

SUNSHADE DAILY SUN DEFENSE- titanium dioxide, zinc oxide cream
BELLAGENA SKINCARE STUDIO & SPA

DRUG FACTS

<p>ACTIVE INGREDIENTS: Titanium Dioxide 10% Zinc Oxide 3%</p> <p>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.</p> <p>WARNINGS: For external use only. Do not use on damaged or broken skin. Stop use and ask a doctor if rash occurs. When using this product, keep out of eyes. Rinse with water to remove. Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>DIRECTIONS:</p> <ul style="list-style-type: none"> • Apply liberally 15 minutes before sun exposure. • Reapply: <ul style="list-style-type: none"> • After 40 minutes of swimming or sweating • Immediately after towel drying • At least every 2 hours • Children under 6 months: Ask a doctor • 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 value of 15 or higher and other sun protection measures including: <ul style="list-style-type: none"> • Limit time in the sun, especially from 10 am-2 pm • Wear long-sleeved shirts, pants, hats, and sunglasses <p>INACTIVE INGREDIENTS: Bismuth Oxychloride, Capric/Caprylic Triglyceride, Caprylhydroxamic Acid, Caprylyl Glycol, Ceteareth-20, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Disodium EDTA, Ethylhexyl Hydroxystearate Benzoate, Glycerin, Iron Oxides, Isododecane, Isohexadecane, Melissa Officinalis (Balm Mint) Extract, Mica, Microcrystalline Wax, Octyldodecyl Neopentanoate, PEG-30 Dipolyhydroxystearate, Sodium Chloride, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Tocopherol, Triethanolamine, Triethoxycaprylylsilane, Water</p> <p>OTHER INFORMATION:</p> <ul style="list-style-type: none"> • Protect this product from excessive heat and direct sun • May stain some fabrics <p>MANUFACTURED FOR: Bellagena LLC 6114 Manatee Ave W. Bradenton FL 34209 941-544-7546 • Bellagena.com</p>	<p>PURPOSE: Sunscreen Sunscreen</p>
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SUNSHADE DAILY SUN DEFENSE			
titanium dioxide, zinc oxide cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85730-258(NDC:58892-258)
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	100 mg in 1 g	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	30 mg in 1 g	
Inactive Ingredients			

Ingredient Name	Strength
TOCOPHEROL (UNII: R0ZB2556P8)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CI 77499 (UNII: XM0M87F357)	
GLYCERIN (UNII: PDC6A3C0OX)	
CI 77491 (UNII: 1K09F3G675)	
CI 77492 (UNII: EX438O2MRT)	
ISODODECANE (UNII: A8289P68Y2)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	
ETHYLHEXYL HYDROXYSTEARATE BENZOATE (UNII: 3W8F25684B)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)	
TRIETHANOLAMINE (UNII: 9O3K93S3TK)	
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	
CETEARETH-20 (UNII: YRC528SWJY)	
DIMETHICONE (UNII: 92RU3N3Y1O)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85730-258-50	53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/09/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	08/09/2023	

Labeler - BELLAGENA SKINCARE STUDIO & SPA (114342283)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85730-258)

Establishment			
Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing INC		793406000	manufacture(85730-258)

Establishment			
Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85730-258)

Revised: 12/2025

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