

## **PREVENTION SUN SERUM SPF 30 TINTED- zinc oxide cream**

### **Allure Labs**

*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.*

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### **Drug Facts**

Active ingredient

Zinc Oxide 15.6%

Purpose

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 • shake well before 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 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

ISODODECANE, SQUALANE, POLYSILICONE-11, PROPANEDIOL DICAPRYLATE/CAPRATE, CAPRYLIC/CAPRIC TRIGLYCERIDE, POLYHYDROXYSTEARIC ACID, POLYGLYCERYL-3 POLYRICINOLEATE, TRIETHOXYCAPRYLYLSILANE, LECITHIN, IRON OXIDES (CI 77492), HYDROGENATED PALM OIL, HYDROGENATED RAPESEED OIL, COCO-CAPRYLATE/CAPRATE, HYDRATED SILICA, CITRUS AURANTIUM DULCIS (ORANGE) PEEL OIL, ZINGIBER OFFICINALE (GINGER) ROOT EXTRACT, LIMONENE, CAMELLIA OLEIFERA SEED OIL, TETRAHEXYLDECYL ASCORBATE, TOCOPHERYL ACETATE, POLYGLYCERYL-6 POLYRICINOLEATE, IRON OXIDES (CI 77491), DILINOLEIC ACID/BUTANEDIOL COPOLYMER, DISODIUM STEAROYL GLUTAMATE, AQUA/WATER/EAU, PRUNUS

ARMENIACA (APRICOT) KERNEL OIL, CARTHAMUS TINCTORIUS (SAFFLOWER) SEED OIL, CASTOR OIL/IPDI COPOLYMER, IRON OXIDES (CI 77499), SODIUM SULFATE, ALOE BARBADENSIS LEAF EXTRACT, CITRAL, LINALOOL, CITRIC ACID.

**Drug Facts**

Active ingredient	Purpose
Zinc Oxide 15.6%	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

**Directions** • shake well before 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 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** ISODODECANE, SQUALANE, POLYSILICONE-11, PROPANEDIOL DICAPRYLATE/CAPRATE, CAPRYLIC/CAPRIC TRIGLYCERIDE, POLYHYDROXYSTEARIC ACID, POLYGLYCERYL-3 POLYRICINOLEATE, TRIETHOXYCAPRYLYLSILANE, LECITHIN, IRON OXIDES (CI 77492), HYDROGENATED PALM OIL, HYDROGENATED RAPESEED OIL, COCO-CAPRYLATE/CAPRATE, HYDRATED SILICA, CITRUS AURANTIUM DULCIS (ORANGE) PEEL OIL, ZINGIBER OFFICINALE (GINGER) ROOT EXTRACT, LIMONENE, CAMELLIA OLIFERA SEED OIL, TETRAHEXYLDECYL ASCORBATE, TOCOPHERYL ACETATE, POLYGLYCERYL-8 POLYRICINOLEATE, IRON OXIDES (CI 77491), DLINDOLEIC ACID/BUTANEDIOL COPOLYMER, DISODIUM STEAROYL GLUTAMATE, AQUA/WATER/EAU, PRUNUS ARMENIACA (APRICOT) KERNEL OIL, CARTHAMUS TINCTORIUS (SAFFLOWER) SEED OIL, CASTOR OIL/IPDI COPOLYMER, IRON OXIDES (CI 77499), SODIUM SULFATE, ALOE BARBADENSIS LEAF EXTRACT, CITRAL, LINALOOL, CITRIC ACID.

**Drug Facts (continued)**

Questions? call 800-796-7546

**clean clinical skincare™**

PHYSICIAN-FORMULATED

Tried, true and tested by skincare professionals

- A mineral SPF 30 sunscreen serum + skin tint in one that provides broad-spectrum UV protection with a light, dewy finish
- Innovative formula features a 100% mineral UV filter in a hydrating serum texture for daily use
- Tinted formula blends seamlessly into most skin tones
- Plant-derived squalane from sugarcane helps to moisturize the skin
- Formulated with antioxidants ginger root extract, vitamin C and vitamin E
- Chamomile helps to soothe the skin

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Global Animal Test Policy

Manufactured for IMAGE Skincare®  
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**IMAGE SKINCARE**

PREVENTION+


sun serum  
SPF 30


pure mineral UV filter

**broad spectrum SPF 30 sunscreen**

tinted

Net wt. 1 oz / 28.3 g

  
 Multi-action daily suncare to fight environmental skin stressors

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

## PREVENTION SUN SERUM SPF 30 TINTED

zinc oxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:62742-4224
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	15.6 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>ISODODECANE</b> (UNII: A8289P68Y2)	
<b>HYDROGENATED RAPESEED OIL</b> (UNII: K168T6Y0YU)	
<b>LIMONENE, (+)-</b> (UNII: GFD7C86Q1W)	

<b>CAMELLIA OIL</b> (UNII: T1PE06G0VE)
<b>SAFFLOWER OIL</b> (UNII: 65UEH262IS)
<b>COCO-CAPRYLATE/CAPRATE</b> (UNII: 8D9H4QU99H)
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)
<b>POLYGLYCERYL-6 POLYRICINOLEATE</b> (UNII: YPM0ZOC2HR)
<b>WATER</b> (UNII: 059QF0KO0R)
<b>PROPANEDIOL DICAPRYLATE/CAPRATE</b> (UNII: F53961BX4F)
<b>POLYGLYCERYL-3 PENTARICINOLEATE</b> (UNII: 7Q0OK5DOT4)
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)
<b>CITRAL</b> (UNII: T7EU009VPP)
<b>ORANGE OIL</b> (UNII: AKN3KSD11B)
<b>APRICOT KERNEL OIL</b> (UNII: 54JB35T06A)
<b>SQUALANE</b> (UNII: GW89575KF9)
<b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5)
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)
<b>DISODIUM STEAROYL GLUTAMATE</b> (UNII: 45ASM2L11M)
<b>CASTOR OIL</b> (UNII: D5340Y2I9G)
<b>LINALOOL, (+/-)-</b> (UNII: D81QY6I88E)
<b>HYDRATED SILICA</b> (UNII: Y6O7T4G8P9)
<b>GINGER</b> (UNII: C5529G5JPQ)
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)
<b>HYDROGENATED PALM OIL</b> (UNII: 257THB963H)
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)
<b>DILINOLEIC ACID/BUTANEDIOL COPOLYMER</b> (UNII: 1F2S8T535O)
<b>SODIUM SULFATE</b> (UNII: 0YPR65R21J)
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62742-4224-1	7 g in 1 TUBE; Type 0: Not a Combination Product	01/04/2023	
2	NDC:62742-4224-3	1 in 1 CARTON	01/04/2023	
2	NDC:62742-4224-2	28.3 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	01/04/2023	

**Labeler** - Allure Labs (926831603)

**Registrant** - Allure Labs (926831603)

**Establishment**

Name	Address	ID/FEI	Business Operations
Allure Labs		926831603	manufacture(62742-4224)

Revised: 1/2023

Allure Labs