

RAYITO DE SOL SPF 35- octinoxate, octisalate, octocrylene, oxybenzone, titanium dioxide cream

Siscom de Argentina S.A.

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.

Drug Facts

Rayito de Sol® 2-in-1 Sport Bronzing Sunscreen SPF 35 - Broad Spectrum Protection - Light Shimmer

Active Ingredients

Octinoxate 7.3%

Octisalate 4.7%

Octocrylene 3.5%

Oxybenzone 4.7%

Titanium Dioxide 0.6%

Purpose

Sunscreen

Uses

- 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 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 the reach of children

If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply liberally 15 minutes before sun exposure
- reapply:
 - after swimming or sweating
 - immediately after towel drying
 - at least every 2 hours
- children under 6 months: Ask a doctor

Inactive Ingredients

alkyl (c12-15) benzoate, allantoin, ammonium acryloyldimethyltaurate/vp copolymer, benzyl alcohol, coumarin, d-citronellol, dimethicone, eugenol, ferric oxide red, ferric oxide yellow, fragrance, geraniol, glycerin, glyceryl monostearate, hexadecyl povidone (4 hexadecyl branches/ repeat), imidurea, isocetyl stearyl stearate, isomethyl-.alpha.-ionone, medium-chain triglycerides, methylchloroisothiazolinone, methylisothiazolinone, mineral oil, phenethyl benzoate, phenoxyethanol, polysorbate 20, stearyl alcohol, styrene/acrylates copolymer, trilaureth-4 phosphate, vp/eicosene copolymer, water.

Other Information

- protect this product from excessive heat and direct sun
- avoid contact with clothing to avoid staining. If staining does occur, launder within 12 hours

Questions or Comments?

Call 305. 672.9486 or send an email to: info@rayitodesolus.com

Rayito de Sol® ·
2 in1 Sport Bronzing
Sunscreen Lotion
SPF 35
Light Shimmer
200 mL · 6.76 FL. OZ.

RAYITO
DE SOL



2 in 1 Sport Bronzing
Sunscreen Lotion

Instant Cooling

35
spf

Light Shimmer

6.75 FL. OZ. e 200 mL

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Made in Argentina

Manufactured for: Siscom de Argentina SA (Uruguay 775 3^{er} B. CABA, Argentina)
Res. 155/98 - Est. Etab. # 129
Distributed by: BLIII Holdings - Miami, FL



www.rayitodesolus.com
NDC # 203687-194-01



RAYITO DE SOL SPF 35

octinoxate, octisalate, octocrylene, oxybenzone, titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:20367-134
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	15.04 g in 200 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	9.68 g in 200 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	9.68 g in 200 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	7.21 g in 200 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	1.24 g in 200 mL

Inactive Ingredients

Ingredient Name	Strength
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ALLANTOIN (UNII: 344S277G0Z)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
COUMARIN (UNII: A4VZ22K1WT)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
EUGENOL (UNII: 3T8H1794QW)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
GERANIOL (UNII: L837108USY)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HEXADECYL POVIDONE (4 HEXADECYL BRANCHES/REPEAT) (UNII: AG75W62QYU)	
IMIDUREA (UNII: M629807ATL)	
ISOCETYL STEAROYL STEARATE (UNII: IJV4LS383R)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
MINERAL OIL (UNII: T5L8T28FGP)	
PHENETHYL BENZOATE (UNII: 0C143929GK)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
TRILAURETH-4 PHOSPHATE (UNII: M96W2OLL2V)	
Water (UNII: 059QF0K00R)	
BUTYL ACRYLATE (UNII: 705NM8U35V)	
N-VINYLPYRROLIDINONE (UNII: 76H9G81541)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:20367-134-01	200 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/11/2013	

Labeler - Siscom de Argentina S.A. (974736332)

Revised: 1/2013

Siscom de Argentina S.A.