PRIVATE LABEL SUPER LIGHT OIL-FREE SPF45- 2.75% octinsalate, 7.50% octinoxate, 8.00% zinc oxide sunscreen lotion
Swiss-American CDMO, LLC

Private Label Super Light Oil-Free SPF45

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 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

Use

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 at least every 2 hours. Use a water resistant sunscreen if swimming or sweating. 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 10a.m. to 2p.m. Wear long sleeve shirts, pants, hats and sunglasses. Children under 6 months: ask a doctor.

Keep out of reach of children

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Active Ingredients

Octinoxate 7.50%

Octisalate 2.75%

Zinc Oxide 8.00%

Inactive Ingredients

Ascorbyl Palmitate, Butylene Glycol, Citric Acid, Cyclopentasiloxane, Sodium Hyaluronate, Hydroxyethyl Acrylate/Sodium Acrylouldimethyl Taurate Copolymer, Idodopropynyl Butylcarbamate, Octyldodecyl neopentanoate, Oleth-3 Phosphate, PEG-7 Triethylolpropane Coconut Ether, Phenoxyethanol, Polyisobutene, Purified Water, Retinyl Palmitate, Triethocycaprylysilane

Labeling

PRIVATE LABEL SUPER LIGHT OIL-FREE SPF45

2.75% octinsalate, 7.50% octinoxate, 8.00% zinc oxide sunscreen lotion

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:60232-0008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	27.5 g in 1000 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75.0 g in 1000 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	80.0 g in 1000 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
OLETH-3 PHOSPHATE (UNII: 8Q0Z18J1VL)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPA.S AT 1%) (UNII: 86FQE96TZ4)	
POLYISOBUTYLENE (1300 MW) (UNII: 241BN7J12Y)	

Product Characteristics

Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60232-0008-2	60 g in 1 BOTTLE; Type 0: Not a Combination Product	03/22/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	03/22/2011	

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(60232-0008)

Revised: 11/2023 Swiss-American CDMO, LLC