SOLVADERM UNIVERSAL TINTED MOISTURIZER SUNSCREEN SPF 30octinoxate, zinc oxide lotion SOLVADERM LLC

Solvaderm Universal Tinted Moisturizer Sunscreen SPF 30

Drug Facts

Active ingredient

Octinoxate 7.50% Zinc Oxide 18.50%

Purpose

Sunscreen

Uses

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

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

Directions

- Apply liberally 15 minutes before sun exposure and as needed.
- Children under 6 months of age: ask a doctor.
- Reapply at least every 2 hours
- Use a water-resistant sunscreen if swimming or sweating
- Sun Protection Measures. Spending time in the sun increases your risk of skin

cancer and early skin aging. To decrease the risk, regularly use a sunscreen with 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-sleeved shirts, pants, hats, and sunglasses.

Other information

• protect the product in this container from excessive heat and direct sun

Inactive ingredients

Butyloctyl Salicylate, Camellia Oleifera Leaf Extract, Caprylic/Capric Triglyceride, Cyclopentasiloxane, Dimethicone, Disodium EDTA, Ethylhexylglycerin, Glycerin, 1,2-Hexanediol, Hydrogenated Polyisobutene, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Iron Oxides (CI 77491, CI 77492, CI 77499), Niacinamide, Octyldodecyl Neopentanoate, Oleth-10, Phenoxyethanol, Polyacrylate-13, Polyglyceryl-3 Polyricinoleate, Polyisobutene, Polysorbate 20, Polysorbate 60, Sodium Hyaluronate, Sorbitan Isostearate, Tocopheryl Acetate, Triethoxycaprylylsilane, Water (Aqua), Xanthan Gum.

Package Labeling:



professional strength

universal tinted moisturizer

Broad Spectrum SPF 30 **Sunscreen**

Niacinamide Sodium Hyaluronate Zinc Oxide

Net wt. 2 fl oz (59ml)

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Distributed By: Solvaderm Skincare Spring Valley, NY 10977

solvaderm.com

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octinoxate, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84197-967
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (ETHYLHEXYL METHOXYCINNAMATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	185 mg in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)		
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)		
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)		
CYCLOPENTASILOXANE (UNII: 0THT5PCIOR)		
DIMETHICONE (UNII: 92RU3N3Y1O)		
EDETATE DISODIUM (UNII: 7FLD91C86K)		
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)		
GLYCERIN (UNII: PDC6A3C0OX)		
1,2-HEXANEDIOL (UNII: TR046Y3K1G)		
FERRIC OXIDE RED (UNII: 1K09F3G675)		
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)		
FERROSOFERRIC OXIDE (UNII: XM0M87F357)		
NIACINAMIDE (UNII: 25X51I8RD4)		
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)		
OLETH-10 (UNII: JD797EF70J)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
POLYACRYLATE-13 (UNII: FS2D4T67EA)		
POLYSORBATE 20 (UNII: 7T1F30V5YH)		
POLYSORBATE 60 (UNII: CAL22UVI4M)		
SODIUM HYALURONATE (UNII: YSE9PPT4TH)		
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)		
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)		
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)		
WATER (UNII: 059QF0KO0R)		
XANTHAN GUM (UNII: TTV12P4NEE)		

l	P	Packaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:84197- 967-00	59 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/19/2025	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	05/19/2025	

Labeler - SOLVADERM LLC (093262409)

Registrant - Pure Source, LLC (080354456)

Revised: 5/2025 SOLVADERM LLC