CENTELLA ASIATICA (UNII: 7M867G6T1U)	
LEUCONOSTOC/RADISH ROOT FERMENT FILTRATE (UNII: D2QHA03458)	
OLEA EUROPAEA LEAF (UNII: MJ95C3OH47)	
LAMINARIA DIGITATA (UNII: 15E7C67EE8)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
ARTEMISIA VULGARIS WHOLE (UNII: JDR81QW9ZQ)	
HYALURONIC ACID (UNII: S270N0TRQY)	
ISOMALT (UNII: S870P55O2W)	
CYPERUS ROTUNDUS TUBER (UNII: 4B51SRR959)	
LONICERA JAPONICA FLOWER (UNII: 4465L2WS4Y)	
XANTHIUM SIBIRICUM FRUIT (UNII: 3HB33L84C2)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	

OPUNTIA FICUS-INDICA STEM (UNII: MUD8892KHL)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
ACETYL HEXAPEPTIDE-8 (UNII: L4EL31FWIL)	
SORBIC ACID (UNII: X045WJ989B)	
WINE GRAPE (UNII: 3GOV20705G)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
ERGOTHIONEINE (UNII: BDZ3DQM98W)	
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
BETA CAROTENE (UNII: 01YAE03M7J)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62742-4175-2	1 in 1 CARTON	10/04/2019	
1	NDC:62742-4175-1	28 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	part352	10/04/2019	

Labeler - Allure Labs Inc (926831603)