

ALIVE PREBIOTIC BALANCING MOISTURIZER SPF 15- zinc oxide lotion

Algenist, LLC

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

Zinc Oxide 13.65%

Purpose

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 product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

Apply to the entire face, neck, and décolleté, avoiding the eye area, in the morning. Use only as directed. 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
- Apply to clean face with fingertips or brush and blend well. Layer for additional coverage as needed.

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), Caprylic/ Capric Triglyceride, Coco-Caprylate, Glycerin, Glyceryl Behenate, Coco-Glucoside, Simmondsia Chinensis (Jojoba) Seed Oil, Cetearyl Alcohol, Glyceryl Caprylate, Sodium Stearoyl Glutamate, Parachlorella Beijerinckii Exopolysaccharides, Chlorella Vulgaris Extract, Lactococcus Ferment Lysate, Alteromonas Ferment Extract, Caesalpinia Spinosa Fruit Pod Extract, Helianthus Annuus (Sunflower) Sprout Extract, Caprylyl Glycol, Microcrystalline Cellulose, Polyglyceryl-3 Polyricinoleate, Xanthan Gum, Butylene Glycol, Isostearic Acid, Caprylhydroxamic Acid, Algin, Calcium Alginate, Propanediol, Maltodextrin, Lactic Acid, Sodium Benzoate, Sodium Chloride.

Other Information

Protect this product from excessive heat and direct sun.

Questions

Call toll free 1-877-650-1837

Principal Display Panel - 10 mL Box Label

ALIVE

Prebiotic Balancing
Moisturizer SPF 15

Soin Prébiotique
Équilibrant FPS 15

*Broad Spectrum
Sunscreen SPF 15*

*Écran Solaire Large
Spectre FPS 15*

ALGENIST

Alguronic Acid + Prebiotic

0.34 US fl. oz. / 10 ml

ALGENIST

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Drug Facts (continued)

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Moisturizer SPF 15

Soin Prébiotique
Équilibrant FPS 15

*Broad Spectrum
Sunscreen SPF 15*

*Écran Solaire Large
Spectre FPS 15*

Prebiotic Balancing Moisturizer SPF 15

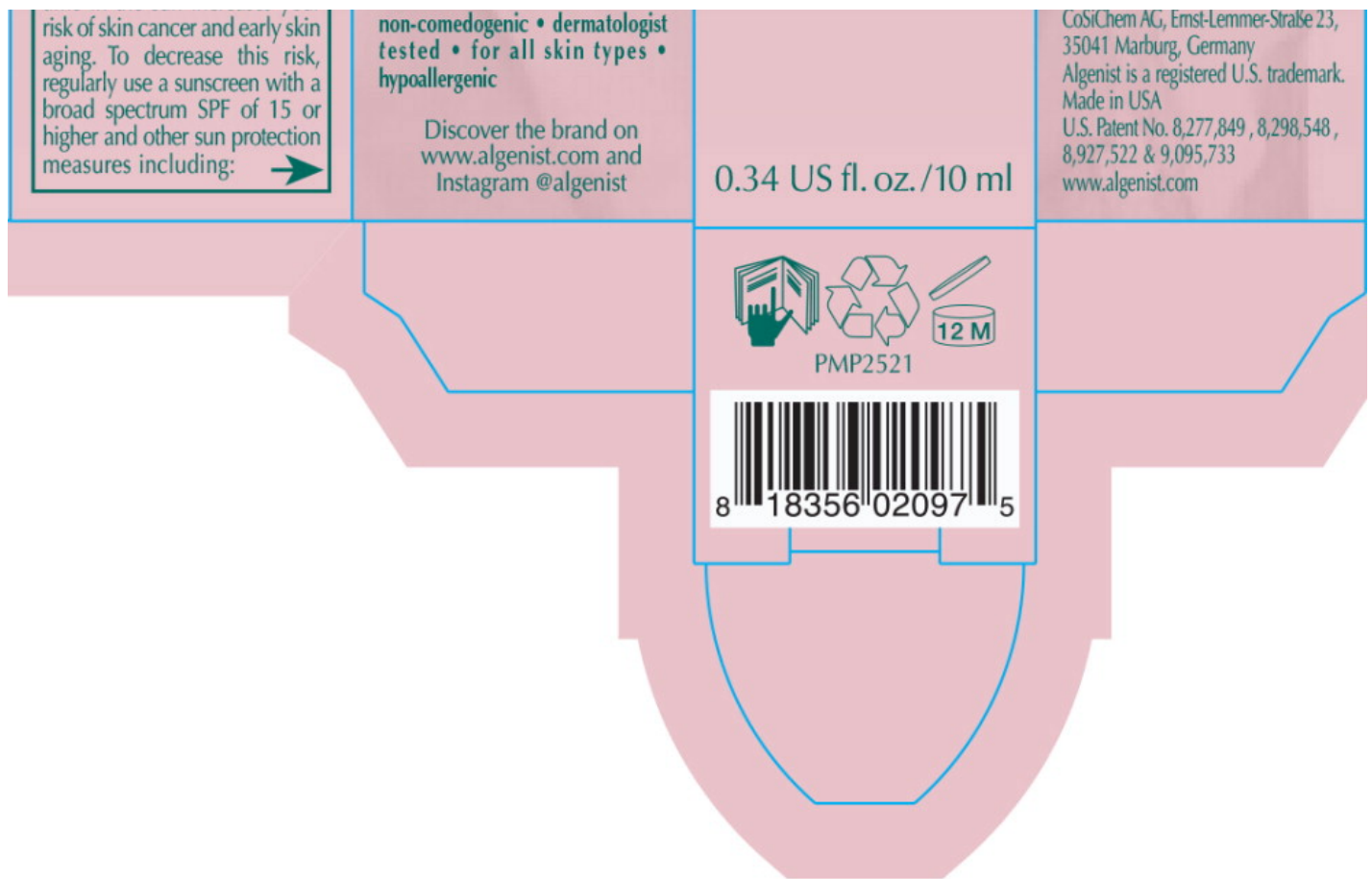
This lightweight moisturizer leaves skin feeling alive and immediately hydrated, balanced and glowing with smoother, more even complexion. Skin is protected from the sun with all mineral SPF 15. Formulated with a prebiotic from algae and a probiotic, paired with our patented Algoronic Acid, to target concerns that may result from unbalanced surface skin bacteria. Probiotics and prebiotics are good for you ingredients that help balance skin's natural surface ecosystem.

