

## **OS-01 FACE SPF BD SPF 30 TINTED MEDIUM/DEEP- zinc oxide cream**

### **Allure Labs**

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#### **Drug Facts**

Active ingredient: Zinc Oxide 17.5 %.

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:**

Apply liberally 15 minutes before sun exposure.

Reapply at least every 2 hours

Use a water-resistant sunscreen If swimming or sweating.

Children under 6 months of age: Ask a Doctor.

Sun Probation 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

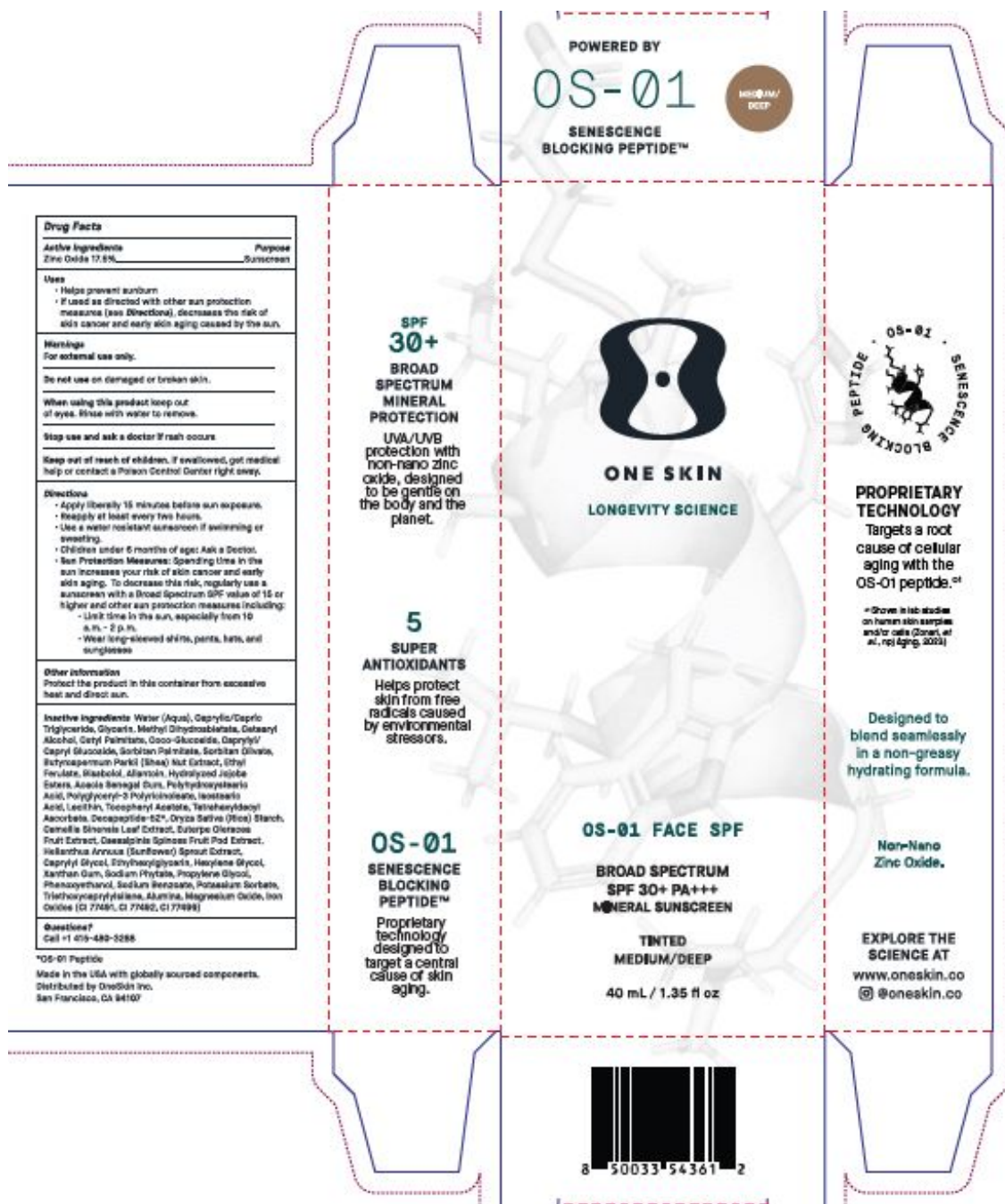
#### **Other information**

Protect the product in this container from excessive heat and direct sun.

#### **Inactive Ingredients**

Water (Aqua),Caprylic/Capric Triglyceride, Glycerin, Methyl Dihydroabietate, Cetearyl Alcohol, Cetyl Palmitate, Coco-Glucoside, Caprylyl/Capryl Glucoside, Sorbitan Palmitate, Sorbitan Olivatate, Butyrospermum Parkii (Shea) Nut Extract, Ethyl Ferulate, Bisabolol, Allantoin, Hydrolyzed Jojoba Esters, Acacia Senegal Gum, Polyhydroxystearic acid, Polyglyceryl-3 Polyricinoleate, Isostearic acid, Lecithin, Tocopheryl Acetate, Tetrahexyldecyl Ascorbate, Decapeptide-52\*,Oryza Sativa (Rice) Starch, Camellia

