

**ALGENIST- avobenzone, homosalate, octisalate 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.*

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**Drug Facts**

**Active Ingredients**

Avobenzone 3.0%

Homosalate 8.0%

Octisalate 5.0%

**Purpose**

Sunscreen

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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 consult** 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 liberally to the entire face, neck, and chest area 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.

**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**

Water/Aqua/Eau, Silica, Butylene Glycol, Pentylene Glycol, Caprylic/Capric Triglyceride, Glycerin, PEG-100 Stearate, Glyceryl Stearate, Butyrospermum Parkii (Shea Butter), Di-C12-15 Alkyl Fumarate, Cetearyl Alcohol, Cetyl Phosphate, Algae Exopolysaccharides, Malus Domestica Fruit (Apple) Cell Culture Extract, Bambusa Vulgaris (Bamboo) Leaf/Stem Extract, Tetrapeptide-21, Pisum Sativum (Pea) Extract, Enantia Chlorantha Bark Extract, Alaria Esculenta Extract, Sodium Ascorbyl Phosphate, Biotin, Glucosamine HCL, Eucalyptus Globulus Leaf Oil, Ergothioneine, Oleanolic Acid, Stearic Acid, Carbomer, Xanthan Gum, Lecithin, Mannitol, Disodium EDTA, Caprylyl Glycol, Ethylhexylglycerin, Aminomethyl Propanol, Hexylene Glycol, Phenoxyethanol.

### **Other Information**

Protect this product from excessive heat and direct sun.

### **Questions Call toll free 1-877-650-1837**

Principal Display Panel – Carton Label

### **ANTI-WRINKLE / ANTI-RIDES**

#### **Regenerative**

**Anti-Aging Moisturizer | SPF 20**

Soin Régénérant Anti-âge | FPS 20

*Broad Spectrum | Ecran Solaire Large Spectre*

### **ALGENIST**

formulated with Algurinic Acid

Biotechnology from San Francisco

2 US fl. oz / 60 mL

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

Distributed by | Distribué par : Algenist, South San Francisco, CA 94080  
Certi+, 14 rue Godefroy Cavaignac 75011 Paris, France  
Made in USA | Fabriqué aux USA | Сделано США | Üretim Yeri A.B.D.  
www.algenist.com  
2 US fl. oz / 60 ml / 60ml



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**Questions** Call toll free 1-877-650-1837



#### SMOOTH SKIN, FIRM & BOOST RADIANCE

##### **Regenerative Anti-Aging Moisturizer SPF 20**

Formulated with Algoronic Acid, the Regenerative Anti-Aging Moisturizer SPF 20 nourishes and restores skin moisture while rebuilding firmness and elasticity. The appearance of wrinkles, fine lines, and pores is minimized. The skin is regenerated and protected against signs of aging caused by UVA and UVB exposure.

##### Within 10 days of daily use:

**Skin is moisturized and nourished in 95%\* of subjects.**

**Skin is protected in 96%\* of subjects.**

##### Within 4 weeks of daily use:

**Fine lines & wrinkles are minimized in 87%\* of subjects.**

**Skin is healthy and regenerated in 91%\* of subjects.**

Directions for use: Apply to the entire face, neck, and chest area in the morning **prior to sun exposure**. Discontinue use if skin irritation develops or increases. If irritation persists, consult a health care practitioner. Avoid contact with eyes.

##### **Biotechnology Expertise for Targeted Skin Cell Regeneration**

While researching renewable energy solutions, a team of biotechnology scientists in San Francisco unexpectedly discovered Algoronic Acid (patent pending), a powerful compound responsible for regenerating and protecting the microalgae cell. When scientifically tested, Algoronic Acid demonstrated significant anti-aging properties: increasing elastin synthesis by up to 32%\*\* and cellular regeneration by up to 55%\*\*\*. Combining Algoronic Acid with powerful, targeted active ingredients, Algenist skincare promotes cell regeneration to deliver anti-aging benefits for youthful and radiant looking skin.

\* Results obtained following a self-assessment of 100 women.  
Average result measured following an in vitro test with algoronic acid (0.1%\*\*; 0.04%\*\*\*).

#### LISSE LA PEAU, RAFFERMIT & STIMULE L'ÉCLAT

##### **Soin Régénérant Anti-âge FPS 20**

Formulé à base d'Acide Algoronique, le Soin Régénérant Anti-âge FPS 20 nourrit et hydrate la peau, tout en lui redonnant fermeté et élasticité. Les rides et ridules sont visiblement lissées, les pores resserrés. La peau est régénérée et préservée des rayons UVA et UVB responsables des signes de vieillissement.

