

## **ENVIRONMENTAL DEFENSE- zinc oxide cream**

### **Avasol 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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### **Drug Facts**

#### **Active Ingredients**

Zinc Oxide (Non-nano) 22.5%

#### **Purpose**

Sunscreen

#### **Uses**

- Helps prevent sunburn

#### **Warnings**

- **For external use only**
- **Keep out of eyes. Rinse with water to remove**

**Stop use and ask a doctor** if rash or irritation occurs.

**Do not use** if allergic to ingredients.

- Test small area first.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

- Apply liberally before sun
- Reapply: after 80 minutes of swimming or sweating, immediately after towel drying, at least every 2 hours, or as needed
- Children under 6 months: Ask a doctor
- May stain some fabrics.

#### **Inactive ingredients**

Caprylic/Capric Triglyceride (Coconut), \*Simmondsia Chinensis (Jojoba) Seed Oil,\*Helianthus annuus (Sun flower) Oil,\*Cocos Nucifera (Coconut) Oil,\*Calophyllum Inophyllum (Tamanu)Oil,\*Argania spinosa (Argan) Oil, Silica, \*Beeswax,\*Theobroma Grandiflorum (Cupuacu) Seed Butter,\*Butyrospermum parkii (Shea Butter),\*\*Mauritia

Flexuosa (Buriti) Fruit Oil, Rubus idaeus (Raspberry) Seed Oil, Tocopherol (Vitamin E), Mica, Iron oxides, \*Vanilla Planifolia(Vanilla) Fruit Extract, Plankton Extract,\*Propolis,\*Rosmarinus Officinalis (Rosemary) Leaf Extract,\*\*Leptospermum scoparium (Manuka)Oil, \*Cinnamomum Zeylanicum (Cinnamon) Bark Oil, Love. **\*Organic \*\*Wildcrafted**

## Other information

Shake well before use. Warm as needed.

## Questions?

Call **888-805-1507** or visit [www.avasol.com](http://www.avasol.com)

## Principal Display Panel - 2 Fl Oz Bottle Label

**avasol®**

**mineral sunscreen**

**30 SPF**

2 FL OZ (59 mL)



- Environmental Defense Cream • Ultra-premium
- Broad spectrum • Water-resistant (80 minutes)
- People-safe • Ocean-safe • 100% Bio-based

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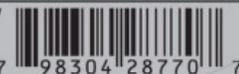
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**Questions?** Call 888-805-1507 or visit [www.avasol.com](http://www.avasol.com)

Manufactured in the USA by  
AVASOL LLC  
P.O. Box 50516  
Santa Barbara, CA 93150 7



# ENVIRONMENTAL DEFENSE

zinc oxide cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58518-010
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	225 mg in 100 mL

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>COCONUT OIL</b> (UNII: Q9L0O73W7L)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>JOJOBA OIL</b> (UNII: 724GKU717M)	
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)	
<b>TAMANU OIL</b> (UNII: JT3LVK84A1)	
<b>ARGAN OIL</b> (UNII: 4V59G5UW9X)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)	
<b>THEOBROMA GRANDIFLORUM SEED</b> (UNII: Q7RNT1G37V)	
<b>SHEANUT</b> (UNII: 84H6HBP32L)	
<b>MAURITIA FLEXUOSA WHOLE</b> (UNII: 83ULF8L5FI)	
<b>RUBUS IDAEUS SEED</b> (UNII: M3CL7US2ZG)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>VANILLA BEAN</b> (UNII: Q74T35078H)	
<b>MICA</b> (UNII: V8A1AW0880)	
<b>HAEMATOCOCCUS PLUVIALIS</b> (UNII: 31TOFF0472)	
<b>FERROUS OXIDE</b> (UNII: G7036X8B5H)	
<b>PROPOLIS WAX</b> (UNII: 6Y8XYV2NOF)	
<b>MANUKA OIL</b> (UNII: M6QU9ZUH2X)	
<b>ROSEMARY</b> (UNII: IJ67X351P9)	
<b>CINNAMON BARK OIL</b> (UNII: XE54U569EC)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:58518-010-02	60 mL in 1 POUCH; Type 0: Not a Combination Product	11/29/2021	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part352	07/18/2013	

**Labeler** - Avasol LLC (078822898)

### **Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Avasol LLC		078822898	MANUFACTURE(58518-010)

Revised: 12/2021

Avasol LLC