PHYSICAL SUNSCREEN SPF50 80 MIN WR 159-100- titanium dioxide, titanium dioxide sunscreen lotion
Swiss-American CDMO, LLC

Physical Sunscreen SPF50 80 min WR 159-100

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.

Active Ingredients

Titanium Dioxide 4.23% Sunscreen
Zinc Oxide 18.28% Sunscreen

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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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.

Keep out of reach of children

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Inactive ingredients

Water, C15-19 Alkane, Octyldodecyl Neopentanoate, Caprylic/Capric Triglyceride, Butyloctyl Salicylate, Dimethicone, Polyglyceryl-4

Diisostearate/Polyhydroxystearate/Sebacate, Glycerin, Hydrogenated Polyisobutene, Polyhydroxystearic Acid, Sodium Chloride, Triethoxycaprylylsilane, Silica, Saccharide Isomerate, Hydroxyacetophenone, Niacinamide, Sorbitan Olivate, Glyceryl Behenate, 1,2-Hexanediol, Caprylyl Glycol, Tocopheryl Acetate, Disodium EDTA, Scenedesmus Rubescens Extract, Gellan Gum, Polygonum Aviculare Extract, citric acid, sodium citrate, potassium sorbate, sodium benzoate

Other information

Protect this product from excessive heat and direct sun.

Questions

Call toll free 1-866-416-2366

Labeling

PHYSICAL SUNSCREEN SPF50 80 MIN WR 159-100

titanium dioxide, titanium dioxide sunscreen lotion

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:60232-0044
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	42.3 g in 1000 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	182.8 g in 1000 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
C15-19 ALKANE (UNII: CI87N1IM01)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POLYGLYCERYL-4 DIISOSTEARATE/POLYHYDROXYSTEARATE/SEBACATE (UNII: 687U3PEB2Y)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
SACCHARIDE ISOMERATE (UNII: W8K377W98I)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
NIACINAMIDE (UNII: 25X51I8RD4)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
GELLAN GUM (LOW ACYL) (UNII: 7593U09I4D)	
POLYGONUM AVICULARE WHOLE (UNII: M990N03611)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GLYCERYL MONOBEHENATE (UNII: A626UU0W2A)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60232-0044-1	90 g in 1 PACKAGE; Type 0: Not a Combination Product	11/09/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/09/2023	

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(60232-0044)

Revised: 11/2023 Swiss-American CDMO, LLC