##### Après 10 jours d'application quotidienne :

**La peau est hydratée et nourrie pour 95%\* des sujets.**

**La peau est protégée pour 96%\* des sujets.**

##### Après 4 semaines d'application quotidienne :

**Les rides et ridules sont lissées pour 87%\* des sujets.**

**La peau est saine et régénérée pour 91%\* des sujets.**

Conseils d'utilisation : Appliquer le matin sur l'ensemble du visage, le cou et le décolleté **avant exposition au soleil**. Cesser d'utiliser si une irritation de la peau se développe ou devient plus sévère. Si l'irritation persiste, consulter un praticien de soins de santé. Éviter tout contact avec les yeux.

##### **Expertise Biotechnologique et Régénération Cellulaire de la Peau**

Des experts en biotechnologie de San Francisco, concentrés sur la recherche de solutions d'énergies renouvelables, ont découvert, de manière inattendue, un composé puissant à l'origine de la régénération et de la protection des cellules de micro-algues, l'Acide Algoronique (brevet déposé). Lors d'études scientifiques, l'Acide Algoronique a démontré des propriétés anti-âge spectaculaires : une augmentation de la synthèse d'élastine jusqu'à 32%\*\* et du renouvellement cellulaire jusqu'à 55%\*\*\*. En associant l'Acide Algoronique à de puissants actifs ciblés, les soins Algenist stimulent la régénération cellulaire pour des bénéfices anti-âge, une peau d'apparence plus jeune et éclatante.

\* Résultats obtenus selon un test d'auto-évaluation réalisé sur 100 femmes.  
Résultat moyen obtenu selon un test in vitro avec l'acide algoronique (0,1%\*\*; 0,04%\*\*\*).

# ALGENIST

avobenzone, homosalate, octisalate cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53407-104
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Avobenzone</b> (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)	Avobenzone	30 mg in 1 mL
<b>Homosalate</b> (UNII: V06SV4M95S) (Homosalate - UNII:V06SV4M95S)	Homosalate	80 mg in 1 mL
<b>Octisalate</b> (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	50 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>Water</b> (UNII: 059QF0KO0R)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>Butylene Glycol</b> (UNII: 3XUS85K0RA)	
<b>Pentylene Glycol</b> (UNII: 50C1307PZG)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>glycerin</b> (UNII: PDC6A3C0OX)	
<b>Peg-100 Stearate</b> (UNII: YD01N1999R)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>SHEA BUTTER</b> (UNII: K49155WL9Y)	
<b>DI-C12-15 ALKYL FUMARATE</b> (UNII: A1CB3Z898P)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>Cetyl Phosphate</b> (UNII: VT07D6X67O)	
<b>APPLE</b> (UNII: B423VGH5S9)	
<b>Tetrapeptide-21</b> (UNII: 179JUC43HU)	
<b>ANNICKIA CHLORANTHA BARK</b> (UNII: H70115MP4A)	
<b>ALARIA ESCULENTA</b> (UNII: EJ9JK8J58D)	
<b>SODIUM ASCORBYL PHOSPHATE</b> (UNII: 836SJG51DR)	
<b>Biotin</b> (UNII: 6SO6U10H04)	
<b>EUCALYPTUS OIL</b> (UNII: 2R04ONI662)	
<b>ERGOTHIONEINE</b> (UNII: BDZ3DQM98W)	
<b>OLEANOLIC ACID</b> (UNII: 6SMK8R7TGJ)	
<b>stearic acid</b> (UNII: 4ELV7Z65AP)	
<b>ethylhexylglycerin</b> (UNII: 147D247K3P)	
<b>caprylyl glycol</b> (UNII: 00YIU5438U)	
<b>CARBOMER HOMO POLYMER TYPE B (ALLYL SUCROSE CROSSLINKED)</b> (UNII: Z135WT9208)	
<b>Xanthan Gum</b> (UNII: TTV12P4NEE)	
<b>EGG PHOSPHOLIPIDS</b> (UNII: 1Z74184RGV)	
<b>mannitol</b> (UNII: 3OWL53L36A)	

<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>AMINOMETHYLPROPANOL</b> (UNII: LU49E6626Q)	
<b>phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>hexylene glycol</b> (UNII: KEH0A3F75J)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53407-104-60	1 in 1 BOX		
1		1 in 1 CARTON		
1		60 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)

### Establishment

Name	Address	ID/FEI	Business Operations
PhytogenX, Inc		010297942	MANUFACTURE(53407-104)

Revised: 8/2012

Solazyme, Inc.