

**TREEACTIV SAFFLOWER OLEOSOMES DAILY NATURAL MOISTURIZING  
SUNSCREEN BROAD SPECTRUM SPF 30- zinc oxide lotion**

**Leiluna 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.*

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**TreeActiv Safflower Oleosomes Daily Natural Moisturizing Sunscreen Broad Spectrum SPF 30**

**Drug Facts**

**Active Ingredient(s)**

Zinc Oxide 13%

**Purpose**

Sunscreen

**Use(s)**

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

**Directions**

- Apply liberally and evenly 15 minutes before sun exposure.
- Use a water resistant sunscreen if swimming or sweating. Reapply at least every 2 hours.
- **Sun Protections Measures.** Spending time in the sun increases our risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF 15 or higher and other sun protection measures including:
  - limiting time in the sun especially from 10:00a.m. - 2:00 p.m.
  - wear long-sleeve shirts, pants, hats, and sunglasses.

**Children under 6 months:** Ask a doctor

**Inactive Ingredients**

Aqua (Water), C12-15 Alkyl Benzoate, Carthamus Tinctorius (Safflower) Oleosomes, Polysorbate 60, Cetyl Alcohol, Glycerin, Helianthus Annuus (Sunflower) Seed Oil<sup>1</sup>, Cetearyl Alcohol, Coco-

Glucoside, Caprylic/Capric Triglyceride, Leuconostoc/Radish Root Ferment Filtrate, Isostearic Acid, Sclerotium Gum, Caprylyl Glycol, Polyhydroxystearic Acid, Phytic Acid, Xanthan Gum, Hamamelis Virginiana (Witch Hazel) Water, Citric Acid, Alcohol

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<sup>1</sup> *Certified organic*

### **Other Information**

- Protect this product from excessive heat and direct sun

### **Questions or comments?**

CustomerCare@treeactiv.com | (888) 201-6444 | www.treeactiv.com

**Distributed by:** Leiluna LLC, Wilmington, DE 19807

### **PRINCIPAL DISPLAY PANEL - 50 ml Bottle Label**

TreeActiv

EARTH GROWN, HAND CRAFTED

SAFFLOWER OLEOSOMES

DAILY NATURAL

MOISTURIZING SUNSCREEN

BROAD SPECTRUM SPF 30

1.7 fl oz (50 ml)



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DAILY NATURAL  
MOISTURIZING SUNSCREEN  
BROAD SPECTRUM SPF 30**

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<b>Active Ingredient(s):</b> Zinc Oxide 13%	<b>Purpose:</b> Sunscreen
<b>Use(s):</b> • helps prevent sunburn • if used as directed with other sun protection measures (see <i>Directions</i> ) decreases the risk of skin cancer and early skin aging caused by the sun	
<b>Warnings:</b> 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 swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions:</b> • Apply liberally and evenly 15 minutes before sun exposure. • Use a water resistant sunscreen if swimming or sweating. Reapply at least every 2 hours. • Sun Protection Measures. Spending time in the sun increases our risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF 15 or higher and other sun protection measures including: • limiting time in the sun especially from 10:00a.m. - 2:00 p.m. • wear long-sleeve shirts, pants, hats, and sunglasses. <b>Children under 6 months:</b> Ask a doctor	
<b>Inactive Ingredients:</b> Aqua (Water), C12-15 Alkyl Benzoate, Carthamus Tinctorius (Safflower) Oleosomes, Polysorbate 60, Cetyl Alcohol, Glycerin, Helianthus Annuus (Sunflower) Seed Oil*, Cetearyl Alcohol, Coco-Glucoside, Caprylic/Capric Triglyceride, Leuconostoc/Radish Root Ferment Filtrate, Isostearic Acid, Sclerotium Gum, Caprylic Glycol, Polyhydroxystearic Acid, Phytic Acid, Xanthan Gum, Hamamelis Virginiana (Witch Hazel) Water, Citric Acid, Alcohol *Certified organic	
<b>Other Information:</b> • Protect this product from excessive heat and direct sun	
<b>Questions or comments?</b> CustomerCare@treeactiv.com   (888) 201-6444   www.treeactiv.com <b>Distributed by:</b> Leiluna LLC, Wilmington, DE 19807	

Safflower Oleosomes provide superior natural moisturization and enhanced Zinc delivery for broad spectrum, natural protection from UVA and UVB exposure which also helps to promote soothing and calming of the skin. Oleosomes are rich in Vitamin E and provide immediate skin barrier protection without harming living skin. Further enhanced with Organic Sunflower Seed Oil, enjoy the extended hydration benefits and anti-aging activity that helps to maintain a defensive barrier which aids in improved moisture retention and helps to shield from environmental damage.



**TREEACTIV SAFFLOWER OLEOSOMES DAILY NATURAL MOISTURIZING  
SUNSCREEN BROAD SPECTRUM SPF 30**

zinc oxide lotion

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72841-101
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	130 mg in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
WATER (UNII: 059QF0KO0R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
COCO GLUCOSIDE (UNII: ICS790225B)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
LEUCONOSTOC/RADISH ROOT FERMENT FILTRATE (UNII: D2QHA03458)	
BETASIZOFIRAN (UNII: 2X51AD1X3T)	
WITCH HAZEL (UNII: 101I4J0U34)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CITRIC ACID ACETATE (UNII: DSO12WL7AU)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
FYTIC ACID (UNII: 7IGF0S7R8I)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72841-101-01	50 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/01/2019	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph final	part352	05/01/2019	

**Labeler** - Leiluna LLC (080065214)**Establishment**

Name	Address	ID/FEI	Business Operations
Island Kinetics, Inc. d.b.a. CoValence Laboratories		959735002	MANUFACTURE(72841-101)