

PROTECTYL SOLEIL MOISTURIZING SUNSCREEN LOTION HIGH PROTECTION SPF 30 - titanium dioxide, octinoxate and octocrylene lotion

Yves Rocher North America Inc

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.

Actives ingredients

Octinoxate 7.5%

Octocrylene 7.0%

Titanium dioxide 8.4%

Purpose

Sunscreen

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Uses

Helps prevent sunburn. Higher SPF gives more sunburn protection.

Warnings:

For external use only. When using this product, keep out of eyes. Rinse with water to remove. Stop use and ask a doctor if rash and irritation develops and lasts.

Directions:

Apply liberally 15 to 30 minutes before sun exposure and as needed. Reapply as needed or after towel drying, swimming, perspiring heavily or washing.

Children under 6 months of age: ask a doctor.

Inactive ingredients:

ACER SACCHARINUM (SUGAR MAPLE) EXTRACT - ALLANTOIN - ALUMINA - ALUMINUM STEARATE - BUTYLENE GLYCOL - BUTYLPARABEN - C12-15 ALKYL BENZOATE - CYCLOHEXASILOXANE - CYCLOPENTASILOXANE - DIMETHICONE - DIMETHICONE CROSSPOLYMER - ETHYLPARABEN - FRAGRANCE (PARFUM) - GLYCERIN - GLYCERYL STEARATE - HYDROGENATED DIMER DILINOLEYL / DIMETHYLCARBONATE COPOLYMER - HUDROXYETHYLCELLULOSE - MANGIFERIN - METHYLPARABEN - METHYLPROPANEDIOL - PEG-100 STEARATE - PHENOXYETHANOL - POLYHYDROXYSTEARIC ACID - PROPYLENE GLYCOL - PROPYLPARABEN - SILICA - SORBITAN STEARATE - STEARETH-100 - TETRASODIUM EDTA - TOCOPHERYL ACETATE - VP/EICOSENE COPOLYMER - WATER (AQUA) - XANTHAN GUM

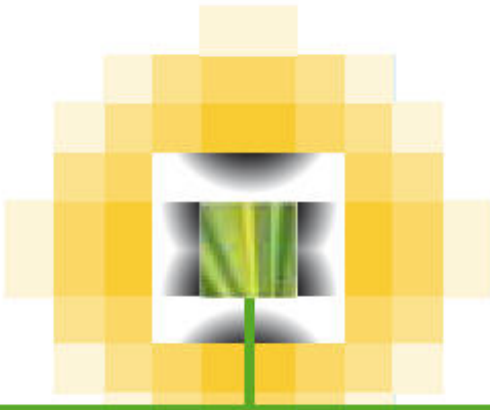
Protectyl Soleil

Moisturizing Sunscreen Lotion
High Protection SPF30

150 ml 5 fl.oz.

PROTECTYL

soleil



SUN CARE INNOVATION
INNOVATION SOLAIRE
INNOVACIÓN SOLAR

Moisturizing
Sunscreen Lotion

High Protection

SPF
30

Lait hydra-protection

Haute protection

FPS
30

Crema Corporal
Hidra-Protección

Protección muy Alta

FPS
30

DIN 02277662

150 ml

Yves
Rocher

5 fl. oz.

DRUG FACTS

Active Ingredients

OCTINOXATE 7.5% • OCTOCRYLENE 7%
TITANIUM DIOXIDE 8.4%

Purpose

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Uses ■ Helps prevent sunburn. ■ Higher SPF gives more sunburn protection.

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Inactive Ingredients / Ingrédients Inactifs

ACER SACCHARUM (SUGAR MAPLE) EXTRACT • ALLANTOIN • ALUMINA
• ALUMINUM STEARATE • BUTYLENE GLYCOL • BUTYLPARABEN •
C12-15 ALKYL BENZOATE • CYCLOHEXASILOXANE •
CYCLOPENTASILOXANE • DIMETHICONE • DIMETHICONE
CROSSPOLYMER • ETHYLPARABEN • PARFUM/FRAGRANCE • GLYCERIN
• GLYCERYL STEARATE • HYDROGENATED DIMER DILINOLEYL /
DIMETHYLCARBONATE COPOLYMER • HYDROXYETHYLCELLULOSE •
MANGIFERIN • METHYLPARABEN • METHYLPROPANEDIOL • PEG-100
STEARATE • PHENOXYETHANOL • POLYHYDROXYSTEARIC ACID •
PROPYLENE GLYCOL • PROPYLPARABEN • SILICA • SORBITAN STEARATE
• STEARETH-100 • TETRASODIUM EDTA • TOCOPHERYL ACETATE •
VP/EICOSENE COPOLYMER • WATER/EAU • XANTHAN GUM

16057

Dist. by/par Yves Rocher
Amérique du Nord Inc.
Longueuil - Québec J4G 2V7



Made in France, Hecho en Francia
Importado por: Y.R. Mexicana,
S.A. de C.V., Poniente 146 -
No. 624 Col. Industrial Vallejo,
C.P. 02300, México

www.yves-rocher.com

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PROTECTYL SOLEIL MOISTURIZING SUNSCREEN LOTION HIGH PROTECTION SPF 30

titanium dioxide, octinoxate and octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63505-156
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
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	7.0 mL in 100 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	8.4 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ACER SACCHARUM BARK/SAP (UNII: Z120VL0KAC)	
ALLANTOIN (UNII: 344S277G0Z)	
ALUMINUM OXIDE (UNII: LM26O6933)	
ALUMINUM STEARATE (UNII: U6XF9NP8HM)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
BUTYLPARABEN (UNII: 3QPIU3FV8)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ETHYLPARABEN (UNII: 14255EXE39)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYDROXYETHYL CELLULOSE (5000 CPS AT 1%) (UNII: X70SE62ZAR)	
MANGIFERIN (UNII: 1M84LD0UMD)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
STEARETH-100 (UNII: 4OH5W9UM87)	
EDETATE SODIUM (UNII: MP1J8420LU)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:63505-156-08	150 mL in 1 BOTTLE, PLASTIC		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part352	05/01/2007		

Labeler - Yves Rocher North America Inc (201908311)

Establishment

Name	Address	ID/FEI	Business Operations
Yves Rocher North America Inc. DBA Laboratoire de biologie vegetal Yves Rocher		347509127	manufacture

Revised: 4/2011

Yves Rocher North America Inc