Soin Prébiotique Équilibrant FPS 15

Ce soin hydratant et léger procure une sensation vivifiante à la peau qui est immédiatement hydratée et rééquilibrée. Le teint est radieux, plus lisse et unifié. La peau est protégée du soleil grâce à un filtre minéral d'indice SPF 15. Formulé avec un prébiotique issu d'algues et un probiotique, associés à notre Acide Algoronique breveté, il cible les principaux problèmes dus au déséquilibre bactérien de la surface de la peau. Les probiotiques et les prébiotiques sont des ingrédients bons pour vous, qui aident à équilibrer l'écosystème naturel de la surface de la peau.

Distributed by:
Algenist, Glendale, CA 91203

ALGENIST
Algoronic Acid + Prebiotic



Principal Display Panel - 50 mL Box Label

ALIVE

Prebiotic Balancing
Moisturizer SPF 15

Soin Prébiotique
Équilibrant FPS 15

*Broad Spectrum
Sunscreen SPF 15*

*Écran Solaire Large
Spectre FPS 15*

ALGENIST

Alguronic Acid + Prebiotic

1.7 US fl. oz. / 50 ml

ALGENIST

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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), Caprylic/Capric Triglyceride, Coco-Caprylate

Drug Facts (continued)

Sodium Stearoyl Glutamate, Parachlorella Beijerinckii Exopolysaccharides, Chlorella Vulgaris Extract, Lactococcus Ferment Lysate, Alteromonas Ferment Extract, Caesalpinia Spinosa Fruit Pod Extract, Helianthus Annuus (Sunflower) Sprout Extract, Caprylyl Glycol, Microcrystalline Cellulose, Polyglyceryl-3 Polyricinoleate, Xanthan Gum, Butylene Glycol, Isostearic Acid, Caprylhydroxamic Acid, Algin, Calcium Alginate, Propanediol, Maltodextrin, Lactic Acid, Sodium Benzoate, Sodium Chloride.

