

RAYITO DE SOL SUNSCREEN SPF 18 - octisalate oxybenzone padimate o cream
Siscom de Argentina SA

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.

Rayito de Sol Sunscreen SPF 18

Active ingredient

Octisalate 4%

Oxybenzone 6%

Padimate O 6%

Purpose

Sunscreen

Sunscreen

Sunscreen

Uses

- Helps prevent sunburn.
- Higher SPF gives more sunburn protection.
- Provides moderate protection against sunburn.

Warnings

For external use only.

When using this product

- do not use in or near the eyes
- if it gets into eyes, rinse thoroughly with water

Stop use and ask a doctor if

- rash or irritation develops and lasts

side effect occur. You may report side effect to FDA at 1-800-FDA-1088

If swallowed, seek medical attention or contact a Poison Control Center immediately.

Keep out of the reach of children.

Directions

- Apply generously 15 minutes before sun exposure.
- Children under six months of age: ask a doctor.
- Reapply every 2 hours or after swimming or sweating or anytime after towelling

Other Information

- moderate sun protection product
- **Sun alert:** limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risk of skin aging, skin cancer and other harmful effects of the sun.
- may stain clothing when freshly applied. Avoid contact with fabric or if fabric contact, launder within the hour

Inactive ingredients

Mineral Oil, Petrolatum, Propylene Glycol, Ceresin, Paraffin, CI 77492 (and) CI 77491 (and) CI 77499, Zinc Stearate, Beeswax, Fragrance, Propylparaben, Benzyl Salicylate, Benzyl Alcohol, Hydroxycitronellal, Linalool, Coumarin, Citronellol, Geraniol, Eugenol, Amyl Cinnamal, Isoeugenol.

Questions or comments?

if you are in United States

(305) 672-9486

Principal Display Panel

Rayito de Sol
Sunscreen SPF 18
70 g/2.4oz

Protección moderada • moderate protection

FPS-SPF
18

Rayito de Sol

Crema Protectora
Sunscreen
con filtro solar

Cont. Neto
Contenido **70g e 2.4 oz** Net Wt.
Industria Argentina • Hecho en Argentina

Ent. Fab. Legajo N° 1292/97 - Int. 155/98
Elaborador para Manufactured for:
SISCOM DE ARGENTINA S.A.
M.T. de Alvear 1381 #42 (1658) Bz. A1, Argentina
BRAS - Distribuido por EXCELLENCE COMERCIAL LTDA.
Avenida Córdoba N° 42 - Centro Empresarial Tembora -
Barranqui - SP - CNPJ: 01.809.395/0001-48 RES ANVS
343/05 MS: 2.02516-9 / SAC: 0800.16.34.34
REG MS N° MS 2.2516.0084.001-6
MEXICO - Importado y distribuido por: BAORAS
S.A. DE C.V. (Montevideo #218) Col. Providencia
Guadalupe Jalisco MEXICO C.P. 46038
RFC: BAQ-000727-EGD
USA - Distributed by: BLIII Holdings, LLC
P.O. Box 652707 Miami, FL, USA - 33165
Phone: (305) 672-9486

18

Instrucciones de Uso
Aplicar sobre la piel generosa y uniformemente 15 minutos antes de la exposición al sol y siempre que sea necesario. Logrará de esta forma que los rayos del sol al actuar sobre la piel le den un magnífico bronceado. Repetir la aplicación cada dos horas, después de haber tenido contacto con el agua, transpirar excesivamente o secarse con toalla para mantener la efectividad del producto. Factor de protección moderada, recomendado para pieles sensibles. Moderada protección contra las quemaduras solares. No ofrece ninguna protección contra la insolación.

Advertencias
Evite el contacto directo con la ropa. Use Externo únicamente. No ingerir. No recomendarle a menores de 6 (seis) meses. Mantenga fuera del alcance de los niños. Evite permanecer demasiado tiempo al sol, aun cuando utilice un protector solar. Mantenga a los bebés y niños pequeños fuera de la luz solar directa. La exposición excesiva al sol es un peligro importante para la salud. Contiene Oxibenzona.

Ingredientes: Vers UVB, Vitamina E, Aqua, Propylparaben, Benzyl Salicylate, Benzyl Alcohol, Hydroxyethyl Urea, Linalool, Coumarin, Citronellol, Geraniol, Eugenol, Amyl Cinnamyl, Isoeugenol.

Modo de Usar
Aplicar generosa y uniformemente por todo el cuerpo 15 minutos antes de exposición al sol e siempre que sea necesario. Reaplicar en intervalos frecuentes (dos horas), após sudar o emagrar-se com a toalha.

Precações e advertências:
Somente para uso externo e adulto. Evite o contato com os olhos; se ocorrer, lave abundantemente com água corrente. Evitando fumaça ou coqueia, suspender o uso imediatamente. Mantenha fora do alcance das crianças. Evite o contato direto com a roupa. Não recomendado a menores de 6 meses. Contém Oxibenzona.

