

ALGENIST- octinoxate, titanium dioxide, zinc oxide cream
Solazyme, 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.

Drug Facts

Active Ingredients

Octinoxate 7.5%

Titanium Dioxide 2.0%

Zinc Oxide 17.1%

Purpose

Sunscreen

Sunscreen

Sunscreen

Uses

Helps prevent sunburn

- If used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun.

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
- **Stop use and ask a doctor** if rash occurs
- **Keep out of reach of children.** If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

Shake bottle well

- Apply liberally to the entire face in the morning or 15 minutes prior to sun exposure
- Reapply at least every 2 hours
- Use a water resistant sunscreen if swimming or sweating
- Children under 6 months: Ask a doctor
- This lightweight fluid can be used alone, over skincare products and under makeup.

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 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-sleeve shirts, pants, hats, and sunglasses.

Inactive Ingredients

Cyclopentasiloxane, Water/Aqua/Eau, Alcohol Denat., Glycerin, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Methyl Methacrylate Crosspolymer, PEG/PPG-18/18 Dimethicone, Algae Exopolysaccharides, Echinacea Purpurea Extract, Tocopheryl Acetate, Camellia Oleifera Leaf Extract, Arctostaphylos Uva Ursi Leaf Extract, Glycyrrhiza Glabra (Licorice) Root Extract, PEG-9 Polydimethylsiloxyethyl Dimethicone, Stearic Acid, Triethoxysilylethyl Polydimethylsiloxyethyl Hexyl Dimethicone, Ethylhexylglycerin, Caprylyl Glycol, Aluminum Hydroxide, Phenoxyethanol, Hexylene Glycol, Fragrance (Parfum).

Other Information

Protect this product from excessive heat and direct sun.

Questions

Call toll free 1-877-650-1837

Principal Display Panel – Carton Label

Ultra Lightweight

UV Defense Fluid SPF 50

Fluide UV Défense

Ultra Léger FPS 50

Broad Spectrum

Ecran Solaire Large Spectre

ALGENIST

formulate with Alguronic Acid

Biotechnology from

San Francisco

1 US fl. oz / 30 mL

ALGENIST

Ultra Lightweight UV Defense Fluid SPF 50

Fluide UV Défense
Ultra Léger FPS 50
*Broad Spectrum
Ecran Solaire Large Spectre*

Ultra Lightweight UV Defense Fluid SPF 50

*Oil-free
Broad Spectrum SPF 50*
This fast-absorbing, ultra lightweight fluid provides daily protection against broad spectrum UVA/UVB damage. Algonic Acid combines with antioxidant-rich botanicals and UVA/UVB protecting actives to delay signs of aging caused by sun and environmental stressors. This oil-free, sheer formula has a silky texture and weightless feel, designed to apply smoothly on top of other skincare products and under makeup for a soft, matte finish.

oil-free • dermatologist tested • for all skin types • non-comedogenic • paraben free • UVA/UVB protection • non-gras • testé sous contrôle dermatologique • pour tout type de peaux • non comédogène • sans paraben

ALGENIST

formulated with Algonic Acid

Biotechnology from
San Francisco

1 US fl. oz / 30 ml

Fluide UV Défense Ultra Léger FPS 50

*Non-gras
Ecran Solaire Large Spectre
FPS 50*

Ce fluide ultra-léger pénétrant rapidement protège quotidiennement votre peau contre les dommages provoqués par les rayons UVA/UVB à large spectre. L'Acide Algonique est associée à des extraits botaniques riches en anti-oxydants et à des actifs protégeant des rayons UVA/UVB pour retarder l'apparition des signes de l'âge provoquée par le soleil et les agressions extérieures. Sa formule non grasse et légère a une texture soyeuse et fine, spécialement conçue pour une application facile à la suite de produits de soin et avant le maquillage pour un fini mat tout en douceur.

Distributed by | Distribué par :
Algenist
South San Francisco, CA 94080
Certi+, 14 rue Godefroy
Cavaignac 75011 Paris,
France
Algenist is a registered U.S. trademark.
Made in USA | Fabriqué aux USA | Сделано США | Üretim Yeri A.B.D.
www.algenist.com
1 US fl. oz / 30 ml / 30 ml

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PMP0256



ALGENIST

octinoxate, titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53407-138
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	75 mg in 1 mL
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	20 mg in 1 mL
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	171 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
water (UNII: 059QF0KO0R)	
alcohol (UNII: 3K9958V90M)	
glycerin (UNII: PDC6A3C0OX)	
METHYL METHACRYLATE (UNII: 196OC77688)	
peg/ppg-18/18 dimethicone (UNII: 9H0AO7T794)	
echinacea purpurea (UNII: QI7G114Y98)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
camellia oleifera seed (UNII: 59ED29FM2J)	
ARCTOSTAPHYLOS UVA-URSILEAF (UNII: 3M5V3D1X36)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
stearic acid (UNII: 4ELV7Z65AP)	
ethylhexylglycerin (UNII: 147D247K3P)	
caprylyl glycol (UNII: 00YIU5438U)	
aluminum hydroxide (UNII: 5QB0T2IUN0)	
phenoxyethanol (UNII: HIE492ZZ3T)	
hexylene glycol (UNII: KEH0A3F75J)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53407-138-30	1 in 1 BOX		
1		1 in 1 CARTON		
1		30 mL in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/01/2012	

Labeler - Solazyme, Inc. (145862012)**Registrant** - PhytogenX, Inc (010297942)**Establishment**

Name	Address	ID/FEI	Business Operations
PhytogenX, Inc		010297942	MANUFACTURE(53407-138)