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ALGENIST

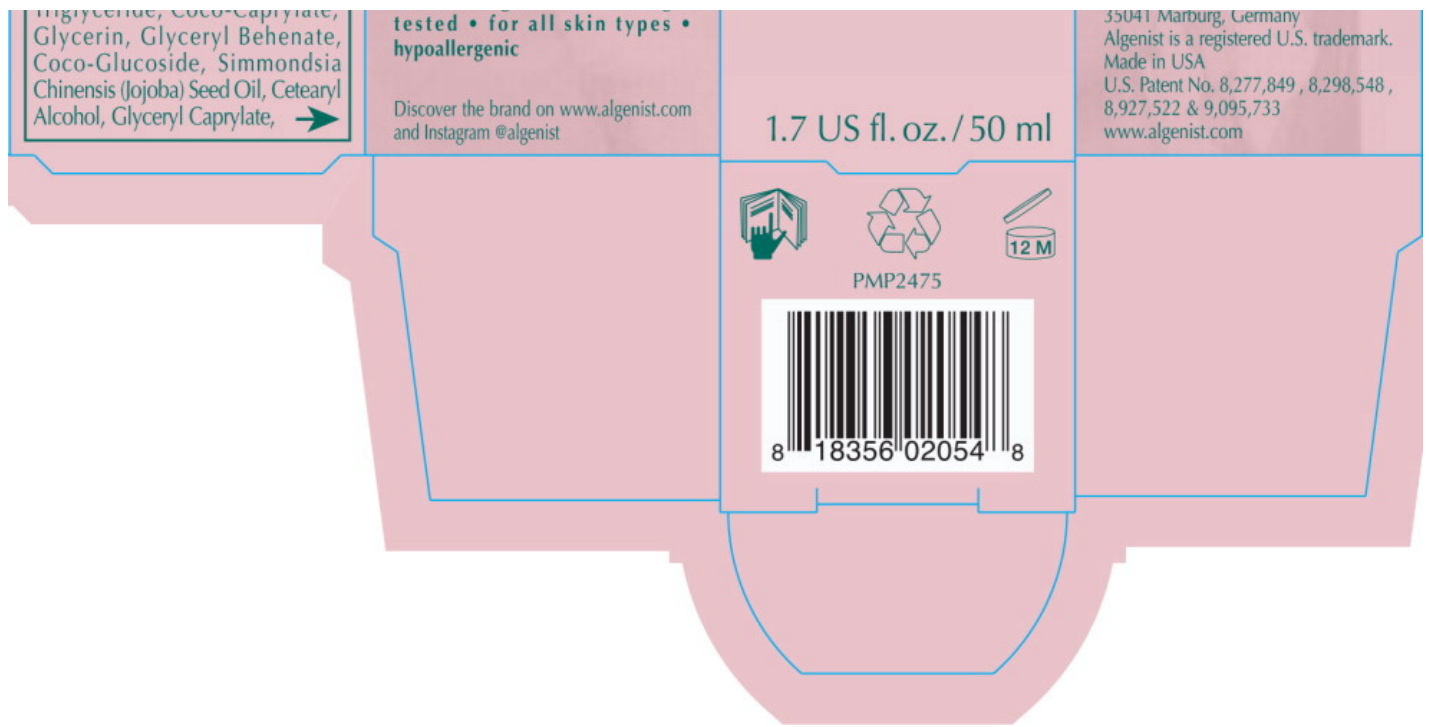
Algoronic Acid + Prebiotic

non-comedogenic • dermatologist

Distributed by:

Algenist, Glendale, CA 91203

CoSiChem AG, Ernst-Lemmer-Straße 23,



ALIVE PREBIOTIC BALANCING MOISTURIZER SPF 15

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71047-262
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.1365 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
COCO-CAPRYLATE (UNII: 4828G836N6)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOBEHENATE (UNII: A626UU0W2A)	
COCO GLUCOSIDE (UNII: ICS790225B)	
JOJOBA OIL (UNII: 724GKU717M)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERYL MONOCAPRYLATE (UNII: TM2TZD4G4A)	
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W)	

XANTHAN GUM (UNII: TTV12P4NEE)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
SODIUM ALGINATE (UNII: C269C4G2ZQ)	
CALCIUM ALGINATE (UNII: 8P20S56HZI)	
PROPANEDIOL (UNII: 5965N8W85T)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CHLORELLA VULGARIS (UNII: RYQ4R60M02)	
CAESALPINIA SPINOSA FRUIT POD (UNII: EXY4496LWD)	
LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71047-262-50	1 in 1 BOX	09/14/2018	
1		50 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:71047-262-10	1 in 1 BOX	09/14/2018	
2		10 mL 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	09/14/2018	

Labeler - Algenist, LLC (080380765)