

**ELTAMD UV LIP BALM SPF31- zinc oxide and octinoxate sunscreen lotion**  
**EltaMD, Inc.**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**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.


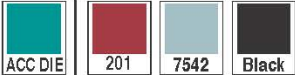


**Directions**

apply liberally 15 minutes before sun exposure reapply: after 80 minutes of swimming or sweating immediately after towel drying 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**

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

**UVLIPBALMUC**

 <b>American Carton Company</b> 607 South Wisteria St. Mansfield, Texas 76063 Phone: 817.477.1983 Fax: 817.473.0533	 <b>ACC DIE</b> 201 7542 Black	 UPC
Customer: Swiss American Description: UV Lip Balm A6691-carton RM3948.pdf 1 7/25/18 8:51 AM CAD #: A6691_SBS ACC Item #: SA0434 Date: 8-2-2018	Revision Number <b>1</b>	 PIC
<small>Please check all components of print (i.e. color, positioning, etc.), fill out proper information below, and return to American Carton Company. This form and any form of proof (i.e. mylar, business, rainbow, color key, etc.) must be returned to ACC before job will proceed any further.</small>		
<b>DEFERRING RETURN OF PROOFS MAY DELAY DELIVERY OF YOUR JOB.</b>		
<input checked="" type="checkbox"/> <b>OK AS IS</b> No responsibility for error is assumed by ACC when work is printed per customer's approval.		
<input type="checkbox"/> <b>SHOW REVISED PROOF</b> If revised proofs are required, request must be made when this proof is returned.		
<small>I hereby authorize American Carton Company to proceed as indicated by my choice above.</small>		
<small>Digitally signed by Carol Chapin Bocell DN: cn=Carol Chapin Bocell, o=Swiss-American, ou=Marketing, email=cbocell@swiss-american.net</small> <i>Carol Chapin Bocell</i> Date: 8/2/2018		



# ELTAMD UV LIP BALM SPF31

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: ZF94AP8MEY)	
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)	
.ALPHA.-TOCOPHEROL 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			

## 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 not final	part352	01/10/2018	

**Labeler** - EltaMD, Inc. (611921669)

**Registrant** - Swiss-American CDMO, LLC (080170933)

## Establishment

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

Revised: 10/2018

EltaMD, Inc.