

**SUN PROTECTIVE DAY MOISTURIZER SUNSCREEN- avobenzone, octinoxate, octocrylene and oxybenzone cream**

**Dr Russo Skincare Ltd**

*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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**SUN PROTECTIVE DAY MOISTURIZER SUNSCREEN**

***Drug Facts***

***Active ingredients***

Avobenzone 3%

Octinoxate 7.5%

Octocrylene 10%

Oxybenzone 6%

***Purpose***

Sunscreen

**Keep out of reach of children.** If product is swallowed, get medical help or contact a Poison Control Center right away.

***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

***Directions***

- Shake well before use
- apply liberally 15 minutes before sun exposure
- 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 this risk, regularly use a sunscreen with a 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-sleeve shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

### ***Inactive ingredients***

Aqua (Water), Acacia Decurrens/Jojoba/Sunflower Seed Cera/ Polyglyceryl-3 Esters, Glycerin, Ascorbyl Glucoside, Tapioca Starch, 1-Methylhydantoin-2-Imide, Adansonia Digitata (Baobab) Seed Oil, Stearic Acid, Butylene Glycol, Caprylic/Capric Glycerides, Betaine, Dimethicone, Phenoxyethanol, Cyclopentasiloxane, Propylene Glycol, Lecithin, Sodium Hyaluronate, Tocopherol, Benzyl Alcohol, Fragrance (Parfum), Sodium Stearoyl Glutamate, Polysilicone-11, Polyacrylamide, Xanthan Gum, Camellia Sinensis Leaf Extract, Disodium EDTA, C13-14 Isoparaffin, Sodium Stearate, Polymethylsilsesquioxane, Dehydroacetic Acid, Laureth-7, Hordeum Distichon (Barley) Extract, Sodium Benzoate, Melissa Officinalis Leaf Extract, Disodium Rutinyl Disulfate, Ethylbisiminomethylguaiaicol Manganese Chloride, Citric Acid, Aspalathus Linearis Leaf Extract, Glyceryl Stearate SE.

### ***Other information***

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

### ***Questions or comments?***

Call Toll free **1-800-295-7051**

Monday - Friday 9-12 a.m (EST)

### **BROAD SPECTRUM SPF 30**

Dr Russo's Sun Protective Day Moisturizer Sunscreen has been specifically formulated to moisturise your skin and protect it from UVA/UVB exposure. UV rays are prevalent all year round. It is important to prevent exposure to UVA and UVB at all times during the day.

**“As a cosmetic surgeon, I see the effects of sun exposure on my patient's skin, every day. As a scientist I know that it can be prevented. This exclusive day moisturiser is formulated to deliver a broad spectrum UVA/UVB SPF 30 sunscreen”.**

### **Dr Mario Luca Russo, MD**

Dr Russo is a leading European cosmetic derma surgeon and founder of The Rejuvenation Clinic & Medispa, known worldwide for its pioneering work on sun damaged and prematurely ageing skin. He is a member of the British Association of Dermatologists, the American Academy of Cosmetic Surgery and a fellow of the American Society of Laser in Medicine and Surgery.

Manufactured for

Dr. Russo Skincare Ltd

102 Harley Street

London W1G 7JB

England

Made in UK

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

MRUS008

**Drug Facts (continued)**

**Inactive ingredients:**

Aqua (Water), Acacia  
Decurrens/Jojoba/Sunflower  
Seed Cera/Polyglyceryl-3 Esters,  
Glycerin, Ascorbyl Glucoside,  
Tapioca Starch, 1-Methylhyan-  
toin-2-Imide, Adansonia Digitata  
(Baobab) Seed Oil, Stearic Acid,  
Butylene Glycol, Caprylic/ Capric  
Glycerides, Betaine,  
Dimethicone, Phenoxyethanol,  
Cyclopentasiloxane, Propylene  
Glycol, Lecithin, Sodium  
Hyaluronate, Tocopherol, Benzyl  
Alcohol, Fragrance (Parfum),  
Sodium Stearoyl Glutamate,  
Polysilicone-11, Polyacrylamide,  
Xanthan Gum, Camellia Sinensis  
Leaf Extract, Disodium EDTA,  
C13-14 Isoparaffin, Sodium  
Stearate, Polymethylsilsesquiox-  
ane, Dehydroacetic Acid,  
Laureth-7, Hordeum Distichon  
(Barley) Extract, Sodium  
Benzoate, Melissa Officinalis  
Leaf Extract, Disodium Rutinyl  
Disulfate, Ethylbisiminomethyl-  
guaiaicol Manganese Chloride,  
Citric Acid, Aspalathus Linearis  
Leaf Extract, Glyceryl Stearate  
SE.

