

ELTAMD UV AOX ELEMENTS- zinc oxide, titanium dioxide sunscreen lotion

CP Skin Health Group, Inc

UV AOX Elements Tinted

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.

Purpose

Sunscreen

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.

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.

Active Ingredients

Titanium Dioxide 4.4% Sunscreen
Zinc Oxide 13.5% Sunscreen

Keep out of reach of children

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Inactive Ingredients

water, dimethicone, butyloctyl salicylate, octyldodecyl neopentanoate, lauryl PEG-9 polydimethylsiloxylethyl dimethicone, cetyl dimethicone, dimethicone/PEG-10/15 crosspolymer, polyhydroxystearic acid, alumina, phenoxyethanol, triethoxycaprylsilane, sodium chloride, hydrogen dimethicone, sodium hyaluronate,









potassium sorbate, tocopheryl acetate, tocopherol, bisabolol, carnosine, dipropylene glycol, ascorbyl palmitate, zingiber officinate (ginger) root extract, iron oxides

Other Information

Protect this product from excessive heat and direct sun.

Questions or Comments?

Call toll free 1-800-633-8872

American Carton Company 907 South Wisteria St. Mansfield, Texas 76063 Phone: 817.477.4747 Fax: 817.478.0583								
	Customer: Swiss American Description: 7899215_RD008545SH_PS0078721_EltaMD_USA_UV_AOX_Elements 1.7oz-48 g_Carton CAD #: A8117 SUBSTRATE: SBS ACC Item #: SA0766_PS0078721 Date: 01-23-2025							Revision Number 0
	Print Output Date:							PIC
	Please check all components of print (i.e. color, positioning, etc.). If our proper information below, and return to American Carton Company. This form and any form of proof (i.e. raster, blueink, rainbow, color key, etc.) must be returned to ACC before job will proceed any further. <input type="checkbox"/> OK AS IS No responsibility for error is assumed by ACC when work is printed per customer's approval. <input type="checkbox"/> SHOW REVISED PROOF If revised proofs are required, request must be made when this proof is returned. I hereby authorize American Carton Company to proceed as indicated by my choice above.							Signature _____ Date _____

JEFFREY FANNEMAN
2/13/2025



ELTAMD UV AOX ELEMENTS

zinc oxide, titanium dioxide sunscreen lotion

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:72043-2522

Route of Administration		TOPICAL	
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)		ZINC CATION	135.1 g in 1000 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (CI 77891 - UNII:15FIX9V2JP)		TITANIUM DIOXIDE	44.3 g in 1000 g
Inactive Ingredients			
Ingredient Name			Strength
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)			
WATER (UNII: 059QF0KO0R)			
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)			
CARNOSINE (UNII: 8HO6PVN24W)			
PHENOXYETHANOL (UNII: HIE492ZZ3T)			
SODIUM CHLORIDE (UNII: 451W47IQ8X)			
CITRIC ACID (UNII: 2968PHW8QP)			
SODIUM HYALURONATE (UNII: YSE9PPT4TH)			
DIMETHICONE (UNII: 92RU3N3Y1O)			
CETYL DIMETHICONE 45 (UNII: IK315POC44)			
ASCORBYL PALMITATE (UNII: QN83US2B0N)			
DIMETHICONE/PEG-10/15 CROSSPOLYMER (UNII: 21AS8B1BSS)			
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)			
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)			
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)			
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)			
BISABOLOL (UNII: 24WE03BX2T)			
ZINGIBER OFFICINALE (GINGER) ROOT OIL (UNII: SAS9Z1SVUK)			
TOCOPHEROL (UNII: R0ZB2556P8)			
CANOLA OIL (UNII: 331KBJ17RK)			
FERROSOFERRIC OXIDE (UNII: XM0M87F357)			
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)			
FERRIC OXIDE RED (UNII: 1K09F3G675)			
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)			
ALUMINA (UNII: LMI26O6933)			
HYDROGEN DIMETHICONE (45 CST) (UNII: L2AFM6S5VW)			
DIPROPYLENE GLYCOL (UNII: E107L85C40)			
Product Characteristics			
Color	brown	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			
Packaging			
		Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72043-2522-1	48 g in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2025	
2	NDC:72043-2522-2	2 g in 1 PACKET; Type 0: Not a Combination Product	05/01/2025	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug		M020	05/01/2025	

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(72043-2522)