

**SUN CARE FOR BODY- octinoxate avobenzone zinc oxide octocrylene emulsion
Zenith Medicosm SL**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active Ingredient

Octinoxate 7.5%

Octocrylene 10%

Avobenzone 3%

Zinc Oxide 24%

Description

SUN CARE CREAM FOR BODY

SPF 25

MEDIUM PROTECTION

UVA - UVB - WATER RESISTANT

Body emulsion rich in anti-age ingredients. Its formula protects skin from UVB and UVA rays while moisturizing and reaffirming the skin (collagen, aloe vera, green tea). Easy to apply for even, translucent coverage. Water resistant.

150ml. 5Fl.Oz.

Warning

TOPICAL USE

Instructions for use

Dry excess sweat and apply as often as necessary.



SUN CARE FOR BODY

octinoxate avobenzene zinc oxide octocrylene emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42248-122
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	11.25 mL in 150 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	4.5 mL in 150 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	36 mL in 150 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	15 mL in 150 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
COLLAGEN, SOLUBLE, FISH SKIN (UNII: 8JC99XGU4W)	
PEG-8 STEARATE (UNII: 2P9L47VI5E)	
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 900 KD) (UNII: B70CUU14M9)	

WATER (UNII: 059QF0KO0R)
TRICAPRYLIN (UNII: 6P92858988)
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
C12-14 ISOPARAFFIN (UNII: WP37Z9V66A)
1-ETHYL-2-PYRROLECARBOXALDEHYDE (UNII: 51J1CE738Y)
RICE GERM (UNII: 7N2B70SFEZ)
GREEN TEA LEAF (UNII: WZU1RY8B0)
CETEARYL ISONONANOATE (UNII: P5O01U99NI)
LAURETH-7 (UNII: Z95S6G8201)
XANTHAN GUM (UNII: TTV12P4NEE)
GLYCERIN (UNII: PDC6A3C0OX)
METHYLPARABEN (UNII: A2I8C7HI9T)
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)
ALLANTOIN (UNII: 344S277G0Z)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
BUTYLPARABEN (UNII: 3QP1U3FV8)
ETHYLPARABEN (UNII: 14255EXE39)
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)
ALCOHOL (UNII: 3K9958V90M)
PEG-32 STEARATE (UNII: 33GX5WQC0M)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42248-122-01	150 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/15/2011	

Labeler - Zenith Medicosm SL (464239694)

Registrant - Zenith Medicosm SL (464239694)

Establishment

Name	Address	ID/FEI	Business Operations
Zenith Medicosm SL		464239694	manufacture