

**CHEMICAL SUNSCREEN SPF50 WITH ANTIPOLLUTION- homosalate, octocrylene, avobenzone, octisalate sunscreen lotion
Swiss-American CDMO, LLC**

Chemical Sunscreen SPF50 with Antipollution

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.

Indications and 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.

Purpose

Sunscreen

Active Ingredients

Homosalate 15.0% Sunscreen
Octocrylene 10.0% Sunscreen
Avobenzone 3.0% Sunscreen
Octisalate 5.0% Sunscreen

Keep out of reach of children

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Directions

Apply liberally 15 minutes before sun exposure. Use a water-resistant sunscreen if swimming or sweating. Reapply 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 information:

Protect this product from excessive heat and direct sun.

Inactive Ingredients

Water, C15-19 Alkane, Triheptanoin C13-16 Isoalkane, Dicaprylyl Carbonate, Butyloctyl Salicylate, Glycerin, Ethylhexyl Methoxycrylene, Cetearyl alcohol, Coco-Glucoside, Glucose, Argania Spinosa Kernel Oil, Phenoxyethanol, Ethylhexylglycerin, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Isohexadecane, Polysorbate 60, Sorbitan Isostearate, Triacontanyl PVP, Biosaccharide Gum-4, 1,2-Hexanediol

Questions

Call toll free 1-866-416-2366

Labeling

homosalate, octocrylene, avobenzone, octisalate sunscreen lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60232-4400
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	150 g in 1000 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	100 g in 1000 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 g in 1000 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 g in 1000 g

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
C15-19 ALKANE (UNII: CI87N1IM01)	
TRIHEPTANOIN (UNII: 2P6O7CFW5K)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
GLYCERIN (UNII: PDC6A3C0OX)	
COCO-GLUCOSIDE (UNII: ICS790225B)	
ARGANIA SPINOSA SEED (UNII: 8H7X7XB54H)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%) (UNII: 86FQE96TZ4)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
TRIACONTANYL PVP (WP-660) (UNII: N0SS3Q238D)	
BIOSACCHARIDE GUM-4 (UNII: 9XRL057X90)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
C13-16 ISOPARAFFIN (UNII: LED42LZG6O)	
ETHYLHEXYL METHOXYCRYLENE (UNII: S3KFG6Q5X8)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
ANHYDROUS DEXTROSE (UNII: 5SL0G7R0OK)	

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60232-4400-1	28 g in 1 TUBE; Type 0: Not a Combination Product	10/18/2024	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug		M020	10/18/2024	

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(60232-4400)

Revised: 10/2024

Swiss-American CDMO, LLC