PRIVATE LABEL SPF45 WATER RESISTANT PARABEN FREE SUNSCREEN-
octinoxate, octisalate, zinc oxide sunscreen lotion
Swiss-American CDMO, LLC

Private Label SPF45 Water Resistant Paraben Free Sunscreen

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.

Uses

Helps prevent sunburn. If used as directed with other sun protection measures (See Directions), decrease the risk of skin cancer and early skin aging caused by the sun

Uses

Helps prevent sunburn. If used as directed with other sun protection measures (See Directions), decrease 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 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 a.m. – 2 p.m., wear long-sleeve shirts, pants, hats and sunglasses. Before use on children under 6 months, ask a physician.

Keep Out of Reach of Children

Keep Out of Reach of Children

Active Ingredients

Zinc Oxide 8.0%, Octinoxate 7.5%, Octisalate 3.0%

Inactive Ingredients

Ascorbyl Palmitate, Butylene Glycol, Cylcopentasiloxane, Dimethicone, Dimethicone/PEG-10/15 Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Ethylhexyl Isonnonanoate, Iodopropynyl Butylcarbamate, Lauryl PEG-9 Polymethylsiloxyethyl

Dimethicone, Phenoxyethanol, Purified Water, Retinyl Palmitate, Sodium Chloride, Triethyoxycaprylylsilane

Labeling

PRIVATE LABEL SPF45 WATER RESISTANT PARABEN FREE

SUNSCREEN

octinoxate, octisalate, zinc oxide sunscreen lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:60232-0006
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	80 g in 1000 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 g in 1000 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	30 g in 1000 g

Inactive Ingredients	
Ingredient Name	**Strength**
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)	
ETHYLHEXYL ISONONANOATE (UNII: I6KB4GE3K4)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	

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

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:60232-0006-1	50 g in 1 BOTTLE; Type 0: Not a Combination Product	08/31/2011	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
OTC Monograph Drug	M020	08/31/2011	

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(60232-0006)

Revised: 11/2023 Swiss-American CDMO, LLC