

**ELTAMD UV RESTORE TINTED- titanium dioxide and zinc oxide
sunscreen lotion
CP Skin Health Group, Inc.**

EltAMD UV Restore 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.

Active Ingredients

Titanium Dioxide 2.0% Sunscreen
Zinc Oxide 15.0% Sunscreen

Keep out of reach of children

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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, coco-caprylate/caprate, butyloctyl salicylate, octyldodecyl neopentanoate, caprylic/capric triglyceride, methyl glucose sesquistearate, silica, glyceryl stearate, PEG-100 stearate, PEG-20 methyl glycoside sesquisterate, phenoxyethanol, triethoxycaprylylsilane, polyhydroxystearic acid, glycerin, saccharide isomerate, glyceryl behenate, xanthan gum, zingiber officinale (ginger) root extract, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, squalene, ethylhexylglycerin, tocopheryl acetate, sclerotium gum, lecithin, pullulan, dimethicone, polysorbate 60, ethylene/methacrylate copolymer, mica, iron oxides

Questions?

Call toll free 1-800-633-8872

Labeling

American Carton Company 607 South Wisteria St. Mansfield, Texas 79063 Phone: 817-477-1983 Fax: 817-473-0583								<input type="checkbox"/> UPC	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, bleeds, rainbow, color key, etc.) must be returned to ACC before job will proceed any further. DELAYING RETURN OF PROOFS MAY DELAY DELIVERY OF YOUR JOB. <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.
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	Description: 7324732_RD005648SH_RM8979							Revision Number	
	CAD #: A8117 SUBSTRATE: SBS							0	
ACC Item #: SA0687_RM8979							Proof Output Date	Signature	Date
Date: 06-13-2023									



ELTAMD UV RESTORE TINTED			
titanium dioxide and zinc oxide sunscreen lotion			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72043-2640

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	20 g in 1000 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	150 g in 1000 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
METHYL GLUCOSE SESQUISTEARATE (UNII: V1YW10H14D)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PEG-20 METHYL GLUCOSE SESQUISTEARATE (UNII: 0345752X7U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
GLYCERIN (UNII: PDC6A3C0OX)	
SACCHARIDE ISOMERATE (UNII: W8K377W98I)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ZINGIBER CASSUMUNAR ROOT (UNII: 3NG517NPD8)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%) (UNII: 86FQE96TZ4)	
GLYCERYL MONOBEHENATE (UNII: A626UU0W2A)	
SQUALANE (UNII: GW89575KF9)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
BETASIZOFIRAN (UNII: 2X51AD1X3T)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
PULLULAN (UNII: 8ZQ0AYU1TT)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
MICA (UNII: V8A1AW0880)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSFERRIC 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:72043-2640-2	57 g in 1 TUBE; Type 0: Not a Combination Product	09/15/2020	
2	NDC:72043-2640-4	2 g in 1 PACKET; Type 0: Not a Combination Product	09/15/2020	
3	NDC:72043-2640-1	14 g in 1 BOTTLE; Type 0: Not a Combination Product	07/07/2022	
4	NDC:72043-2640-3	48 g in 1 BOTTLE; Type 0: Not a Combination Product	06/10/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	09/15/2020	

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(72043-2640)

Revised: 6/2024

CP Skin Health Group, Inc.