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Manufactured for:  
Dr Russo Skincare Ltd  
102 Harley Street  
London W1G 7JB  
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Made in UK  
www.drrussoskincare.com

Lot No: 511703  
Expiry: 12/31/2016

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DAY MOISTURIZER  
SUNSCREEN**  
BROAD SPECTRUM SPF 30

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DRUSSO

**SUN PROTECTIVE  
DAY MOISTURIZER  
SUNSCREEN**

BROAD SPECTRUM SPF 30

1.69 fl oz (50 mL)

**Drug Facts**

Active ingredients	Purpose
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Octinoxate 7.5%	
Octocrylene 10%	
Oxybenzone 6%	

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**Stop use and ask a doctor if**

- rash occurs
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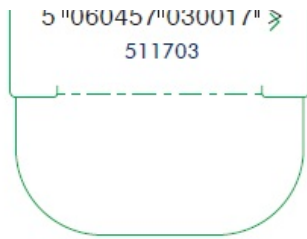
**Directions**

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## SUN PROTECTIVE DAY MOISTURIZER SUNSCREEN

avobenzone, octinoxate, octocrylene and oxybenzone cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70081-002
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 mL
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	6 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ACACIA DECURRENS WHOLE</b> (UNII: 8KZ75S2VSK)	
<b>JOJOBA OIL</b> (UNII: 724GKU717M)	
<b>HELIANTHUS ANNUUS SEED WAX</b> (UNII: 42DG15CHXV)	
<b>POLYGLYCERIN-3</b> (UNII: 4A0NCJ6RD6)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>ASCORBYL GLUCOSIDE</b> (UNII: 2V52R0NHXW)	
<b>STARCH, TAPIOCA</b> (UNII: 24SC3U704I)	
<b>CREATININE</b> (UNII: AY18EX34EU)	
<b>ADANSONIA DIGITATA SEED OIL</b> (UNII: 77MKL7AR5I)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>PEG-6 CAPRYLIC/CAPRIC GLYCERIDES</b> (UNII: GO50W2HWO8)	
<b>BETAINE</b> (UNII: 3SCV180C9W)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PC10R)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>SODIUM STEAROYL GLUTAMATE</b> (UNII: 65A9F4P024)	

<b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5)
<b>POLYACRYLAMIDE (10000 MW)</b> (UNII: E2KR9C9V2I)
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)
<b>C13-14 ISOPARAFFIN</b> (UNII: E4F12ROE70)
<b>SODIUM STEARATE</b> (UNII: QU7E2XA9TG)
<b>POLYMETHYLSILSESQUOXANE (11 MICRONS)</b> (UNII: Z570VEV8XK)
<b>DEHYDROACETIC ACID</b> (UNII: 2KAG279R6R)
<b>LAURETH-7</b> (UNII: Z95S6G8201)
<b>BARLEY</b> (UNII: 5PWM7YLI7R)
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)
<b>MELISSA OFFICINALIS LEAF</b> (UNII: 50D2ZE9219)
<b>DISODIUM RUTINYL DISULFATE</b> (UNII: V5J3537PND)
<b>ETHYLBISIMINOMETHYLGUAIACOL MANGANESE CHLORIDE</b> (UNII: SM5YJ88LTU)
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)
<b>ASPALATHUS LINEARIS LEAF</b> (UNII: H7UGK1GJCU)
<b>GLYCERYL STEARATE SE</b> (UNII: FCZ5MH785I)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70081-002-50	1 in 1 CARTON	10/24/2015	
1		50 mL in 1 BOTTLE, PUMP; 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	10/24/2015	

**Labeler** - Dr Russo Skincare Ltd (217516653)

### Establishment

Name	Address	ID/FEI	Business Operations
Orean Personal Care Ltd.		211403363	manufacture(70081-002)

Revised: 10/2015

Dr Russo Skincare Ltd