

**SUN PROTECTIVE DAY CLEANSER SUNSCREEN- avobenzone, octinoxate and octocrylene 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 CLEANSER SUNSCREEN**

***Drug Facts***

***Active ingredients***

Avobenzone 2.75%

Octinoxate 7.2%

Octocrylene 7.04%

***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:
  - after 80 minutes of swimming or sweating
  - immediately after towel drying
  - at least every 2 hours
- **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***

Water, Sodium Lauryl Sulfate, Sodium Laureth Sulfate, Cocamidopropyl Betaine, Polyquaternium-10, Glycerin, Dimethicone, Sorbitan Monooleate, Polyamide-3, Polysorbate 20, Gellan Gum, PG-Hydroxyethylcellulose Stearyldimonium Chloride, Carboxymethylcellulose Na, Cocodimonium Hydroxypropyl Hydrolyzed Keratin, Sodium Alginate, Lauryldimoniumhydroxypropyl Decylglucosides Chloride, Carrageenan, Sodium Lauryl Glucose Carboxylate, Butyrospermum Park (Shea) Oil, Lauryl Glucoside, Sorbitan Stearate, Tetrasodium EDTA, Acrylates/C12-22 Alkyl Methacrylate Copolymer, RubusIdaeus (Red Raspberry) Oil, Punica Granatum (Pomegranate) Seed Oil, Vaccinium Macrocarpon (Cranberry) Seed Oil, Camellia Oleifera Seed Oil, Vitis Vinifera (Grape) Seed Oil, Arctium Lappa (Burdock Root) Extract, Phenoxyethanol, Caprylyl Glycol, Sodium Chloride, Citric Acid

### ***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**

**WATER RESISTANT (80 MINUTES)**

Dr Russo's Sun Protective Day Cleanser Sunscreen has been specifically formulated to gently cleanse 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.

**“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 Sunscreen Day Cleanser 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

