

ERA ORGANICS MINERAL BASED SPF 15- titanium dioxide, zinc oxide cream

Era Organics, 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.

Era Organics Mineral Based SPF 15

DRUG FACTS

Active Ingredients

Titanium Dioxide 3.50%

Zinc Oxide 3.50%

Purpose

Sunscreen

***Protect this product from excessive heat and direct sunlight.**

USES:

Helps prevent sunburn.

If used as directed with other sun protection measure (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 physician

if irritation or rash develops.

Keep out of reach of children.

If product is swallowed, get medical attention or contact poison control center immediately

DIRECTIONS:

Apply liberally 15-minutes before sun exposure.

REAPPLY: At least every two hours.

- Immediately after swimming, sweating or towel drying.

SUN PROTECTION MEASURES: Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use sunscreen with broad spectrum protection and an SPF rating of 15 or higher, along with other sun protection measures including:

- Limit time in the sun, especially between 10am and 2pm.
- Wear long sleeve shirts, pants, hats and sunglasses.
- For children under 6-months, consult a physician.

Other Ingredients:

Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua, Camellia Sinensis (Green Tea) Extract, Ethylhexylglycerin, Glycerin, Helianthus Annuus (Sunflower) Oil, Lecithin, Octyl Palmitate, Phenoxyethanol, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Sesamum Indicum (Sesame) Seed Oil, Sodium Laurylglucosides Hydroxypropylsulfonate, Theobroma Cacao (Cocoa) Butter, Tocopherol (Vitamin E), Xanthan Gum.

Package Labeling:



Artwork for FDA Approval and OTC Registration

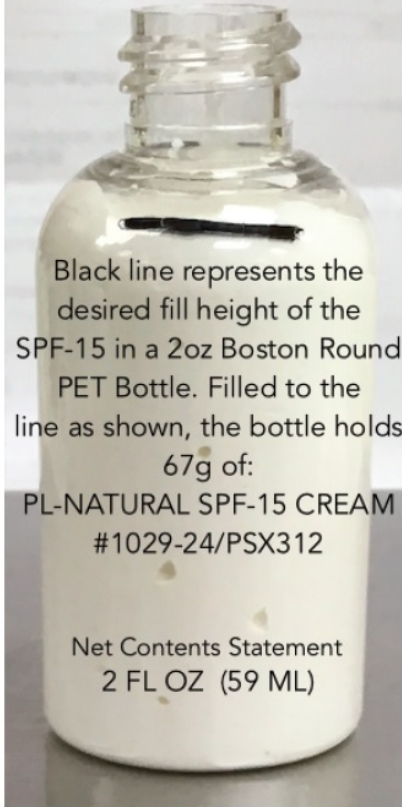
<p>Drug Facts</p> <p>DRUG FACTS:</p> <table border="1"> <tr> <th>Active Ingredients</th> <th>Purpose</th> </tr> <tr> <td>Titanium Dioxide 3.50%</td> <td>Sunscreen</td> </tr> <tr> <td>Zinc Oxide 3.50%</td> <td>Sunscreen</td> </tr> </table> <p><i>*Protect this product from excessive heat and direct sunlight.</i></p> <p>USES: Helps prevent sunburn. If used as directed with other sun protection measure (see directions), decreases the risk of skin cancer and early skin aging caused by the sun.</p> <p>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 physician if irritation or rash develops. Keep out of reach of children. If product is swallowed, get medical attention or contact poison control center immediately.</p>	Active Ingredients	Purpose	Titanium Dioxide 3.50%	Sunscreen	Zinc Oxide 3.50%	Sunscreen	<p>Mineral Based SPF 15 Broad - Spectrum Face Cream</p> <p>Aloe Vera • Green Tea • Sunflower Oil Sesame Seed Oil • Cocoa Butter</p> <p>Extra light, non-toxic formula</p>	<p>Drug Facts Continued:</p> <p>DIRECTIONS: Apply liberally 15-minutes before sun exposure.</p> <p>REAPPLY: At least every two hours. -Immediately after swimming, sweating or towel drying.</p> <p>SUN PROTECTION MEASURES: Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use sunscreen with broad spectrum protection and an SPF rating of 15 or higher, along with other sun protection measures including:</p> <ul style="list-style-type: none"> • Limit time in the sun, especially between 10am and 2pm. • Wear long sleeve shirts, pants, hats and sunglasses. • For children under 6-months, consult a physician. <p>Other Ingredients: Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua, Camellia Sinensis (Green Tea) Extract, Ethylhexylglycerin, Glycerin, Helianthus Annuus (Sunflower) Oil, Lecithin, Octyl Palmitate, Phenoxyethanol, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Sesamum Indicum (Sesame) Seed Oil, Sodium Laurylglucosides Hydroxypropylsulfonate, Theobroma Cacao (Cocoa) Butter, Tocopherol (Vitamin E), Xanthan Gum.</p>
Active Ingredients	Purpose							
Titanium Dioxide 3.50%	Sunscreen							
Zinc Oxide 3.50%	Sunscreen							
<p>Distributed by: Era Organics Inc. Clearwater, FL 33755 Learn More At EraOrganics.com</p>	<p>2 FL OZ (59mL)</p>							



Era Organics Brand SPF-15 Face Cream

Ingredients: Titanium Dioxide(3.50%), Zinc Oxide (3.50%)
 Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua, Camellia Sinensis (Green Tea) Extract, Ethylhexylglycerin, Glycerin, Helianthus Annuus (Sunflower) Oil, Lecithin, Octyl Palmitate, Phenoxyethanol, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Sesamum Indicum (Sesame) Seed Oil, Sodium Laurylglucosides Hydroxypropylsulfonate, Theobroma Cacao (Cocoa) Butter, Tocopherol (Vitamin E), Xanthan Gum.

FILL TEST RESULTS 5.7.18



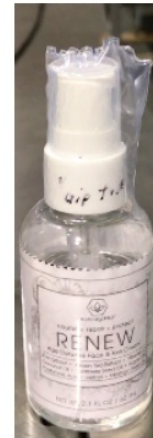
Black line represents the desired fill height of the SPF-15 in a 2oz Boston Round PET Bottle. Filled to the line as shown, the bottle holds 67g of:
 PL-NATURAL SPF-15 CREAM
 #1029-24/PSX312
 Net Contents Statement
 2 FL OZ (59 ML)



Packaging/Size:
 2oz Clear Boston Round PET, 20-410 neck finish. With white Emsar Treatment Pump. Pressure Sensitive Label and Shink Sleeve.

Scent: Unscented

Packout:
 Case Size: 10" x 10" x 10"
 Case Count: 72 bottles per case
 Case Weight: 13 lbs



Shink Bands:
 Shrink bands will be supplied to Pure Source

Torque Values:
 torque values for white pump on this bottle is 6 lbs -10 lbs.

CONFIDENTIAL



Product Guidelines for Era Organics SPF-15 Face Cream
 Fill Test, Net Contents, Gram Weight, Label Placement

Formulated and Filled by Pure Source

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ERA ORGANICS MINERAL BASED SPF 15

titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72400-752
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	35 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	35 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ALMOND OIL (UNII: 66YXD4DKO9)	
SESAME OIL (UNII: QX10HYY4QV)	
COCOA (UNII: D9108TZ9KG)	

TOCOPHEROL (UNII: R0ZB2556P8)

XANTHAN GUM (UNII: TTV12P4NEE)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72400-752-02	59 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/01/2018	

Labeler - Era Organics, Inc. (080454125)

Revised: 7/2018

Era Organics, Inc.