

MINERAL SUNSCREEN BROAD SPECTRUM SPF 45- 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

Titanium Dioxide - 7.36%

Zinc Oxide - 5.14%

Helps prevent sunburn

if used as directed with other sun protection measures, decreases the risk of skin cancer and early skin aging caused by the sun.

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.

if product is swallowed, get medical help or contact a Poison Control Center right away.

apply liberally 15 minutes before sun exposure.

use a water resistant sunscreen if swimming or sweating.

reapply:

immediately after swimming, sweating or towel drying.

at least every 2 hours.

children under 6 months: ask doctor

Sun protection measures:

Spending time in the sun increases 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 protector measures including:

limit time in the sun, especially from 10:00 am to 2:00 pm.

wear long sleeved shirts, pants, hats and sun glasses.

May stain or damage some fabrics or surfaces. Avoid long term storage above 40C (120F). Protect the product in this container from excessive heat and direct sunlight.

Water (Aqua), Caprylic/Capric Triglyceride, Ethylhexyl Palmitate, Dimethicone, Glycerin, Polyglyceryl-3 Ricinoleate, Methylpropanediol, Aloe Barbadensis Leaf Juice, Polyhydroxystearic Acid, Aluminum Stearate, Tocopherol, Zinc Stearate, Magnesium Sulfate, Simmondsia Chinesis (Jojoba) Seed Oil, Vitis Vinifera (Grape) Seed Oil, Hydrogenated Castor oil, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Ubiquinone, Camellia Oleifera Leaf Extract, Sodium Hyaluronate, Vitis Vinifera (Grape) Seed Extract, Bisabolol, Panthenol, Tetrahexyldecyl Ascorbate, Carrageenan, Glucose, Myristoyl Pentapeptide-11, Triethoxycaprylylsilane, Alumina, Xanthan Gum, Sodium Benzoate, Potassium Sorbate, Citric Acid, Thymus Vulgaris (Thyme) Flower/Leaf Oil, Mentha Viridis (Spearmint) Leaf Oil, Fusanus Spicatus Wood Oil, Salvia Sclarea (Clary) Oil, Rosa Damascena Flower Oil, Mentha Piperita (Peppermint) Oil, Citrus Reticulata (Tangerine) Leaf Oil, Pogostemon Cablin Oil, Citrus Aurantium Dulcis (Orange) Peel Oil, Myrica Fragrans (Nutmeg) Kernel Oil, Commiphora Myrrha Oil, Citrus Aurantifolia (Lime) Oil, Citrus Limon (Lemon) Peel Oil, Lavandula Angustifolia (Lavender) Oil, Citrus Grandis (Grapefruit) Peel oil, Abies Sibirica Oil, Eucalyptus Globulus Leaf Oil, Juniperus Virginiana Oil, Citrus Aurantium Bergamia (Bergamot) Fruit Extract, Citrus Nobilis (Mandarin Orange) Peel Oil, Pelargonium Graveolens Flower Oil, Ferula Galbaniflua (Galbanum) Resin Oil, Triethyl Citrate, Vanillin, ethyl Vanillin, Limonene, Linalool, benzyl Alcohol, Geraniol.

Distributed By:

The Soleil Group, LLC.

Bronxville, NY 10708

Energie 43

1271 EC Huizen, Netherlands

www.soleiltoujours.com

MADE IN U.S.A.

Directions:

- Apply liberally 15 minutes before sun exposure.
- Use a water resistant sunscreen if swimming or sweating.
- Reapply:
 - immediately after swimming, sweating or towel drying.
 - at least every 2 hours.
- Children under 6 months: Ask a doctor.
- 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: May stain or damage some fabrics or surfaces. Avoid long term storage above 40°C (120°F). Protect the product in this container from excessive heat and direct sunlight.

Questions or comments:
Call (+1) 877-320-2381

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MADE IN U.S.A.

