

OSCAR DE LA RENTA MOISTURIZING SUNSCREEN SPF 30 - octinoxate, octisalate, oxybenzone cream

Oscar de la Renta LLC

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.

Oscar de la Renta Moisturizing Sunscreen Cream SPF 30

Drug Facts

Active ingredients

Octinoxate 7.5%

Octisalate 5%

Oxybenzone 6%

Use

- helps prevent sunburn

Warnings

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, **not** skin cancer or early skin aging.

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 Poison Control Center right away.

Directions

For sunscreen use

- apply liberally 15 minutes before sun exposure
- reapply at least every 2 hours
- use a water resistant sunscreen if swimming or sweating
- children 6 months of age: Ask a doctor

Other information

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

Inactive ingredients

WATER, ISODECYL NEOPENTANOATE, GLYCERIN, FRAGRANCE, CETEARYL GLUCOSIDE, CETEARYL ALCOHOL, GLYCERYL STEARATE, POTASSIUM CETYL PHOSPHATE, COCOGLYCERIDES, PHENOXYETHANOL, CYCLOPENTASILOXANE, SODIUM POLYACRYLATE, CAPRYLYL GLYCOL, HEXYL CINNAMAL, BENZYL SALICYLATE, OAT (AVENA SATIVA) KERNEL EXTRACT, LIMONENE, SORBIC ACID, BHT, HYDROXYCITRONELLOL, CYCLOHEXASILOXANE, LINALOOL, CITRONELLOL, GERANIOL, ETHYLHEXYLLAURATE, COCOYL HYDROLYZED WHEAT PROTEIN, HYDROLYZED SOY PROTEIN

Purpose

Sunscreen

Oscar de La Renta MOISTURIZING SUNSCREEN CREAM SPF 30 e120 ML 5 FL OZ
DISTRIBUTED BY: Oscar de La Renta 6 AVENUE DEL'EUROPE 77600 BUSSY SAINT
GEORGES, FRANCE
II WEST 42ND STREET NEW YORK, NY 10018 MADE IN USE oscardelarenta.com

Oscar de la Renta Moisturizing Sunscreen Cream SPF 30 120ml/5 Fl OZ (45124-001-05)

Oscar de la Renta

MOISTURIZING
SUNSCREEN CREAM
SPF 30

e 120 ML 5 FL OZ

Crema Bronzeadora Humectante
Formula protectora del Sol 30

Drug Facts

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Directions

- For sunscreen use
- 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

Other information

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

Inactive ingredients

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DISTRIBUTED BY:

Oscar de la Renta

6 AVENUE DE L'EUROPE
77600 BUSSY SAINT GEORGES, FRANCE

11 WEST 42ND STREET
NEW YORK, NY 10018

MADE IN USA



oscardelarenta.com

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crema bronceadora humectante
formula protectora del sol 30

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MOISTURIZING
SUNSCREEN CREAM
SPF 30

e 120 ML 5 FL OZ

OSCAR DE LA RENTA MOISTURIZING SUNSCREEN SPF 30

octinoxate, octisalate, oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45124-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 mL in 100 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 mL in 100 mL
OXYBENZONE (UNII: 950OS7VE0 Y) (OXYBENZONE - UNII:950OS7VE0 Y)	OXYBENZONE	6 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISODECYL NEOPENTANOATE (UNII: W60 VYE24XC)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
COCO-GLYCERIDES (UNII: ISE9I7DNUG)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)	
BENZYL SALICYLATE (UNII: WAO5MKN9TU)	
OAT (UNII: Z6J799EAJK)	
SORBIC ACID (UNII: X045WJ989B)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
HYDROXYCITRONELLOL (UNII: R0B4U2I48W)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
GERANIOL (UNII: L837108USY)	
ETHYLHEXYL LAURATE (UNII: 8J6M396U72)	
SOY PROTEIN (UNII: R44IWB3RN5)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45124-001-05	1 in 1 CARTON		
1		120 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	04/11/2012	

Labeler - Oscar de la Renta LLC (071007918)

Establishment

Name	Address	ID/FEI	Business Operations
Suite K Value Added Services LLC		036822144	manufacture

Revised: 4/2012

Oscar de la Renta LLC