

RAYITO DE SOL SUNSCREEN SPF 6 - octisalate oxybenzone 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 6

Active ingredient

Octisalate 4%

Oxybenzone 1%

Purpose

Sunscreen

Sunscreen

Uses

- Helps prevent sunburn.
- Higher SPF gives more sunburn protection.
- Provides minimal 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 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

- Minimal 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, Cera Alba, 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 6
70g/2.4oz

Protección baja · low protection

Rayito de Sol

Crema Bronceadora Sunscreen

con filtro solar

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

baixa proteção · low protection

Rayito de Sol

Creme Bronzeador Sunscreen

com filtro solar

Cont. Neto **70g e 2.4 oz** Net Wt.
Fabricado na Argentina · Made In Argentina

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 actúen sobre la piel le den un magnífico bronceado. Retener la aplicación cada dos horas, después de haber tenido contacto con el agua, transpirar excesivamente o secarse con toallas para mantener la efectividad del producto. Factor de protección bajo, recomendado para pieles poco sensibles. Baja protección contra las quemaduras solares. No ofrece ninguna protección contra la insolación.

Advertencias
Evite el contacto directo con la ropa. Uso externo únicamente. No ingerir. No recomendable para menores de 6 (seis) meses. Mantenga fuera del alcance de los niños. Evite permanecer demasiado tiempo al sol, aún 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: *emulsão* água, Vaselina Líquida 301, Yodina Líquida 7014, Propileno Glicol, Cera de Parafina, Salicilato de Fenilacetileno, Cloreto de 2,2,4,4-Tetracloro-1,1-Difenil-etano, Cera Alba, Oxibenzona, Fragância, Propilparabeno, Salicilato-benzílico, Alcool de benzoílo, Hidroxitoloneno, Linalol, Coumarina, Citronelol, Geraniol, Eugenol, Arnica, Citronelol, Isoeugenol.

Modo de Usar
Aplicar generosa e uniformemente por todo o corpo 15 minutos antes da exposição ao sol e sempre que necessário. Reaplicar em intervalos frequentes (a cada duas horas), após nadar ou suar-se com a toalha.

Precauciones e advertências:
Somente para uso externo e adulto. Evite o contato com os olhos; se ocorrer, lave abundantemente com água corrente. Cessando o irritação ou coceira, suspenda o uso imediatamente. Mantenha fora do alcance das crianças. Evite o contato direto com a roupa. Não recomendado a menores de 6 meses. Não oferece nenhuma proteção contra a insolação. Contém Oxibenzona.

Factor de Proteção Solar 6 - Fototipo de pele: pouco sensível. Comportamento da pele à radiação solar: sensivelmente apresenta eritemas. Nível de proteção: Baixa (baixa proteção contra queimaduras solar). Este produto foi formulado de maneira a minimizar possível surgimento de alergia. Evite a exposição prolongada ao sol, ainda quando utilize um protetor solar. Mantenha as crianças protegidas da luz solar direta. A exposição excessiva ao sol representa um perigo importante para a saúde.

Ingredients / Composição:
Parafina Líquida, Petrolatum, Propylene Glycol, Ceresin, Paraffin, Ethylhexyl Salicylate, Zinc Stearate, Cera Alba, CI 77492, CI 77491, Benzophenone-3, CI 77493, Paraffin, Propylparaben, Benzyl Salicylate, Benzyl Alcohol, Hydroxytolonene, Linalol, Coumarin, Citronellol, Geraniol, Eugenol, Arnica, Citronellol, Isoeugenol.

Testeado Dermatológicamente Hipoaalergénico

Dúvidas ou Comentários
Argentina: 5252-1393 Brasil: 0800-16.34.34
info@rayito.com.ar - www.rayitodecsol.com.ar

Lotura / Validade em data de embalagem.
Conserve em local fresco e seco, longe de luz e umidade.

Sunscreen SPF 6
hypoallergenic
dermatologist tested

Drug Facts

Active ingredient Purpose
Oxitalate 4 %Sunscreen
Oxybenzone 1 %Sunscreen

Uses

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

Warnings

For external use only

When using this product

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- if it gets into eyes, rinse thoroughly with water

Stop use and ask a doctor if

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

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Directions

- apply generously 15 minutes before sun exposure
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- reapply every 2 hours or after swimming or sweating or anytime after toweling

Other information

- minimal 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, Ferric Oxide Yellow, Ferric Oxide Red, Ferrous Oxide, Zinc Stearate, Beeswax, Fragrance, Propylparaben, Benzyl Salicylate, Benzyl Alcohol, Hydroxytolonene, Linalol, 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 / registration date printed on box

RAYITO DE SOL SUNSCREEN SPF 6

octisalate oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:20367-111
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	0.7 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: 3T8HI794QW)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
Isoeugenol (UNII: 5M0MWY797U)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:20367-111-01	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)