Factor de Proteção Solar 18 (Fotoprotector de pele sensível). Comportamento da pele à radiação solar: frequentemente apresenta eritema. Nível de proteção: Moderada proteção contra queimaduras solar. Este produto foi formulado de maneira a minimizar possível surgimento de alergias. Evite a exposição prolongada ao sol, ainda quando utilize um protetor solar. Mantenha crianças protegidas da luz solar direta. A exposição excessiva ao sol representa um perigo importante para a saúde, validade e integridade embalagem.

Ingredients/Composição: Parafinum Liquidum, Petrolatum, Propylene Glycol, Benzophenone-3, Ethylhexyl Dimethyl PABA, Ceresin, Paraffin, Ethylhexyl Salicylate, Zinc Stearate, Cera Alba, CI 77491, CI 77490, CI 77499, Parfums, Propylparaben, Benzyl Salicylate, Benzyl Alcohol, Hydroxyethyl Urea, Linalool, Coumarin, Citronellol, Geraniol, Eugenol, Amyl Cinnamyl, Isoeugenol.

Testeado Dermatológicamente Hipoalergénico

**Dudas o Comentarios
Dúvidas ou Comentários**
Argentina: 5252-1293 Brasil: 0800.1634.34
sac@beauty.com.ar - www.rayitodesol.com.ar

Use e validade vide embalagem.
Consumir preferencialmente antes da data de validade.

Proteção moderada • moderate protection

FPS-SPF
18

Rayito de Sol

Crema Bronzeador
Sunscreen
con filtro solar

Cont. Neto
Contenido **70g e 2.4 oz** Net Wt.
Fabricado en Argentina - Made in Argentina

Sunscreen SPF 18
hypoallergenic
dermatologist tested

Drug Facts

Active ingredient	Purpose
Octisalate 4%	Sunscreens
Oxybenzone 6%	Sunscreens
Padimate O 6%	Sunscreens

Uses

- helps prevent sunburn
- higher SPF gives more sunburn protection
- provides moderate protection against sunburn

Warnings

For external use only

When using this product

- do not use in or near the eyes
- if it gets into eyes, rinse thoroughly with water

Stop use and ask a doctor if

- rash or irritation develops and lasts side effect occur. You may report side effects to FDA at 1-800-FDA-1088

If swallowed, seek medical attention or contact a Poison Control Center immediately.

Keep out of reach of children

Directions

- apply generously 15 minutes before sun exposure
- children under six months of age, ask a doctor
- reapply every 2 hours or after swimming or sweating or anytime after towelling

Other information

- moderate sun protection product
- sun-protecting sun exposure, wearing protective clothing and using sunscreens may reduce the risk of skin aging, skin cancer and other harmful effects of the sun
- may stain clothing when freshly applied. Avoid contact with fabric or if fabric contact, launder within the hour

Inactive ingredients

Mineral Oil, Petrolatum, Propylene Glycol, Ceresin, Paraffin, CI 77492 (and) CI 77491 (and) CI 77499, Zinc Stearate, Beeswax, Fragrance, Propylparaben, Benzyl Salicylate, Benzyl Alcohol, Hydroxyethyl Urea, Linalool, Coumarin, Citronellol, Geraniol, Eugenol, Amyl Cinnamyl, Isoeugenol.

Questions or comments? if you are in United States (305) 672-9486

Distributed in USA by:
BLIII Holdings, LLC
P.O. Box 652707 Miami, FL, USA - 33165
Phone: (305) 672-9486
batch/expiration date per label on top

RAYITO DE SOL SUNSCREEN SPF 18

octisalate oxybenzone padimate o cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:20367-113
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	2.8 g in 70 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	4.2 g in 70 g
Padimate O (UNII: Z11006CMUZ) (Padimate O - UNII:Z11006CMUZ)	Padimate O	4.2 g in 70 g

Inactive Ingredients	
Ingredient Name	Strength
Mineral Oil (UNII: T5L8T28FGP)	
Petrolatum (UNII: 4T6H12BN9U)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Ceresin (UNII: Q1LS2UJO3A)	
Paraffin (UNII: I9O0E3H2ZE)	
Zinc Stearate (UNII: H92E6QA4FV)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
Propylparaben (UNII: Z8IX2SC1OH)	
Benzyl Salicylate (UNII: WAO5MNK9TU)	
Benzyl Alcohol (UNII: LKG8494WBH)	
Hydroxycitronellal (UNII: 8SQ0VA4YUR)	
LINALOOL, DL- (UNII: D81QY6I88E)	
Coumarin (UNII: A4VZ22K1WT)	
.BETA.-CITRONELLOL, (+/-)- (UNII: 565OK72VNF)	
Geraniol (UNII: L837108USY)	
Eugenol (UNII: 3T8H1794QW)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
Isoeugenol (UNII: 5M0MWY797U)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:20367-113-01	1 in 1 BOX		
1		70 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/14/2011	

Labeler - Siscom de Argentina SA (974736332)