

SOLAIRE PEAU PARFAITE 100% MINERAL FLUID FLAWLESS SKIN- zinc oxide, titanium dioxide lotion

Autumn Harp, 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.

Yves Rocher Solaire Peau Parfaite 100% Mineral Fluid Flawless Skin

Drug Facts

Active Ingredients

Titanium Dioxide 2.5%

Zinc Oxide 7.2%

Purpose

Sunscreen

Titanium Dioxide 2.5%

Zinc Oxide 7.2%

Uses

Helps prevent sunburn

Warnings

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.

Discontinue use and ask a doctor if rash occurs.

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

Directions

Apply generously and evenly every morning on cleansed face and neck 15 minutes before sun exposure

For sunscreen use:

- reapply at least every 2 hours
- use a water-resistant sunscreen if swimming or sweating
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF value of 15 or higher and other sun protection measures including:
 - limit time in the sun, especially from 10 a.m.-2 p.m.
 - wear long-sleeved shirts, pants, hats, and sunglasses
 - For use on children less than 6 months of age, consult a doctor.

Other information

- Protect the product in this container from excessive heat and direct sun

Inactive ingredients

water, ethylhexyl palmitate, caprylic/capric triglyceride, cyclopentasiloxane, diisopropyl sebacate, isononyl isononanoate, polyglyceryl-6 polyricinoleate, polymethylsilsesquioxane, glycerin, argania spinosa kernel oil, polyglyceryl-2 isostearate, tocopheryl acetate, silica, caesalpinia spinosa fruit extract, vaccinium vitis-idaea fruit extract, kappaphycus alvarezii extract, terminalia ferdinandiana fruit extract, chlorella vulgaris extract, aloe barbadensis leaf juice powder, raspberry seed oil/tocopheryl succinate aminopropanediol esters, olive oil decyl esters, hydrolyzed pea protein, sea salt, squalene*, saccharide isomerate, bisabolol, isopropyl myristate, hydrogenated castor oil, xanthan gum, gluconolactone, calcium gluconate, hydrated silica, tocopherol, sodium chloride, magnesium stearate, disteardimonium hectorite, stearammonium hectorite, propylene carbonate, polyhydroxystearic acid, bentonite, alumina, isopropyl titanium triisostearate, lactic acid, citric acid, phenoxyethanol, potassium sorbate, sodium benzoate, mica, iron oxides (CI 77491, CI 77492, CI 77499), titanium dioxide (CI 77891).

* Botanically derived

Questions or comments?

Call: 1-800-321-3434

Principle Display Panel

R12944_Tube_Approved_Proof_12.4.18.jpg

R12945_03809 UnC PL Fluide 100 Mineral Zero Defaut FPS30 30ml zan_vs12.jpg

Drug Facts (continued) / Information (suite) • limit time in the sun, especially from 10 am - 2 pm • wear hats and sunglasses. • For use on children less than 6 months of age, consult a doctor. / • Appliquer généreusement et de façon uniforme chaque matin sur la peau propre du visage et du cou 15 minutes avant l'exposition au soleil. • Pour utilisation comme écran solaire: • Appliquer de nouveau au moins toutes les 2 heures. • Utiliser un écran solaire résistant à l'eau lors d'une activité aquatique ou s'il y a transpiration. • Mesures de protection contre le soleil: Passer du temps au soleil augmente le risque de cancer de la peau et de	Drug Facts (continued) / Information (suite) Inactive ingredients / Ingrédients inactifs Water/Eau, Ethylhexyl Palmitate, Caprylic/Capric Triglyceride, Cyclopentasiloxane, Diisopropyl Sebacate, Isononyl Isononanoate, Polyglyceryl-6 Polyricinoleate, Polymethylsilsesquioxane, Glycerin, Argania Spinosa Kernel Oil, Polyglyceryl-2 Isostearate, Tocopheryl Acetate, Silica, Phenoxyethanol, Disteardimonium Hectorite, Polyhydroxystearic Acid, Hydrogenated Castor Oil, Sodium	YVES ROCHER SOLAIRE PEAU PARFAITE	Drug Facts / Information sur le médicament Active ingredients w/w / Purpose/ Ingrédients actifs p/p Titanium Dioxide 2.5%, Zinc Oxide 7.2% } Sunscreen/ Écran solaire Use/ Usage • Helps prevent sunburn / • Aide à prévenir les coups de soleil Warnings / Mises en garde For external use only / Pour usage externe seulement.
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risque de cancer de la peau et de vieillissement prématuré de la peau. Afin de diminuer ce risque, il convient d'utiliser régulièrement un écran solaire avec un F.P.S. à large spectre d'au moins 15 et d'appliquer d'autres mesures de protection contre le soleil telles que: ♦ limiter le temps passé au soleil, notamment entre 10 et 14 heures ♦ porter un chapeau et des lunettes de soleil. ♦ Pour les enfants âgés de moins de 6 mois, consulter un médecin.

