CHEMICAL SUNSCREEN SPF50- octisalate, avobenzone, homosalate, octocrylene sunscreen spray
Swiss-American CDMO, LLC

Chemical Sunscreen SPF50

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.

Directions

Apply liberally 15 minutes before sun exposure. Reapply after 40 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.

Active Ingredients

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

KEEP OUT OF REACH OF CHILDREN

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Inactive Ingredients

Water, Dicaprylyl Carbhonate, Triheptanoin C13-16 Isoalkane, Butyloctyl Salicylate, Glycerin, Ethylhexyl Methoxycrylene, Triacontanyl PVP, Phenoxyethanol, Ethylhexylglycerin, Ceterayl Alcohol, Coco-Glucoside, Glucose, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Isohexane, Polysorbate 60, Sorbitan Isostearate.

Purpose

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.

Questions

Call toll free 1-866-416-2366

Labeling

CHEMICAL SUNSCREEN SPF50

octisalate, avobenzone, homosalate, octocrylene sunscreen spray

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:60232-0043
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ARGAN OIL (UNII: 4V59G5UW9X)	
TRIHEPTANOIN (UNII: 2P6O7CFW5K)	
COCO-GLUCOSIDE (UNII: ICS790225B)	
DEXTROSE (UNII: IY9XDZ35W2)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
TRIACONTANYL PVP (WP-660) (UNII: N0SS3Q238D)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
ETHYLHEXYL METHOXYCRYLENE (UNII: S3KFG6Q5X8)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%) (UNII: 86FQE96TZ4)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60232-0043-1	90 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/29/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	03/29/2024	

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(60232-0043)

Revised: 5/2024 Swiss-American CDMO, LLC