

**DERM INSTITUTE DAILY DEFENSE PROTECTION SUNSCREEN BROAD SPECTRUM SPF50- titanium dioxide, zinc oxide lotion**  
**Beautcella Inc.**

*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.*

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**Derm Institute Daily Defense Protection Sunscreen Broad Spectrum SPF50+**

**Drug Facts**

**Active ingredients**

Titanium Dioxide 8.85%

Zinc Oxide 1.91%

**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**

- Use in the a.m. after serum and before foundation or makeup
- apply liberally 15 minutes before sun exposure
- reapply at least every 2 hours
- use a water-resistant sunscreen if swimming or sweating
- children under 6 months of age: 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:
- 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.

## **Questions?**

212-708-3998

## **Inactive ingredients**

Water (Aqua), Isononyl Isononanoate, Butylene Glycol, Caprylic/Capric Triglyceride, Cetyl Ethylhexanoate, Propanediol, Sodium Chloride, Diethylhexyl Carmonate, Stearic Acid, Alumina, Distearidimonium Hectorite, Polyhydroxystearic Acid, Iron Oxides (CI 77492), Phenoxyethanol, Bacopa Monnieri Extract, Lavandula Angustifolia (Lavender) Oil, Polyglyceryl-6 Polyricinoleate, Glycerin, Butyrospermum Parkii (Shea) Butter, Acetyl Tyrosine, Tocopheryl Acetate, Urea, Allantoin, o-Cymen-5-ol, Iron Oxides (CI 77491), Proline, Ethylhexylglycerin, Iron Oxides (CI 77499), Melaleuca Alternifolia (Tea Tree) Leaf Oil, Hydrolyzed Vegetable Protein, Adenosine Triphosphate, Hydroxyethylcellulose, Xanthophylls, PEG-12 Glyceryl Laurate, Rosmarinus Officininalis (Rosemary) Leaf Oil, PEG-35 Castor Oil, PVP, Lecithin, Alteromonas Ferment Extract, Magnesium Ascorbyl Phosphate, Silybum Marianum Extract, Potassium Sorbate, Caprylyl Glycol, Disodium EDTA, Tocopherol, Xanthan Gum, Ergothioneine, Chondrus Crispus Extract

## **Company Information**

Distributed by: Beautcella Inc. New York, NY 10021 USA

[www.DiSkincare.com](http://www.DiSkincare.com)

## **Product Packaging**

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DERM INSTITUTE

DAILY DEFENSE  
PROTECTION

PROTECTION DÉFENSE QUOTIDIENNE

SUNSCREEN BROAD SPECTRUM

SPF50+ PA++++

0.85fl.oz. e 25ml

Distributed by:  
BEAUTCELLA INC.  
New York, NY 10021, USA  
www.DISkinCare.com  
RP, MSL, BLS 5NB, UK / STE 5335,  
27 UPPER PEMBROKE ST, DUBLIN, IE

Made in USA



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**Drug Facts** (continued)

**[Inactive ingredients]**

Water (Aqua), Iscoryl, Isocyanate, Butylene Glycol, Caprylic/Capric Triglyceride, Cetyl Ethylhexanoate, Propylparaben, Sodium Chloride, Diethylhexyl Carbonate, Stearic Acid, Alumina, Distearidimonium Hectorite, Polyhydroxyesteric Acid, Iron Oxides (CI 77492), Phenoxyethanol, Baobab Monolaurate, Lavandula Angustifolia (Lavender) Oil, Polyglyceryl-6 Polyristoinoate, Glycerin, Butyrospermum Parkii (Shea) Butter, Acetyl Tyrosine, Tocopheryl Acetate, Urea, Allantoin, e-Cymen-5-ol, Iron Oxides (CI 77491), Prolin, Ethylhexylglycerin, Iron Oxides (CI 77498), Molaleuca Alternifolia (Tea Tree) Leaf Oil, Hydrolyzed Vegetable Protein, Adenosine Triphosphate, Hydroxyethylcellulose, Xanthophylls, PEG-12 Glyceryl Laurate, Rosmarinus Officinalis (Rosemary) Leaf Oil, PEG-33 Castor Oil, PVP, Lecithin, Altracomense Ferment Extract, Magnesium Ascorbyl Phosphate, Silybum Marianum Extract, Potassium Sorbate, Caprylyl Glycol, Disodium EDTA, Tocopherol, Xanthan Gum, Ergothioneine, Chondrus Crispus Extract



