DRUNK ELEPHANT UMBRE TINTE PHYSICAL DAILY DEFENSE PROTECTION SPF-30- zinc oxide lotion Drunk Elephant, LLC

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.

Drunk Elephant[™] Umbre Tinte[™] Physical Daily Defense Protection SPF-30

Drug Facts

Active Ingredient

Zinc Oxide 20%

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

Directions

For sunscreen use:

- apply liberally 15 minutes before sun exposure
- 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 the 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-sleeve shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

Other information

• protect this product from excessive heat and direct sun.

Inactive ingredients

water, caprylic/capric triglyceride, dicaprylyl carbonate, glycerin, pentylene glycol, steareth-2, propanediol, steareth-21, polyhydroxystearic acid, cetearyl alcohol, silica, sclerocarya birrea seed oil, aloe barbadensis leaf extract, chondrus crispus extract, haematococcus pluvialis extract, helianthus annuus (sunflower) sprout extract, vitis vinifera (grape) juice extract, helianthus annuus (sunflower) seed oil, simmondsia chinensis (jojoba) seed oil, raspberry seed oil/tocopheryl succinate aminopropanediol esters, hydrolyzed wheat protein, tocopheryl acetate, tocopherol, sea water, acetyl glucosamine, cetearyl glucoside, sodium stearoyl glutamate, tetrahexyldecyl ascorbate, glycine, sucrose, lecithin, triethoxycaprylylsilane, xanthan gum, trisodium ethylenediamine disuccinate, caprylhydroxamic acid, caprylyl glycol, sodium C14-16 olefin sulfonate, phenoxyethanol, chlorphenesin, sodium dehydroacetate, iron oxides (CI 77491, CI 77492, CI 77499)

Questions or Comments

• 800.604.1795

Dist. by: Drunk Elephant[®] Newport Beach, CA 92663, USA

PRINCIPAL DISPLAY PANEL - 60 ml Tube Box

EST^D 2012 DRUNK ELEPHANT[™]

Umbra Tinte[™] Physical Daily Defense

PROTECT + GLOW

SUNSCREEN BROAD SPECTRUM SPF 30

20% Zinc Oxide Sunflower Shoot Extract

This tinted, physical sunscreen delivers UVA/UVB protection and is loaded with potent antioxidants like astaxanthin, grape juice and sunflower shoot extracts to minimize the appearance of photoaging for a more youthful-looking complexion. Plus, a hint of tint for a gorgeous, glowing finish. Infused with raspberry seed and marula oils, Umbra Tinte™ delivers essential moisture and minimizes the look of fine lines and wrinkles for skin that appears healthy and preserved. This unique formulation is ideal for daily use without any residue or greasiness, and has a universally flattering tint for all skin tones. Umbra Tinte™ is suitable for all skin, including the most sensitive. Suggested Use: Every morning, apply evenly onto face, neck and chest. Tip: Mix with C-FirmaTM for an extra boost of vitamin C and antioxidants. 100% Free of essential oils, silicones and fragrance.

Drug Facts

Active Ingredient Zinc Oxide 20%

Purpose

- 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

Stop use and ask a doctor if

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

- For sunscreen use:

 apply liberally 15 minutes
 before sun exposure
 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 the 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, especi-
- ally from 10 a,m, 2 p,m, wear long-sleeve shirts, pants, hats, and sunglasses
 children under 6 months:
- Ask a doctor

DRUNK ELEPHANT™

Umbra Tinte[™] Physical Daily Defense Protection quotidienne

PROTECT + GLOW

SUNSCREEN **BROAD SPECTRUM** SPF 30



20% Zinc Oxide Sunflower Shoot Extract

60 ml / 2 fl oz

Drug Facts (cont.)

Other information

protect this product from excessive heat and direct sun,

Inactive ingredients

sodium dehydroacetate, iron oxi (Cl 77491, Cl 77492, Cl 77499)

Questions or Comments

Dist. by: Drunk Elephant⁸ Newport Beach, CA 92663, USA









DRUNK ELEPHANT UMBRE TINTE PHYSICAL DAILY DEFENSE PROTECTION SPF-30

zinc oxide lotion

Product Information

| Product Type HUMAN OTC | RUG Item Code (Source) | NDC:69455-463 |
|------------------------|------------------------|---------------|
|------------------------|------------------------|---------------|

Route of Administration TOPICAL

| Active Ingredient/Active Moiety | | | |
|--|-------------------|-----------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| ZINC OXIDE (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z) | ZINC OXIDE | 20 mg in 100 mL | |

| Inactive Ingredients | |
|--|----------|
| Ingredient Name | Strength |
| WATER (UNII: 059QF0KO0R) | |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | |
| DICAPRYLYL CARBONATE (UNII: 609A3V1SUA) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| PENTYLENE GLYCOL (UNII: 50C1307PZG) | |
| STEARETH-2 (UNII: V56DFE46J5) | |
| PROPANEDIOL (UNII: 5965N8W85T) | |
| STEARETH-21 (UNII: 53J3F32P58) | |
| POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F) | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| SCLEROCARYA BIRREA SEED OIL (UNII: WDO4TLS35F) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| CHONDRUS CRISPUS (UNII: OQS23HUA1X) | |
| HAEMATOCOCCUS PLUVIALIS (UNII: 31T0FF0472) | |
| HELIANTHUS ANNUUS SPROUT (UNII: 4P26HG1S5W) | |
| WINE GRAPE JUICE (UNII: JHQ6158A7R) | |
| SUNFLOWER OIL (UNII: 3W1JG795YI) | |
| JOJOBA OIL (UNII: 724GKU717M) | |
| RASPBERRY SEED OIL (UNII: 9S8867952A) | |
| HYDROLYZED WHEAT PROTEIN (ENZYMATIC; 3000 MW) (UNII: J2S07SB0YL) | |
| .ALPHATOCOPHEROL SUCCINATE, D- (UNII: LU4B53JYVE) | |
| AMINOPROPANEDIOL (UNII: RH369P864X) | |
| .ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| TOCOPHEROL (UNII: R0ZB2556P8) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| N-ACETYLGLUCOSAMINE (UNII: V956696549) | |
| CETEARYL GLUCOSIDE (UNII: 09FUA47KNA) | |
| SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024) | |
| TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ) | |
| GLYCINE (UNII: TE7660XO1C) | |
| SUCROSE (UNII: C151H8M554) | |
| SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U) | |
| LECITHIN, SUNFLOWER (UNII: 834K0WOS5G) | |
| TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |
| TRISODIUM ETHYLENEDIAMINE DISUCCINATE (UNII: YA22H34H9Q) | |
| CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W) | |

| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | |
|--|--|
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| CHLORPHENESIN (UNII: 1670DAL4SZ) | |
| SODIUM DEHYDROACETATE (UNII: 8W46YN971G) | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | |
| FERRIC OXIDE YELLOW (UNII: EX43802MRT) | |
| FERROSOFERRIC OXIDE (UNII: XM0M87F357) | |

| Product Characteristics | | | |
|-------------------------|-------------|--------------|--|
| Color | BROWN (TAN) | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

| P | Packaging | | | |
|---|----------------------|--|-------------------------|-----------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:69455-463- 11 | 1 in 1 BOX | 01/15/2019 | |
| 1 | | 60 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 | 01/15/2019 | |
| | | | |

Labeler - Drunk Elephant, LLC (057204632)

Revised: 8/2022 Drunk Elephant, LLC