

**PRIVATE LABEL MOISTURIZING OIL FREE PARABEN FREE SPF43-
sunscreen lotion
Swiss-American CDMO, LLC**

Private Label Moisturizing Oil Free Paraben Free SPF43

Warnings

For external use only. Do not use on damaged or broken skin. Stop use and ask doctor if rash occurs. When using the product keep out of eyes; rinse with water to remove. Keep out of reach of children. If swallowed, get medical help or contact poison control immediately. Protect this product from excessive heat and direct sun.

Uses

Helps prevent sunburn and photo damage caused by UVA/UVB exposure. 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 exposure to the sun. Use a water resistant sunscreen if swimming or sweating. Reapply at least every 2 hours. Children under 6 months of age, ask physician. 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 value of 15 or higher and other sun protection measures including: limit time in the sun, especially from 10 a.m. to 2 p.m. Wear long-sleeved shirts, pants, hats and sunglasses.

Active Ingredients

Zinc Oxide 7.50%

Octinoxate 7.50%

Octisalate 2.50%

Keep out of reach of children

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Other Ingredients

Water, Isopropyl Palmitate, Octyl Stearate, Ethylhexyl Isononanoate, Cyclopentasiloxane, Cetearyl Glucoside, Dimethicone, Glycerth-26, Sodium Hyaluronate, Panthenol, Allantoin, Tocopheryl Acetate, Ascorbyl Palmitate, Oleth-3 Phosphate, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Polyisobutene, PEG-7 Trimethylopropane Coconut Ether, Polyether-1, Phenoxyethanol, Butylene Glycol, Iodopropynyl Butylcarbamate, Triethoxycaprylsilane

Labeling

PRIVATE LABEL MOISTURIZING OIL FREE PARABEN FREE SPF43

sunscreen lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60232-0007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	75 g in 1000 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 g in 1000 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	25 g in 1000 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
GLYCERETH-26 (UNII: NNE56F2N14)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
OCTYL STEARATE (UNII: 772Y4UFC8B)	
OLETH-3 PHOSPHATE (UNII: 8Q0Z18J1VL)	
ETHYLHEXYL ISONONANOATE (UNII: I6KB4GE3K4)	
PANTHENOL (UNII: WW9CM0O67Z)	
ALLANTOIN (UNII: 344S277G0Z)	
HYALURONIC ACID (UNII: S270N0TRQY)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPA.S AT 1%) (UNII: 86FQE96TZ4)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60232-0007-1	50 g in 1 BOTTLE; Type 0: Not a Combination Product	05/07/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	05/07/2010	

Labeler - Swiss-American CDMO, LLC (080170933)

Registrant - Swiss-American CDMO, LLC (080170933)

Establishment

Name	Address	ID/FEI	Business Operations
Swiss-American CDMO, LLC		080170933	manufacture(60232-0007)

Revised: 11/2023

Swiss-American CDMO, LLC