ELTAMD UV SHIELD SPF45- zinc oxide and octinoxate sunscreen lotion CP Skin Health Group, Inc.

EltaMD UV Shield SPF45

Warnings

For external use only Do not use on damaged or broken skin When using this product keep out of eyes Stop use and ask a physician if rash occurs Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Active Ingredients

Zinc Oxide 9.0% Sunscreen
Octinoxate 7.5% 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.

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Directions

apply liberally 15 minutes before sun exposure. Use a water-resistant sunscreen if swimming or sweating. reapply at lest every 2 hours. 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 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 physician

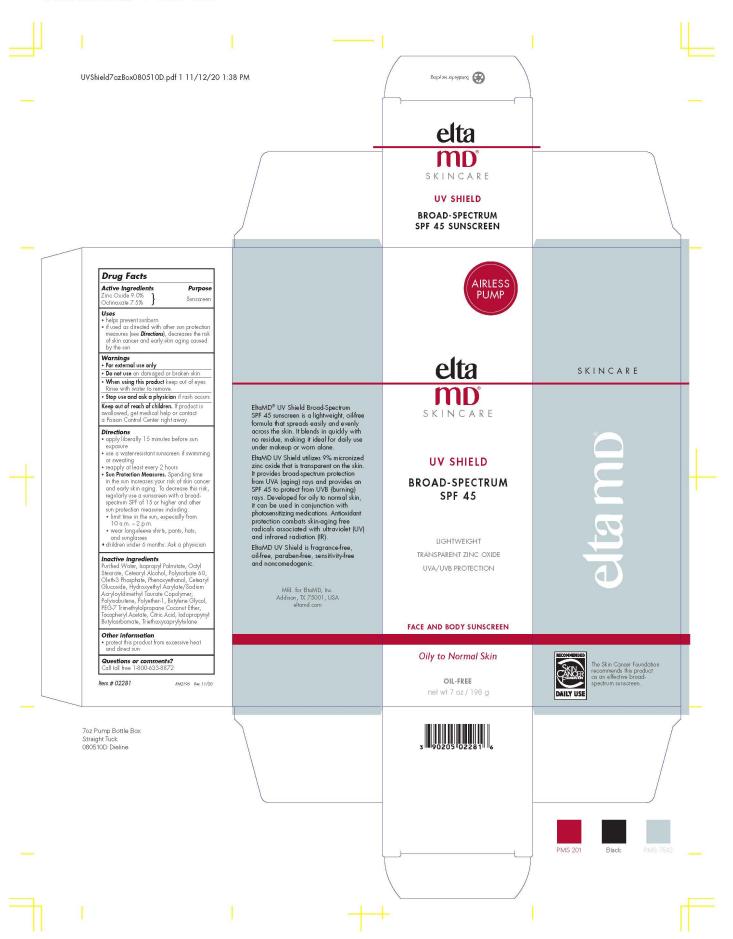
Inactive Ingredients

Purified Water, Isopropyl Palmitate, Octyl Stearate, Cetearyl Alcohol, Polysorbate 60, Oleth-3 Phosphate, Phenoxyethanol, Cetearyl Glucoside, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Polyisobutene, Polyether-1, Butylene Glycol, PEG-7 Trimethylolpropane Coconut Ether, Tocopheryl Acetate, Citric Acid, Iodopropynyl Butylcarbamate, Triethoxycaprylylsilane

KEEP OUT OF REACH OF CHILDREN

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Labeling



ELTAMD UV SHIELD SPF45

zinc oxide and octinoxate sunscreen lotion

| Product Information | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:72043-2282 |
| Route of Administration | TOPICAL | | |

| Active Ingredient/Active Moiety | | | |
|---|--------------------------|----------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37) | ZINC CATION | 90 g in 1000 g | |
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 75 g in 1000 g | |

| Inactive Ingredients | | | | |
|---|----------|--|--|--|
| Ingredient Name | Strength | | | |
| WATER (UNII: 059QF0KO0R) | | | | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | | | | |
| CETEARYL GLUCOSIDE (UNII: 09FUA47KNA) | | | | |
| ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M) | | | | |
| OCTYL STEARATE (UNII: 772Y4UFC8B) | | | | |
| OLETH-3 PHOSPHATE (UNII: 8Q0Z18J1VL) | | | | |
| TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E) | | | | |
| POLYSORBATE 60 (UNII: CAL22UVI4M) | | | | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | | | | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | | | | |
| .ALPHATOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) | | | | |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | | | | |
| IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB) | | | | |
| HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%) (UNII: 86FQE96TZ4) | | | | |
| POLYISOBUTYLENE (1000 MW) (UNII: 5XB3A63Y52) | | | | |

| Product Characteristics | | | |
|-------------------------|-------|--------------|--|
| Color | white | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

| Packaging | | | | |
|-----------|----------------------|--|-------------------------|-----------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:72043- 2282-3 | 85 g in 1 TUBE; Type 0: Not a Combination Product | 01/10/2018 | |
| 2 | NDC:72043- 2282-8 | 198 g in 1 BOTTLE; Type 0: Not a Combination Product | 01/10/2018 | 07/07/2022 |
| 2 | NDC:72043- | 50 g in 1 TUBE; Type 0: Not a Combination | 04/20/2022 | |

| 4 | .0.5 g in 1 TUBE; Type 0: Not a Combination Product | 04/20/2022 | | |
|-----------------------|---|-------------------------|-----------------------|--|
| | | | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC Monograph Drug | M020 | 01/10/2018 | | |
| | | | | |

U4/ZU/ZUZZ

Labeler - CP Skin Health Group, Inc. (611921669)

Product

2282-1

Registrant - Swiss-American CDMO, LLC (080170933)

| Establishment | | | | |
|--------------------------|---------|-----------|----------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Swiss-American CDMO, LLC | | 080170933 | manufacture(72043-2282) | |

Revised: 11/2023 CP Skin Health Group, Inc.