45

110

SOLEIL
TOUJOURS®

spf 45

EXTRÊME UV

CRÈME SOLAIRE MINÉRALE
MINERAL SUNSCREEN
BROAD SPECTRUM SPF 45

FACE • VISAGE

40 mL e 1.35 fl.oz.

DRUG FACTS
(continued)

Inactive Ingredients:
Water (Aqua), Caprylic/Capric Triglyceride, Ethylhexyl Palmitate, Dimethicone, Glycerin, Polyglyceryl-3 Ricinoleate, Methylpropanediol, Aloe Barbadensis Leaf Juice, Polyhydroxystearic Acid, Aluminum Stearate, Tocopherol, Zinc Stearate, Magnesium Sulfate, Simmondsia Chinensis (Jojoba) Seed Oil, Vitis Vinifera (Grape) Seed Oil, Hydrogenated Castor Oil, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Ubiquinone, Camellia Oleifera Leaf Extract, Sodium Hyaluronate, Vitis Vinifera (Grape) Seed Extract, Bisabolol, Panthenol, Tetrahexyldecyl Ascorbate, Carrageenan, Glucose, Myristoyl Pentapeptide-11, Triethoxycaprylylsilane, Alumina, Xanthan Gum, Sodium Benzoate, Potassium Sorbate, Citric Acid, Thymus Vulgaris (Thyme) Flower/Leaf Oil, Mentha Viridis (Spearmint) Leaf Oil, Fusanus Spicatus Wood Oil, Salvia Sclarea (Clary) Oil, Rosa Damascena Flower Oil, Mentha Piperita (Peppermint) Oil, Citrus Reticulata (Tangerine) Leaf Oil, Pogostemon Cablin Oil, Citrus Aurantium Dulcis (Orange) Peel Oil, Myristica Fragrans (Nutmeg) Kernel Oil, Commiphora Myrrha Oil, Citrus Aurantifolia (Lime) Oil, Citrus Limon (Lemon) Peel Oil, Lavandula Angustifolia (Lavender) Oil, Citrus Grandis (Grapefruit) Peel Oil, Abies Sibirica Oil, Eucalyptus Globulus Leaf Oil, Juniperus Virginiana Oil, Citrus Aurantium Bergamia (Bergamot) Fruit Extract, Citrus Nobilis (Mandarin Orange) Peel Oil, Pelargonium Graveolens Flower Oil, Ferula Galbaniflua (Galbanum) Resin Oil, Triethyl Citrate, Vanillin, Ethyl Vanillin, Limonene, Linalool, Benzyl Alcohol, Geraniol

Protect your skin from damaging UV rays naturally. Formulated specifically for the face, this non-chemical sunscreen provides superior high-level SPF coverage for intense sun exposure. Hydrates. Helps reduce the appearance of fine lines.

Red Algae, Vitamin C Ester, Vitamin E & Bisabolol - helps scavenge free radicals, reduce UV induced damage, prevent loss of firmness and increase skin smoothness & brightness.

Titanium dioxide and zinc oxide provide superior & natural protection from UVA & UVB rays that cause long-term cell damage and burning.

Pentapeptide-11, CoQ10, sodium hyaluronate and green tea leaf extract help firm skin and reduce UV-induced DNA damage.

NO parabens, petrolatum, phthalates, propylene glycol, oxybenzone, retinyl palmitate, animal ingredients, synthetic colors or fragrances.

DRUG FACTS

Active Ingredients:

| | | |
|------------------|-------|-------------------------|
| Titanium Dioxide | 7.36% | } Purpose: Sunscreen |
| Zinc Oxide | 5.14% | |

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 product is swallowed, get medical help or contact a Poison Control Center right away.

