ELTAMD UV LIP BALM SPF31- zinc oxide and octinoxate sunscreen lotion CP Skin Health, Inc

EltaMD UV Lip Balm SPF31

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

Octinoxate 7.5% Sunscreen Zinc Oxide 9.0% 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.

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Directions

apply liberally 15 minutes before sun exposure reapply: after 80 minutes of swimming or sweating immediately after towel drying 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 int he sun, especially from 10 a.m. - 2 p.m. wear long-sleeve shirts, pants, hats and sunglasses children under 6 months: Ask a physician

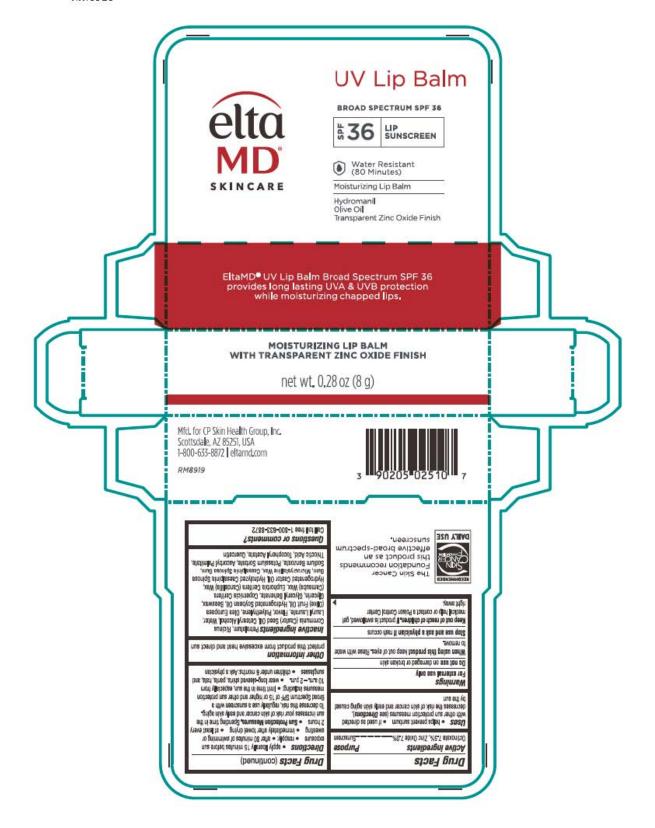
Inactive Ingredients

Petrolatum, Ricinus Communis (Castor) Seed Oil, Cetearyl Alcohol, Lauryl Laurate, Purified Water, Flavor, Polyethylene, Hydrogenated Castor Oil, Olea Europaea (Olive) Fruit Oil, Cera Alba, Glycerin, Copernicia Cerifera (Carnauba) Wax, Glyceryl Behenate, Microcrystalline Wax, Quercetin, Thiotic Acid, Ascorbyl Palmitate, Tocopheryl Acetate, Euphorbia Cerifera (Candelilla) Wax, Hydrogenated Soybean Oil, Hydrolyzed Caesalpinia Spinosa Gum, Glyceryl Stearate, Caesalpinia Spinosa Gum

KEEP OUT OF REACH OF CHILDREN

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Labeling



zinc oxide and octinoxate sunscreen lotion

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72043-2510	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	50 g in 1000 g		
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 g in 1000 g		

Inactive Ingredients		
Ingredient Name	Strength	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)		
PETROLATUM (UNII: 4T6H12BN9U)		
CASTOR OIL (UNII: D5340Y2I9G)		
LAURYL LAURATE (UNII: GPW77G0937)		
OLIVE OIL (UNII: 6UYK2W1W1E)		
HYDROGENATED CASTOR OIL (UNII: Z F94AP8MEY)		
WHITE WAX (UNII: 7G1J5DA97F)		
CARNAUBA WAX (UNII: R12CBM0EIZ)		
CANDELILLA WAX (UNII: WL0328HX19)		
HYDROGENATED SOYBEAN OIL (UNII: A2M91M918C)		
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)		
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)		
GLYCERYL DIBEHENATE (UNII: R8WTH25YS2)		
.ALPHATOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)		
ASCORBYL PALMITATE (UNII: QN83US2B0N)		
THIOCTIC ACID (UNII: 73Y7P0K73Y)		
QUERCETIN (UNII: 9IKM0I5T1E)		
CAESALPINIA SPINOSA RESIN (UNII: WL3883U2PO)		
GLYCERIN (UNII: PDC6A3C0OX)		

Product Characteristics				
Color	white	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:72043- 2510-8	8 g in 1 TUBE; Type 0: Not a Combination Product	01/10/2018		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M020	01/10/2018		
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Labeler - CP Skin Health, Inc (611921669)

Registrant - Swiss-American CDMO, LLC (080170933)

Establishment				
Name	Address	ID/FEI	Business Operations	
Swiss-American CDMO, LLC		080170933	manufacture(72043-2510)	

Revised: 1/2024 CP Skin Health, Inc