Other Information / Autre renseignement

♦ Protect the product in this container from excessive heat and direct sun./ ♦ Tenir loin de la chaleur excessive ou des rayons de soleil./ ♦ Store at 15-30°C (59-86°F)/ ♦ Conserver entre 15-30°C (59-86°F).

Imported / Distributed by :
Importé / Distribué par :
Yves Rocher Amérique du Nord Inc.
Longueuil, Québec J4G 2V7
www.yves-rocher.com

Made in USA from globally sourced materials. /
Fabriqué aux États-Unis à partir d'ingrédients
des quatre coins du monde.

Vegan formula - Formule végétalienne
Gluten free - Sans gluten



Chloride, Magnesium Stearate, Bisabolol, Aloe Barbadensis Leaf Juice Powder, Alumina, Isopropyl Myristate, Raspberry Seed Oil Tocopheryl Succinate Aminopropanediol Esters, Caesalpinia Spinosa Fruit Extract, Bentonite, Vaccinium Vitis-Idaea Fruit Extract, Kappaphycus Alvarezii Extract, Hydrolyzed Pea Protein, Isopropyl Titanium Trisostearate, Stearalkonium Hectorite, Olive Oil Decyl Esters, Tocopherol, Citric Acid, Hydrated Silica, Propylene Carbonate, Lactic Acid, Terminalia Ferdinandiana Fruit Extract, Saccharide Isomerate, Squalene*, Xanthan Gum, Potassium Sorbate, Gluconolactone, Chlorella Vulgaris Extract, Sodium Benzoate, Sea Salt/Sel Marin, Calcium Gluconate, Mica, Iron Oxides (CI 77491, CI 77492, CI 77499), Titanium Dioxide (CI 77891).

*Botanically derived • Dérivé de plantes

**Questions? Composez le /
Call : CAN 1-800-361-2746 /
USA 1 - 800-321-3434.**

FPS 30 SPF UVA UVB
PROTECTION À LARGE SPECTRE
BROAD SPECTRUM PROTECTION

Fluide 100% Minéral
Zéro Défaut

100% Mineral Fluid
Flawless Skin



VISAGE - FACE
Teint Universel - Universal Tint

ÉCRAN SOLAIRE / SUNSCREEN
NPN : 80089330

30 ml 1 fl. oz.



03809



Do not use on damaged or broken skin / **Ne pas utiliser** sur la peau endommagée ou présentant des lésions

When using this product keep out of eyes. Rinse with water to remove. / **Lorsque vous utilisez ce produit** éviter tout contact avec les yeux. Rincer à l'eau le cas échéant.

Discontinue use and ask a doctor if rash occurs / **Cesser l'utilisation et consulter un médecin** si une éruption cutanée apparaît.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. / **Garder hors de la portée des enfants.** En cas d'ingestion, consulter un médecin immédiatement ou appeler un centre antipoison.

Directions / Mode d'emploi

♦ Apply generously and evenly every morning on cleansed face and neck 15 minutes before sun exposure ♦ For sunscreen use : ♦ reapply at least every 2 hours. ♦ use a water-resistant sunscreen if swimming or sweating. ♦ **Sun Protection Measures** : Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:

ACTIVE INGREDIENTS (W/W) / INGRÉDIENTS ACTIFS (P/P) : Titanium Dioxide 2.5%, Zinc Oxide 7.2%

USE: Broad Spectrum SPF 30. Helps prevent sunburn. Filters/screens UVA/UVB rays.

DIRECTIONS : Apply generously and evenly 15 minutes before sun exposure. Reapply at least every 2 hours. For use on children less than 6 months of age, consult a healthcare practitioner. Use a water-resistant sunscreen if swimming or sweating.

