

MINERAL SUNSCREEN MOISTURIZER BROAD SPECTRUM SPF 20- 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 - 4.80%

Zinc Oxide - 5.00%

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.

Aloe Barbadensis Leaf Juice, Caprylic/Capric Triglyceride, Ethylhexyl Palmitate, Glycerin, Cetearyl Alcohol, Cetyl Alcohol, Polyhydroxystearic Acid, Vitis Vinifera (Grape) Seed Oil, Sodium Stearoyl Glutamate, Glyceryl Stearate, Cetearyl Glucoside, Sorbitan Stearate, Tetrahexyldecyl Ascorbate, Pichia/Resveratrol Ferment Extract, Malus Domestica Fruit Cell Culture Extract, Simmondsia Chinensis (Jojoba) Seed Oil, Sodium Hyaluronate, Carrageenan, Glucose, Tocopherol, Myristoyl Pentapeptide-11, Bisabolol, Benzylidene Dimethoxydimethylindanone, Tetrahydrodiferuloylmethane, Glyceryl Isostearate, Water (Aqua), Aluminum Stearate, Alumina, Microcrystalline Cellulose, Cellulose Gum, Phenoxyethanol, Xanthan Gum, Ethylhexylglycerin, Caprylyl Glycol, Lecithin, Citric Acid, Disodium EDTA, 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, Feraniol, Citronellol.

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 (104°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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45



110

spf 20

40 mL e 1.35 fl oz.

DRUG FACTS
(continued)

Inactive Ingredients:
Aloe Barbadosensis Leaf Juice, Caprylic/Capric Triglyceride, Glycerin, Ethylhexyl Palmitate, Cetearyl Alcohol, Cetyl Alcohol, Polyhydroxystearic Acid, Vitis Vinifera (Grape) Seed Oil, Sodium Stearoyl Glutamate, Glyceryl Stearate, Cetearyl Glucoside, Sorbitan Stearate, Tetrahydroxyldecyl Ascorbate, Pichia/Resveratrol Ferment Extract, Malus Domestica Fruit Cell Culture Extract, Simmondsia Chinensis (Jojoba) Seed Oil, Sodium Hyaluronate, Carrageenan, Glucose, Tocopherol, Myristoyl Pentapeptide-11, Bisabolol, Benzylidene Dimethoxydimethylindanone, Tetrahydrodiferuloylmethane, Glycerol Isostearate, Water (Aqua), Aluminum Stearate, Alumina, Microcrystalline Cellulose, Cellulose Gum, Phenoxylethanol, Xanthan Gum, Ethylhexylglycerin, Caprylyl Glycol, Lecithin, Citric Acid, Disodium EDTA, 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, Vanilla, Ethyl Vanillin, Limonene, Linalool, Benzyl Alcohol, Geraniol, Citronellol

Shield your skin from damaging UV rays naturally. Packed with anti-aging benefits. Apply this luxurious yet lightweight cream daily for year-round SPF protection and care. Deeply hydrates. Anti-oxidants help reduce the effects of UV damage to skin.

EcoSun COMPLEX

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.

Peptides, resveratrol, apple stem cells and turmeric extract help firm and brighten 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:

Zinc Oxide	5.0%	}	Purpose: Sunscreen
Titanium Dioxide	4.8%		

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 MOISTURIZER BROAD SPECTRUM SPF 20

zinc oxide and titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62742-4153
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	50.0 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	48.0 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE (UNII: V5VD430YW9)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
GLYCERIN (UNII: PDC6A3C0OX)	

ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
VITIS VINIFERA SEED (UNII: C34U15ICXA)	
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
MALUS DOMESTICA FLOWER (UNII: EF626V855K)	
SIMMONDSIA CHINENSIS SEED (UNII: D24K2Q1F6H)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
TOCOPHEROL (UNII: R0ZB2556P8)	
.ALPHA.-BISABOLOL, (+/-)- (UNII: 36HQN158VC)	
BENZYLIDENE DIMETHOXYDIMETHYLINDANONE (UNII: 75HIF3C97L)	
TETRAHYDRODIFERULOLYLMETHANE (UNII: 00U0645U03)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
WATER (UNII: 059QF0KO0R)	
ALUMINUM STEARATE (UNII: U6XF9NP8HM)	
ALUMINUM OXIDE (UNII: LM26O6933)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
THYMUS VULGARIS LEAF (UNII: GRX3499643)	
SPEARMINT OIL (UNII: C3M81465G5)	
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 PEEL (UNII: T19T76XD44)	
NUTMEG OIL (UNII: Z1CLM48948)	
MYRRH OIL (UNII: H74221J5J4)	
LIME OIL (UNII: UZH29XGA8G)	
LEMON OIL (UNII: I9GRO824LL)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
GRAPEFRUIT PEEL (UNII: 3582N05Q44)	
ABIES SIBIRICA LEAF OIL (UNII: XRY0V4VZKZ)	
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLW6E6)	
JUNIPERUS VIRGINIANA OIL (UNII: PAD4FN7P2G)	
BERGAMOT OIL (UNII: 39W1PKE3J)	

MANDARIN OIL (UNII: NJO720F72R)	
GALBANUM OIL (UNII: 211UF7M8N1)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
VANILLIN (UNII: CH1530446X)	
ETHYL VANILLIN (UNII: YC9ST449YJ)	
LIMONENE OXIDE, (+)- (UNII: 278IM94GXB)	
LINALOOL, (+)- (UNII: F4VNO44C09)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
GERANIOL (UNII: L837108USY)	
CITRONELLOL ACETATE, (R)- (UNII: 9X45FJL446)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62742-4153-2	1 in 1 CARTON	12/12/2017	
1	NDC:62742-4153-1	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	12/12/2017	

Labeler - Allure Labs, Inc (926831603)

Registrant - Allure Labs, Inc (926831603)

Establishment

Name	Address	ID/FEI	Business Operations
Allure Labs, Inc		926831603	manufacture(62742-4153)

Revised: 12/2017

Allure Labs, Inc