Sinensis Leaf Extract, Euterpe Oleracea Fruit Extract, Caesalpinia Spinosa Fruit Pod Extract, Helianthus Annuus (Sunflower) Sprout Extract, Caprylyl Glycol, Ethylhexylglycerin, Hexylene Glycol, Xanthan Gum, Sodium Phytate, Propylene Glycol, Phenoxyethanol, Sodium Benzoate, Potassium Sorbate, Triethoxycaprylylsilane, Alumina, Magnesium Oxide, Iron Oxides (CI 77491, CI 77492, CI 77499)

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zinc oxide cream

## Product Information

|                                |                |                           |                |
|--------------------------------|----------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:62742-4272 |
| <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        | 17.5 g in 100 g |
|                                                                     |                   |                 |
| Inactive Ingredients                                                |                   |                 |
| Ingredient Name                                                     | Strength          |                 |
| <b>HYDROLYZED JOJOBA ESTERS</b> (UNII: UDR641JW8W)                  |                   |                 |
| <b>ACACIA SENEGAL GUM</b> (UNII: 5C5403N26O)                        |                   |                 |
| <b>SODIUM PHYTATE</b> (UNII: 88496G1ERL)                            |                   |                 |
| <b>CETEARYL ALCOHOL</b> (UNII: 2DMT128M1S)                          |                   |                 |
| <b>ALLANTOIN</b> (UNII: 344S277G0Z)                                 |                   |                 |
| <b>POLYGLYCERYL-3 PENTARICINOLEATE</b> (UNII: 7Q0OK5DOT4)           |                   |                 |
| <b>CI 77491</b> (UNII: 1K09F3G675)                                  |                   |                 |
| <b>ISOSTEARIC ACID</b> (UNII: X33R8U0062)                           |                   |                 |
| <b>CAESALPINIA SPINOSA FRUIT POD</b> (UNII: EXY4496LWD)             |                   |                 |
| <b>HEXYLENE GLYCOL</b> (UNII: KEH0A3F75J)                           |                   |                 |
| <b>XANTHAN GUM</b> (UNII: TTV12P4NEE)                               |                   |                 |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)                          |                   |                 |
| <b>CI 77499</b> (UNII: XM0M87F357)                                  |                   |                 |
| <b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)         |                   |                 |
| <b>ACAI</b> (UNII: 46AM2VJ0AW)                                      |                   |                 |
| <b>SORBITAN OLIVATE</b> (UNII: MDL271E3GR)                          |                   |                 |
| <b>METHYL DIHYDROABIETATE</b> (UNII: 7666FJ0J9F)                    |                   |                 |
| <b>CAPRYLYL/CAPRYL GLUCOSIDE</b> (UNII: E00JL9G9K0)                 |                   |                 |
| <b>SORBITAN PALMITATE</b> (UNII: 77K6Z421KU)                        |                   |                 |
| <b>HELIANTHUS ANNUUS SPROUT</b> (UNII: 4P26HG1S5W)                  |                   |                 |
| <b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)                           |                   |                 |
| <b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)                   |                   |                 |
| <b>CI 77492</b> (UNII: EX438O2MRT)                                  |                   |                 |
| <b>CAPRYLIC/CAPRIC TRIGLYCERIDE</b> (UNII: C9H2L21V7U)              |                   |                 |
| <b>CETYL PALMITATE</b> (UNII: 5ZA2S6B08X)                           |                   |                 |
| <b>LECITHIN, SUNFLOWER</b> (UNII: 834K0WOS5G)                       |                   |                 |
| <b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)                |                   |                 |
| <b>ORYZA SATIVA (RICE) STARCH</b> (UNII: 4DGK8B7I3S)                |                   |                 |
| <b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)                        |                   |                 |
| <b>ETHYL FERULATE</b> (UNII: 5B8915UELW)                            |                   |                 |
| <b>BISABOLOL</b> (UNII: 24WE03BX2T)                                 |                   |                 |
| <b>ALUMINA</b> (UNII: LMI26O6933)                                   |                   |                 |
| <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)                            |                   |                 |
| <b>MAGNESIUM OXIDE</b> (UNII: 3A3U0GI71G)                           |                   |                 |
| <b>COCO-GLUCOSIDE</b> (UNII: ICS790225B)                            |                   |                 |
| <b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)                 |                   |                 |
| <b>CAMELLIA SINENSIS LEAF</b> (UNII: W2ZU1RY8B0)                    |                   |                 |
| <b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)                           |                   |                 |
| <b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)                         |                   |                 |
| <b>WATER</b> (UNII: 059QF0KO0R)                                     |                   |                 |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                                  |                   |                 |
| <b>SHEANUT</b> (UNII: 84H6HBP32L)                                   |                   |                 |

## Packaging

| # | Item Code        | Package Description                               | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------------------------------------|----------------------|--------------------|
| 1 | NDC:62742-4272-2 | 1 in 1 CARTON                                     | 05/12/2025           |                    |
| 1 | NDC:62742-4272-1 | 40 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 Drug | M020                                     | 05/12/2025           |                    |

**Labeler** - Allure Labs (926831603)

**Registrant** - Allure Labs (926831603)

## Establishment

| Name        | Address | ID/FEI    | Business Operations     |
|-------------|---------|-----------|-------------------------|
| Allure Labs |         | 926831603 | manufacture(62742-4272) |

Revised: 5/2025

Allure Labs