

SUN SHIELD SPF 50- 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 - 8.6%

Titanium Dioxide - 6.5%

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.

For external use only.

Do not use on damaged or broken skin.

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.

Directions:

- Apply liberally 15 minutes prior to sun exposure.
- Reapply: after 80 minutes of swimming or sweating. Immediately after towel drying. 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 the risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including:
 - limit time in sun sun, especially from 10 am - 2 pm.
 - wear long-sleeve shirts, pants, hats and sunglasses.
 - Children under 6 months: Ask a doctor.

Water (Aqua), Cyclopentasiloxane, C12-15 Alkyl Benzoate, Dimethicone, Cyclotetrasiloxane, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Aluminum Hydroxide, Stearic Acid, Dimethicone/PEG-10/15 Crosspolymer, Glycerin, Sodium Chloride, Polyglyceryl-4 Isostearate, Vitis Vinifera, Cetyl PEG/PPG-10/1 Dimethicone, Hexyl Laurate, Cetearyl Oliviate, Sorbitan Oliviate, Cyclohexasiloxane, Tocopherol, Tocopheryl Acetate, PEG/PPG-18/18 Dimethicone, Dimethicone/Polyglycerin-3 Crosspolymer, Isomalt, Dimethicone / Vinyl Dimethicone Crosspolymer Triethoxysilylethyl Polydimethylsiloxyethyl Hexyl Dimethicone, Ethylhexyl Palmitate, Silica Dimethyl Silylate, Butylene Glycol, Sodium Hyaluronate, Phenoxyethanol, Caprylyl Glycol, Ethylhexylglycerin, Hexylene Glycol, PEG-8, Ascorbic Acid, Ascorbyl Palmitate, Citric Acid, Sodium Benzoate.

Protect this product from excessive heat and direct sun.

Call toll free 1-800 830-1491 in the USA.

info@atzen.com

Toll free in USA: 800.830.1491

Email: info@atzen.com

www.atzen.com

Developed in France. Made in USA.

ATZEN[®]
SINCE 1978

Advanced Home Spa System

1 2 3 4 5

Step 1: cleanser, Step 2: toner,
Optional Step 3: serum &/or
corrective product, Step 4:
moisturizer, Step 5: sun screen.

Use scrub 2 or 3 times a week.

Séquence d'utilisation

1 2 3 4 5

1: nettoyer/ démaquiller, 2: tonifier,
3: sérum &/ou produit correctif
(optionnel), 4: crème/gel
hydratant*, 5: protection solaire.

Utiliser le gommage et le masque 2 à 3
fois par semaine.

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90 ml/3.0 fl.oz. SKU: A50005

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*organic ingredients

Other information

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Questions or comments?

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Healthy, with natural zinc oxide and titanium dioxide, no parabens, cruelty-free pharmaceutical grade antioxidant formulations. High concentration of actives.

Bon pour la santé, avec oxyde de zinc et oxyde de titane naturels, sans parabens, de qualité pharmaceutique, protège des radicaux libres. Pourcentage élevé d'actifs. Pas testé sur animaux.

Saludable, natural de óxido de zinc y dióxido de titanio, sin parabenos, formulaciones antioxidantes grado farmacéutico sin crueldad. Alta concentración de principios activos.

健康、天然の氧化鋅與二氧化鈦，不含苯甲酸酯，无动物实验，应用医药级抗氧化配方，最高效活性成分。

PROTECT™
Enjoy the Sun Safely™

Sun Shield

Guard Against Sun & Pollution,
Broad Spectrum, Water Resistant
80 minutes

Prévention

Ecrans Minéraux, Résistant à
L'eau 80 Minutes

SPF50+

Face & Body

Unscented

Very high protection suitable for sensitive skin & around eyes. Easy to spread & invisible. Recommended for children. Use for sports, sunny climates, & long exposure to sun.

Sans parfum

Tres haute protection pour les peaux sensibles & autour des yeux. Facile à utiliser. Recommandé pour les enfants. Parfait pour le sport, les climats ensoleillés & longues expositions au soleil.

Sin perfume

Protección muy alta para la piel sensible y alrededor de los ojos. Fácil de aplicar y invisible. Recomendado para niños. Uso para los deportes, los climas soleados, y durante la exposición prolongada al sol.

无气味

对于敏感肌肤以及眼部肌肤的高度保护容易覆盖，不留痕迹。推荐儿童使用。可用于运动，晴天气候和长时间阳光暴晒。

Sensitive / Allergic Skin

Advanced Home Spa System

1 2 3 4 5

Step 1: cleanser, Step 2: toner, Optional Step 3: serum &/or corrective product, Step 4: moisturizer, Step 5: sun screen.

Use scrub 2 or 3 times a week.

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对于敏感肌肤以及眼部肌肤的高度保护容易覆盖,不留痕迹,推荐儿童使用,可用于运动,晴天气候和长时间阳光曝晒。

SUN SHIELD SPF 50

zinc oxide and titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62742-416 1
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	86 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	65 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPa.S) (UNII: RLA2U05Z4Q)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
VITIS VINIFERA FRUIT RIND (UNII: 653OHN32Q1)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
TOCOPHEROL (UNII: R0ZB2556P8)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SODIUM CHONDROITIN SULFATE (PORCINE; 5500 MW) (UNII: H5BJH23Z9A)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
TRIEPOXYCYCLOHEXASILANE (UNII: 066Q83563R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62742-4161-2	1 in 1 CARTON	12/15/2017	
1	NDC:62742-4161-1	90 mL 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	12/11/2017	

Labeler - ALLURE LABS INC (926831603)

Revised: 12/2017

ALLURE LABS INC