SOLVADERM DERMAXSOL DERMAL DEFENSE MOISTURIZER SPF-30octocrylene, zinc oxide cream SOLVADERM LLC

SOLVADERM Dermaxsol Dermal Defense Moisturizer SPF-30

DRUG FACTS

ACTIVE INGREDIENTS:

Octocrylene 10.0% Zinc Oxide 7.0%

PURPOSE

Sunscreen

USES:

Helps prevent sunburn.

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 doctor if

rash occurs.

Keep out of reach of children.

If product is swallowed, get medical help or contact a Poison Control Center right away.

DIRECTIONS:

Apply to all skin exposed to the sun.

- *Apply liberally and evenly 15 minutes before sun exposure.
- *Reapply at least every 2 hours.
- *Use a water-resistant sunscreen if swimming or sweating.

- *If pregnant or breast-feeding, ask a health care professional before use.
- *For children under 6 months of age: Ask a doctor.

INACTIVE INGREDIENTS:

Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aluminum Starch Octenyl succinate, Aqua (Deionized Water), Beeswax, Calendula Officinalis Extract, Camellia Sinensis (Green Tea) Extract, Chamomilla Matricaria Extract, Cetearyl Alcohol, Cyclopentasiloxane, Diisopropyl Adipate, Dimethicone, Dimethiconol, Ethylhexylglycerin, Glycerin, Glyceryl Laurate, Glyceryl Stearate, Hyaluronic Acid, C13-14 Isoparaffin, Laureth-7, Parfum (Fragrance)., PEG-100 Stearate, Phenoxyethanol, Polyacrylamide, Sorbitan Stearate, Stearyl Alcohol, Tocopheryl Acetate (Vitamin E).

OTHER INFORMATION:

Protect the product in this container from excessive heat and direct sun.

Package Labeling:



DRUG FACTS:	DIRECTIONS: Apply to all skin exposed to the sun. 'Apply liberally and evenly 15 minutes before sun exposure. 'Reapply at least every 2 hours. 'Use a water-resistant sunscreen if swimming or sweating.' If pregnant or breast-feeding, ask a health care]
ACTIVE INGREDIENTS: PURPOSE Octocrylene 10.0% Sunscreen Zinc Oxide 7.0% Sunscreen	professional before use. For children under 6 months of age: Ask a doctor. INACTIVE INGREDIENTS: Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aluminum	
USES: Helps prevent sunburn.	Starch Octenyl succinate, Aqua (Deionized Water), Beeswax, Calendula Officinalis Extract, Camellia Sinensis (Green Tea) Extract, Chamomilla Matricaria Extract, Cetearyl Alcohol,	l
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 doctor if rash occurs. Keep out of reach of children. If product is		Distributed By:
swallowed, get medical help or contact a Poison Control Center right away.		Solvaderm Skincare Spring Valley, NY 10977 www.solvaderm.com

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octocrylene, zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84197-467
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	100 mg in 1 g	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	70 mg in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
ALOE VERA LEAF (UNII: ZY81Z83H0X)		
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: 19PJ0O6294)		
WATER (UNII: 059QF0KO0R)		
YELLOW WAX (UNII: 2ZA36H0S2V)		

CALENDULA OFFICINALIS FLOWER (UNII: POM7O4Y7YD)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
DIISOPROPYL ADIPATE (UNII: P7E6YFV72X)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL LAURATE (UNII: Y98611C087)	
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)	
HYALURONIC ACID (UNII: S270N0TRQY)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
LAURETH-7 (UNII: Z95S6G8201)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SORBITAN MONOSTEARATE (UNII: NVZ 410H58X)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84197-467- 00	1 in 1 BOX	03/04/2024	
1		50 g in 1 JAR; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	03/04/2024	

Labeler - SOLVADERM LLC (093262409)

Revised: 3/2024 SOLVADERM LLC