MINERAL SUNSCREEN BROAD SPECTRUM SPF 45

zinc oxide and titanium dioxide cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:62742-4152 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|-----------------|
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37) | ZINC CATION | 51.4 mg in 1 mL |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE | 73.6 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| WATER (UNII: 059QF0K00R) | |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | |
| ETHYLHEXYL PALMITATE (UNII: 2865993309) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |

| | |
|---|--|
| GLYCERIN (UNII: PDC6A3C0OX) | |
| POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W) | |
| METHYLPROPANEDIOL (UNII: N8F53B3R4R) | |
| aloe (UNII: V5VD430YW9) | |
| POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F) | |
| ALUMINUM STEARATE (UNII: U6XF9NP8HM) | |
| TOCOPHEROL (UNII: R0ZB2556P8) | |
| ZINC STEARATE (UNII: H92E6QA4FV) | |
| MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB) | |
| SIMMONDSIA CHINENSIS SEED (UNII: D24K2Q1F6H) | |
| VITIS VINIFERA SEED (UNII: C34U15ICXA) | |
| HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY) | |
| ALMOND OIL (UNII: 66YXD4DKO9) | |
| UBIQUINONE Q2 (UNII: I7T5V2W47R) | |
| CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60) | |
| HYALURONATE SODIUM (UNII: YSE9PPT4TH) | |
| .ALPHA.-BISABOLOL, (+)- (UNII: 105S6I733Z) | |
| PANTHENOL (UNII: WV9CM0O67Z) | |
| TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ) | |
| CARRAGEENAN (UNII: 5C69YCD2YJ) | |
| DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2) | |
| TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E) | |
| ALUMINUM OXIDE (UNII: LM26O6933) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| THYMUS VULGARIS LEAF (UNII: GRX3499643) | |
| SPEARMINT OIL (UNII: C3M81465G5) | |
| CLARY SAGE OIL (UNII: 87L0D4U3M0) | |
| SANTALUM SPICATUM OIL (UNII: H9LVS6REV4) | |
| ROSA DAMASCENA FLOWER OIL (UNII: 18920M3T13) | |
| PEPPERMINT OIL (UNII: AV092KU4JH) | |
| CITRUS RETICULATA LEAF OIL (UNII: 1515UE78IH) | |
| PATCHOULI OIL (UNII: F3IN55X5PO) | |
| ORANGE OIL (UNII: AKN3KSD11B) | |
| MYRRH OIL (UNII: H74221J5J4) | |
| LIME OIL (UNII: UZH29XGA8G) | |
| LEMON OIL (UNII: I9GRO824LL) | |
| LAVENDER OIL (UNII: ZBP1YXW0H8) | |
| GRAPEFRUIT OIL (UNII: YR377U58W9) | |
| ABIES SIBIRICA LEAF OIL (UNII: XRY0V4VZKZ) | |
| EUCALYPTUS GLOBULUS LEAF (UNII: S546YLW6E6) | |
| JUNIPERUS VIRGINIANA OIL (UNII: PAD4FN7P2G) | |
| BERGAMOT OIL (UNII: 39W1PKE3J1) | |
| TANGERINE (UNII: KH3E3096OO) | |
| PELARGONIUM GRAVEOLENS FLOWER OIL (UNII: 3K0J1S7QGC) | |
| GALBANUM OIL (UNII: 211UF7M8N1) | |
| TRIETHYL CITRATE (UNII: 8Z96QXD6UM) | |
| VANILLIN (UNII: CHI530446X) | |

| | |
|------------------------------------|--|
| ETHYL VANILLIN (UNII: YC9ST449 YJ) | |
| LIMONENE, (+)- (UNII: GFD7C86Q1W) | |
| LINALOOL, (+)- (UNII: F4VNO44C09) | |
| BENZYL ALCOHOL (UNII: LKG8494WBH) | |
| GERANIOL (UNII: L837108USY) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:62742-4152-2 | 1 in 1 CARTON | 12/11/2017 | |
| 1 | NDC:62742-4152-1 | 40 mL in 1 BOTTLE; 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 | 12/11/2017 | |

Labeler - Allure Labs, Inc (926831603)

Registrant - Allure Labs, Inc (926831603)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------|---------|-----------|-------------------------|
| Allure Labs, Inc | | 926831603 | manufacture(62742-4152) |

Revised: 12/2017

Allure Labs, Inc