

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

Yves Rocher North America Inc. DBA Laboratoire de biologie vegetal Yves Rocher

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

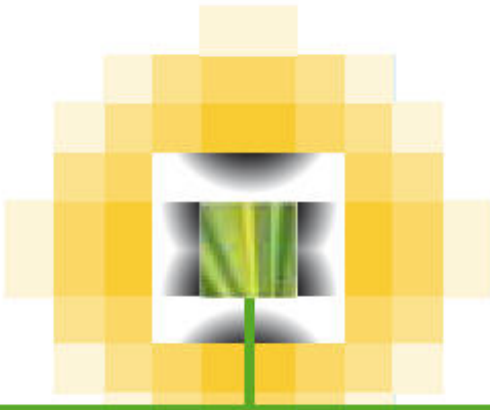
Protectyl Soleil

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 | Purpose |
|----------------------------------|-----------|
| OCTINOXATE 7.5% • OCTOCRYLENE 7% | Sunscreen |
| TITANIUM DIOXIDE 8.4% | |

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

Directions ■ Apply liberally 15 to 30 minutes before sun exposure and as needed. ■ Children under 6 months of age: ask a doctor ■ Reapply as needed or after towel drying, swimming, perspiring heavily or washing.

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

Open
Ouvrir
Abrir

USA 1-800-321-3434 / CANADA 1-800-361-2746

PROTECTYL SOLEIL MOISTURIZING SUNSCREEN LOTION HIGH PROTECTION SPF 30

titanium dioxide, octinoxate and octocrylene cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:54235-204 |
| 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 |
|----------|------------------|----------------------------|-----------------------------|---------------------------|
|----------|------------------|----------------------------|-----------------------------|---------------------------|

| | | | | |
|------------------------------|---|-----------------------------|---------------------------|--|
| 1 | NDC:54235-204-08 | 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. DBA Laboratoire de biologie vegetal Yves Rocher (347509127)

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. DBA Laboratoire de biologie vegetal Yves Rocher