WARNINGS : Refer to outer packaging for full information. For external use only. Keep out of reach of children.

USAGE : Protection à large spectre FPS 30. Aide à prévenir les coups de soleil. Filtre/bloque les rayons UVA et UVB.

MODE D'EMPLOI : Appliquer généreusement et de façon uniforme 15 minutes avant l'exposition au soleil. Réappliquer au moins toutes les 2 heures. Pour les enfants de moins de 6 mois, consulter un professionnel des soins de santé. Utiliser un écran solaire résistant à l'eau si vous nagez ou suiez.

MISE EN GARDE : pour plus d'information, se reporter à l'emballage extérieur. Pour usage externe seulement. Garder hors de portée des enfants.

STORAGE • CONSERVATION :
15°C – 30°C (59 - 86°F)

QUESTIONS? CAN 1-800-361-2746 /
USA 1-800-321-3434

Imported / Distributed by • Importé / Distribué par:
Yves Rocher Amérique du Nord Inc.
Longueuil, Québec J4G 2V7
www.yves-rocher.com

Made in USA, globally sourced./
Fabriqué aux É.-U., ingrédients internationaux.

Vegan formula - Formule végétalienne
Gluten free - Sans gluten

03809



YVES ROCHER

SOLAIRE PEAU PARFAITE

FPS 30 SPF UVA UVB

PROTECTION À LARGE SPECTRE
BROAD SPECTRUM PROTECTION

Fluide 100% Minéral
Zéro Défaut

100% Mineral Fluid
Flawless Skin

Recognized
Sun Protection
Canadian
Dermatology
Association



Reconnu
Protection solaire
Association
canadienne de
dermatologie

VISAGE - FACE
Teint Universel - Universal Tint

ÉCRAN SOLAIRE / SUNSCREEN
NPN : 80089330

30 ml

1 fl. oz.

SOLAIRE PEAU PARFAITE 100% MINERAL FLUID FLAWLESS SKIN

zinc oxide, titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51514-0354
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2.5 mg in 100 mg
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	7.2 mg in 100 mg

Inactive Ingredients

Ingredient Name	Strength
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
TOCOPHEROL (UNII: R0ZB2556P8)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
CALCIUM GLUCONATE (UNII: SQE6VB453K)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STEARALKONIUM HECTORITE (UNII: O LX698AH5P)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
BENTONITE (UNII: A3N5ZCN45C)	
ALUMINUM OXIDE (UNII: LM26O6933)	
ISOPROPYL TITANIUM TRIISO STEARATE (UNII: 949E3KBJ1I)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
MICA (UNII: V8A1AW0880)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
SEA SALT (UNII: 87GE52P74G)	
POLYGLYCERYL-2 MONOISO STEARATE (UNII: 7B8OE71MQC)	
ARGAN OIL (UNII: 4V59G5UW9X)	
LINGONBERRY (UNII: 0UNK9RZQ7X)	
SQUALENE (UNII: 7QWM220FJH)	
LEVOMENOL (UNII: 24WE03BX2T)	
XANTHAN GUM (UNII: TTV12P4NEE)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
CHLORELLA VULGARIS (UNII: RYQ4R60M02)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
DIISOPROPYL SEBACATE (UNII: J8T3X564IH)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
KAPPAPHYCUS ALVAREZII (UNII: T479H08K2O)	
KAKADU PLUM (UNII: 0ZQ1D2FDLI)	

ALOE VERA LEAF (UNII: ZY81Z83H0X)
OLIVE OIL DECYL ESTERS (UNII: 3AQ222F18X)
SACCHARIDE ISOMERATE (UNII: W8K377W98I)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
LACTIC ACID, DL- (UNII: 3B8D35Y7S4)
GLYCERIN (UNII: PDC6A3C0OX)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
WATER (UNII: 059QF0KO0R)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51514-0354-1	1 in 1 CARTON	05/01/2019	
1		3000 mg in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/07/2019	

Labeler - Autumn Harp, Inc. (064187883)

Registrant - Autumn Harp, Inc. (064187883)

Establishment			
Name	Address	ID/FEI	Business Operations
Autumn Harp, Inc.		064187883	manufacture(51514-0354)