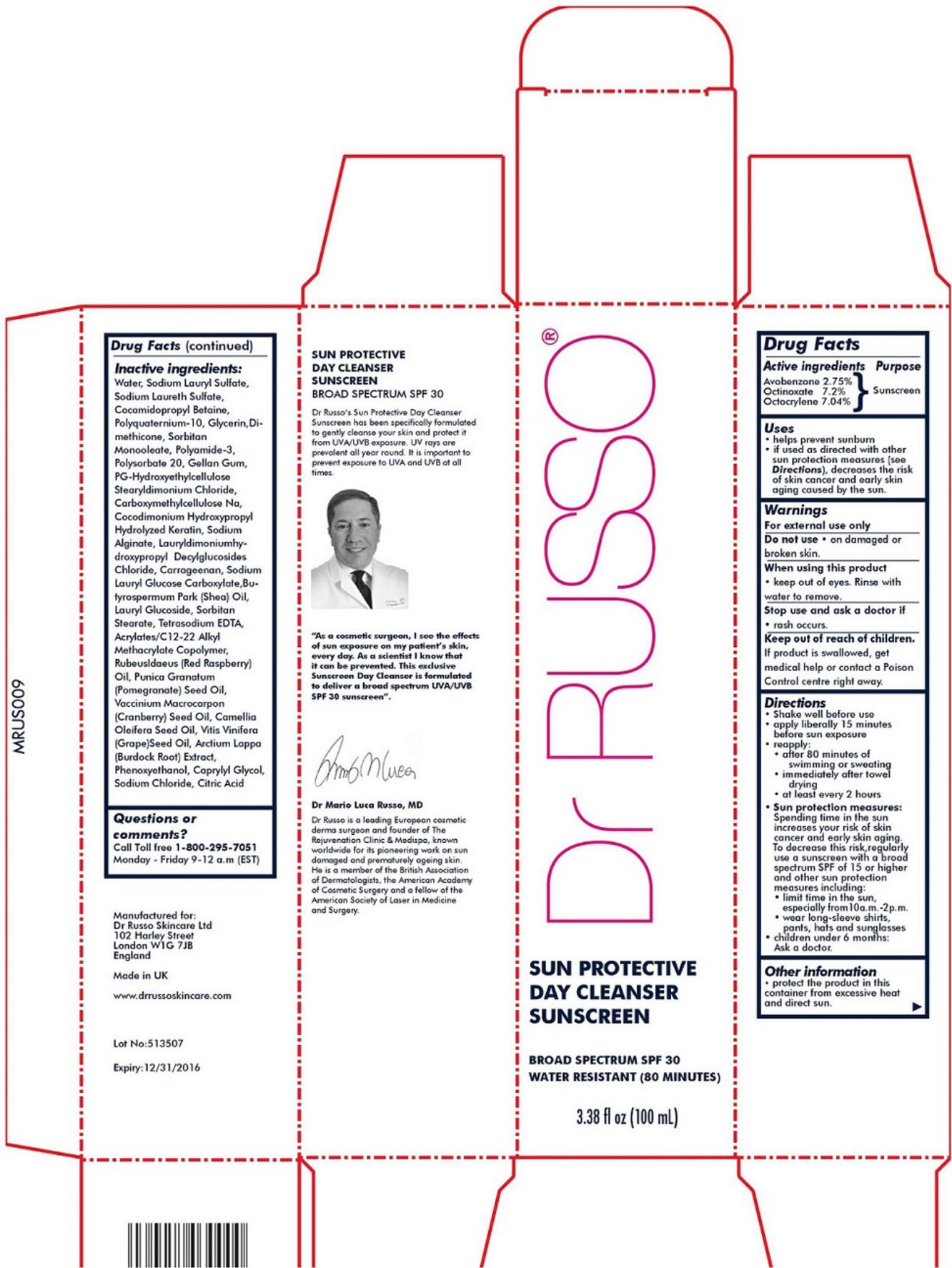
102 Harley Street

London W1G 7JB

England

Made in UK

Packaging



MRUS009

**Drug Facts (continued)**

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 Water, Sodium Lauryl Sulfate, Sodium Laureth Sulfate, Cocamidopropyl Betaine, Polyquaternium-10, Glycerin, Dimethicone, Sorbitan Monooleate, Polyamide-3, Polysorbate 20, Gellan Gum, PG-Hydroxyethylcellulose, Stearyltrimonium Chloride, Carbocymethylcellulose Na, Cocodimonium Hydroxypropyl Hydrolyzed Keratin, Sodium Alginate, Lauryldimoniumhydroxypropyl Decylglucosides Chloride, Carrageenan, Sodium Lauryl Glucose Carboxylate, Butyrospermum Park (Shea) Oil, Lauryl Glucoside, Sorbitan Stearate, Tetrasodium EDTA, Acrylates/C12-22 Alkyl Methacrylate Copolymer, Rubusidaeus (Red Raspberry) Oil, Punica Granatum (Pomegranate) Seed Oil, Vaccinium Macrocarpon (Cranberry) Seed Oil, Camellia Oleifera Seed Oil, Vitis Vinifera (Grape)Seed Oil, Arctium Lappa (Burdock Root) Extract, Phenoxethanol, Caprylyl Glycol, Sodium Chloride, Citric Acid

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Manufactured for:  
 Dr Russo Skincare Ltd  
 102 Harley Street  
 London W1G 7JB  
 England

Made in UK

www.drussoskincare.com

Lot No:513507  
 Expiry:12/31/2016



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**BROAD SPECTRUM SPF 30**

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DRUSSO

**SUN PROTECTIVE DAY CLEANSER SUNSCREEN**

**BROAD SPECTRUM SPF 30 WATER RESISTANT (80 MINUTES)**

3.38 fl oz (100 mL)

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Active ingredients	Purpose
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Octinoxate 7.2%	
Octocrylene 7.04%	

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## SUN PROTECTIVE DAY CLEANSER SUNSCREEN

avobenzone, octinoxate and octocrylene cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70081-001
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2.75 g in 100 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.2 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	7.04 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
POLYQUATERNIUM-10 (125 MPA.S AT 2 %) (UNII: L45WU8S981)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SORBITAN MONOLEATE (UNII: 06XEA2VD56)	
POLYACRYLAMIDE (1500 MW) (UNII: 5D6TC4BRWV)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
GELLAN GUM (LOW ACYL) (UNII: 7593U09I4D)	
PROPYLENE GLYCOL-HYDROXYETHYLCELLULOSE STEARYLDIMONIUM CHLORIDE (UNII: 3479326GXB)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
HYDROLYZED ELASTIN, BOVINE, ALKALINE (1000 MW) (UNII: ZR28QKN0WT)	
SODIUM ALGINATE (UNII: C269C4G2ZQ)	
HYDROXYETHYL LAURDIMONIUM CHLORIDE (UNII: 8467K53E3Y)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
SODIUM LAURYL GLYCOL CARBOXYLATE (UNII: 8L0472VMYL)	
SHEANUT OIL (UNII: O88E196QRF)	
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
EDETATE SODIUM (UNII: MP1J8420LU)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	

<b>RASPBERRY SEED OIL</b> (UNII: 9S8867952A)	
<b>PUNICA GRANATUM SEED OIL</b> (UNII: 0UI45XV0T6)	
<b>CRANBERRY SEED OIL</b> (UNII: 73KDS3BW5E)	
<b>CAMELLIA OIL</b> (UNII: T1PE06G0VE)	
<b>VITIS VINIFERA SEED</b> (UNII: C34U15ICXA)	
<b>ARCTIUM LAPPA ROOT</b> (UNII: 597E9B3Z3)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70081-001-10	1 in 1 CARTON	10/26/2015	
1		100 mL in 1 TUBE; Type 0: Not a Combination Product		

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/26/2015	

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

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Orean Personal Care Ltd.		211403363	manufacture(70081-001)

Revised: 10/2015

Dr Russo Skincare Ltd