6mm

defends UVA & UVB  
protects against air pollution  
illuminates and hydrates skin



/ protection solaire contre UVA & UVB  
/ protège contre la pollution atmosphérique  
/ illumine la peau et l'hydrate

This powerful moisturizer sunscreen enriches with superb anti-oxidant complex, long-lasting hydrators and broad spectrum SPF50+ protection plus anti pollution technology. Advanced anti oxidant complex helps fight the appearance of free radical damage. Broad spectrum SPF50+ plus anti-pollution technology protects skin from harmful rays UVA/UVB and environmental pollution.

**Drug Facts**

Active ingredients		Purpose
Titanium Dioxide	2.85%	Sunscreen
Zinc Oxide	1.91%	Sunscreen

**Uses**

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**Warnings**

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# DERM INSTITUTE DAILY DEFENSE PROTECTION SUNSCREEN BROAD SPECTRUM SPF50

titanium dioxide, zinc oxide lotion

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:81521-001
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	88.5 mg in 1 mL
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	19.1 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>DIETHYLHEXYL CARBONATE</b> (UNII: YCD5000Z6L)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)	
<b>CETYL ETHYLHEXANOATE</b> (UNII: 134647WMX4)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ISONONYL ISONONANOATE</b> (UNII: S4V5BS6GCX)	
<b>O-CYMEN-5-OL</b> (UNII: H41B6Q1I9L)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>LUTEIN</b> (UNII: X72A60C9MT)	
<b>ROSEMARY OIL</b> (UNII: 8LGU7VM393)	
<b>BACOPA MONNIERI WHOLE</b> (UNII: DUB5K84ELI)	
<b>SHEA BUTTER</b> (UNII: K49155WL9Y)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>ALLANTOIN</b> (UNII: 344S277G0Z)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>DISTEARDIMONIUM HECTORITE</b> (UNII: X687XDK09L)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>ERGOTHIONEINE</b> (UNII: BDZ3DQM98W)	
<b>CHONDRUS CRISPUS CARRAGEENAN</b> (UNII: UE856F2T78)	
<b>LAVENDER OIL</b> (UNII: ZBP1YXW0H8)	
<b>POLYGLYCERYL-6 POLYRICINOLEATE</b> (UNII: YPM0ZOC2HR)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PEG-12 GLYCERYL LAURATE</b> (UNII: J07WW42G15)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>MAGNESIUM ASCORBYL PHOSPHATE</b> (UNII: 0R822556M5)	

<b>MILK THISTLE</b> (UNII: U946SH95EE)
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)
<b>PROLINE</b> (UNII: 9DLQ4CIU6V)
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)
<b>TEA TREE OIL</b> (UNII: VIF565UC2G)
<b>ADENOSINE TRIPHOSPHATE</b> (UNII: 8L70Q75FXE)
<b>HYDROXYETHYL CELLULOSE, UNSPECIFIED</b> (UNII: T4V6TWG28D)
<b>POLYOXYL 35 CASTOR OIL</b> (UNII: 6D4M1DAL6O)
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)
<b>ACETYL L-TYROSINE</b> (UNII: DA8G610ZO5)
<b>UREA</b> (UNII: 8W8T17847W)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81521-001-01	1 in 1 CARTON	05/01/2021	
1		25 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/01/2021	

**Labeler** - Beautcella Inc. (928453625)

Revised: 2/2021

Beautcella Inc.