PRIVATE LABEL SPF 50 80 MIN WATER RESISTANT- homosalate, octisalate, zinc oxide sunscreen cream
Swiss-American CDMO, LLC

Private Label SPF 50 80 min Water Resistant

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.

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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Active Ingredients

Homosalate 10.0% Sunscreen
Octisalate 5.0%
Zinc Oxide 16.5% Sunscreen

Directions

Apply liberally 15 minutes before sun exposure. Reapply after 80 minutes of swimming or sweating, immediately after towel drying and 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 safety information

Protect this product from excessive heat and direct sun.

Inactive Ingredients

C15-19 Alkane, Calcium gluconate, citric acid, dimethicone, disodium EDTA, disteardimonium hectorite, ethylhexylglycerin, gluconolactone, Gossypium hirsutum (cotton) extract, glycerin, glyceryl behenate, hydrogenated polyisobutene, lecithin, octyldodecyl neopentanoate, phenoxyethanol, polyglyercyl-2 isostearate, polyglyceryl-6 polyricinoleate, polyhydroxystearic acid, polysilicone-11, pullulan, saccharide isomerate, sclerotium gum, silica, sodium benzoate, sodium chloride, sodium citrate, sodium hydroxide, sodium olivate, tocopherol, tocopheryl acetate, triethoxycaprylysilane, xanthan gum, water

Questions?

Call toll free 1-866-416-2366

Labeling

PRIVATE LABEL SPF 50 80 MIN WATER RESISTANT

homosalate, octisalate, zinc oxide sunscreen cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:60232-0035
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 g in 1000 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 g in 1000 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	165 g in 1000 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
C15-19 ALKANE (UNII: CI87N1IM01)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TOCOPHEROL (UNII: R0ZB2556P8)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
POLYGLYCERYL-2 ISOSTEARATE (UNII: 7B8OE71MQC)	
POLYGLYCERYL-6 POLYRICINOLEATE (UNII: YPM0ZOC2HR)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CALCIUM GLUCONATE (UNII: SQE6VB453K)	
SACCHARIDE ISOMERATE (UNII: W8K377W98I)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	
GOSSYPIUM HIRSUTUM LEAF (UNII: 7S4U9R5259)	
GLYCERYL MONOBEHENATE (UNII: A626UU0W2A)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
XANTHAN GUM (UNII: TTV12P4NEE)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
PULLULAN (UNII: 8ZQ0AYU1TT)	
BETASIZOFIRAN (UNII: 2X51AD1X3T)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60232-0035-1	1000 g in 1 TUBE; Type 0: Not a Combination Product	12/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	12/01/2020	

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(60232-0035)

Revised: 11/2023 Swiss-American CDMO, LLC