

**ELTAMD UV SPF35- octinoxate, zinc oxide sunscreen lotion**  
**CP Skin Health Group, Inc**

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**EltAMD UV SPF35**

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

**Active ingredients**

Octinoxate 7.5% Sunscreen  
Zinc Oxide 9.0% Sunscreen

**Indications & Uses:**

Helps prevent sunburn. If used as directed with other sun protection measure (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 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 am to 2 pm. Wear long-sleeve shirts, pants, hats, and sunglasses. Children under 6 months: ask a physician.

**Other information:**

Protect this product from excessive heat and direct sun.

## **Inactive ingredients**

water, petrolatum, isopropyl palmitate, ethylhexyl stearate, dimethicone, phenoxyethanol, glyceryl stearate, PEG-100 stearate, oleth-3 phosphate, cetearyl alcohol, cetearyl glucoside, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, polyisobutene, polyether-1, ethylhexylglycerin, PEG-7 trimethylolpropane coconut ether, citric acid, tocopheryl acetate, sodium hyaluronate, triethoxycaprylylsilane

## **Questions?**

Call toll free 1-800-633-8872

## **Labeling**

**American Carton Company**  
 807 South Waterloo St.  
 Mansfield, Texas 75083  
 Phone: 817.477.1933  
 Fax: 817.478.0583

ACC DIE KO 10416 75-10 412 Skin Variant

Customer: Swiss American  
 Description: 7414719\_RD006785SH\_PS0062993\_EltaMD\_Suncare\_USA\_UV\_Lotion\_8oz  
 CAD #: A9805 SUBSTRATE: SBS  
 ACC Item #: SA0722\_RM10156  
 Date: 01-16-2024

Revision Number: 0  
 Pool Output Date: \_\_\_\_\_

UPC  
 PIC

Please check all components of part (i.e. color, printing, etc.), fill out proper information below, and return to American Carton Company. The form and any form of proof (i.e. ruler, scale, photos, color key, etc.) must be returned to ACC unless you fill provided any further.

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Thank you to American Carton Company for proofed as indicated by my check above.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_



**Drug Facts**

Active Ingredients	Purpose
Octinoxate 7.5%, Zinc Oxide 7.0%	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 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 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.
  - use long-sleeved shirts, pants, hats, and sunglasses
  - children under 6 months. Ask a physician

**Other information**

protect this product from excessive heat and direct sun

**Inactive Ingredients**

Water, Petrolatum, Isopropyl Palmitate, Ethylhexyl Stearate, Dimethicone, Triethylsiloxane, Glyceryl Stearate, PEG-10 Stearate, C12-13 Phosphatidyl, Cetylalcohol, Cetylalcohol, Stearic Acid, Hydroxyethyl Acrylate/Sodium Acrylate/Dimethyl Itaconate Copolymer, Polyacrylamide, Polysiloxane-1, Ethylhexylglycerin, PEG-7 Dimethylpropylsqualane Coconut Ether, Citric Acid, Tocopheryl Acetate, Sodium Hyaluronate, Triethylhexylsilane

**Questions or comments?**

Call toll free 1-800-853-8872

PS0062993

EltaMD UV Lotion Broad-Spectrum SPF 35 is a moisturizing sunscreen for the entire body. Use it every day to guard against sun damage and keep the skin hydrated. EltaMD UV Lotion is formulated with zinc oxide to protect skin from UVA (aging) and UVB (burning) rays and hyaluronic acid to help retain moisture. EltaMD UV Lotion is fragrance-free, paraben-free, non-comedogenic, and hypoallergenic.

Mfd. for CP Skin Health Group, Inc.  
 Scottsdale, AZ 85251, USA  
 1-800-853-8872 | eltamd.com

# ELTAMD UV SPF35

octinoxate, zinc oxide sunscreen lotion

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72043-6808
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	70 g in 1000 g
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 g in 1000 g

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>ISOPROPYL PALMITATE</b> (UNII: 8CRQ2TH63M)	
<b>OCTYL STEARATE</b> (UNII: 772Y4UFC8B)	
<b>OLETH-3 PHOSPHATE</b> (UNII: 8Q0Z18J1VL)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>CETEARYL GLUCOSIDE</b> (UNII: 09FUA47KNA)	
<b>GLYCERYL STEARATE/PEG-100 STEARATE</b> (UNII: RD25J5V947)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>HYALURONIC ACID</b> (UNII: S270N0TRQY)	
<b>POLYISOBUTYLENE (1000 MW)</b> (UNII: 5XB3A63Y52)	
<b>HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%)</b> (UNII: 86FQE96TZ4)	
<b>PEG-7 TRIMETHYLOLPROPANE COCONUT ETHER</b> (UNII: MVJ3AD73GG)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72043-6808-8	226 g in 1 TUBE; Type 0: Not a Combination Product	05/31/2024	

2	NDC:72043-6808-2	2 g in 1 PACKET; Type 0: Not a Combination Product	08/01/2024	
3	NDC:72043-6808-3	85 g in 1 TUBE; Type 0: Not a Combination Product	06/04/2025	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	05/31/2024	

**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(72043-6808)

Revised: 12/2025

CP Skin Health Group, Inc