

**ELTAMD UV CLEAR TINTED SPF46- zinc oxide and octinoxate
sunscreen lotion
CP Skin Health Group, Inc.**

EltAMD UV Clear Tinted SPF46

Warnings

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

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 to face and neck 15 minutes before sun exposure. use a water resistant sunscreen if swimming or sweating. reapply 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 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, cyclopentasiloxane, nicotinamide, octyldodecyl neopentanoate, butylene glycol, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, polyisobutene, PEG-7 trimethylolpropane coconut ether, sodium hyaluronate, tocopheryl acetate, lactic acid, oleth-3 phosphate, phenoxyethanol, iodopropynyl butylcarbamate, isopropyl palmitate, octyl stearate, iron oxides, triethoxycaprylsilane

KEEP OUT OF REACH OF CHILDREN

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Labeling

CAD #: A8117 SUBSTRATE: SBS

ACC Item #: SA0631

Date: 09-12-2022

Revision Number

0

Proof Output Date

I hereby authorize American Carton Company to proceed as indicated by my choice above.

Signature

Date



Drug Facts (continued)

Other information
protect this product from excessive heat and direct sun

Inactive Ingredients Water, Cyclopentasiloxane, Niacinamide, Octyldodecyl Neopentanoate, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Butylene Glycol, Phenoxypolymethyl Polyisobutane, Triethoxycaprylylsilane, Iron Oxides, Isopropyl Palmitate, Ethylhexyl Stearate, Tocopheryl Acetate, PEG-7 Trimethylolpropane Coconut Ether, Diethyl-3 Phosphate, Iodopropynyl Butylcarbamate, Lactic Acid, Sodium Hyaluronate, Phosphoric Acid

Questions or comments?
Call toll free 1-800-633-8872

EltaMD® UV Clear Broad Spectrum SPF 46 is a lightweight sunscreen with a sheer tint to help even skin tone. Formulated with high-purity niacinamide (vitamin B3) to help reduce the appearance of blemishes and discoloration on your skin for a more smooth appearance. This broad spectrum sunscreen contains micronized zinc oxide to protect your skin from damaging UVA (aging) and UVB (burning) rays.

Ideal for daily use on various skin types, fragrance-free, paraben-free and non-comedogenic.

Mfd. for CP Skin Health Group, Inc.
Scottsdale, AZ 85251, USA
1-800-633-8872 | eltamd.com

BROAD SPECTRUM SPF 46

SPF 46 TINTED FACE SUNSCREEN

Calms and Protects Skin
Prone to Acne and Rosacea

Niacinamide
Transparent Zinc Oxide
Finish

net wt. 1.7 oz (48 g)

3 90205 02520 6

Drug Facts

Active Ingredients	Purpose
Octinoxate 7.5%, Zinc Oxide 9.0%	Sunscreen

Uses • helps prevent sunburn • If used as directed with other sun protection measures (see Directions), decrease 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 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.

Directions • apply liberally to face and neck 15 minutes before sun exposure • use a water-resistant sunscreen if swimming or sweating • reapply 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 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

RM8528

RECOMMENDED

SKIN CANCER FOUNDATION

DAILY USE

The Skin Cancer Foundation recommends this product as an effective broad spectrum sunscreen.

zinc oxide and octinoxate sunscreen lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72043-2520
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
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
WATER (UNII: 059QF0KO0R)	
LACTIC ACID (UNII: 33X04XA5AT)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
NIACINAMIDE (UNII: 25X51I8RD4)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
OCTYL STEARATE (UNII: 772Y4UFC8B)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
OLETH-3 PHOSPHATE (UNII: 8Q0Z18J1VL)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%) (UNII: 86FQE96TZ4)	
POLYISOBUTYLENE (1000 MW) (UNII: 5XB3A63Y52)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	

Product Characteristics

Color	brown	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72043-2520-1	48 g in 1 BOTTLE; Type 0: Not a Combination Product	01/10/2018	

2	NDC:72043-2520-2	2 g in 1 PACKET; Type 0: Not a Combination Product	07/06/2022
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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	01/10/2018	

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

Registrant - Swiss-American CDMO, LLC (080170933)

Establishment

Name	Address	ID/FEI	Business Operations
Swiss-American CDMO, LLC		080170933	manufacture(72043-2520)

Revised: 11/2023

CP Skin Health Group, Inc.