

## **ATTITUDE 100% MINERAL SUNSCREEN - TROPICAL- zinc oxide cream**

### **Bio Spectra**

*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.*

-----

### **ATTITUDE®**

### **100% Mineral sunscreen - Tropical**

#### **DRUG FACTS:**

#### **Active ingredient**

Zinc oxide (20%)

#### **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. If rash occurs, stop use and ask a doctor.

**When using this product** keep out of eyes. Rinse with water to remove.

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

#### **DIRECTIONS**

- Apply liberally 15 minutes before sun exposure
- Reapply:
  - At least every 2 hours
  - After 40 minutes of swimming or sweating
  - Immediately after towel drying
- Ask a doctor for use on children under 6 months of age.

**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 value of 15 or higher and other sun protection measures including:
  - Limit time in the sun, especially from 10am–2pm

- Wear long-sleeved shirts, pants, hats, and sunglasses.

### **Inactive or non-medicinal ingredients**

Aqua, caprylic/capric triglyceride, cetearyl alcohol, cetearyl glucoside, glyceryl isostearate, glyceryl stearate, C10-18 triglycerides, glycerin, polyhydroxystearic acid, ethylhexylglycerin, caprylyl glycol, xanthan gum, sodium gluconate, triethyl citrate, gamma-undecalactone (sweet fruit).

### **Other Information**

Store at temperatures below 90oF.

### **PRINCIPAL DISPLAY PANEL - 150 g Tube Label**

BIO SPECTRA  
ATTITUDE®

live consciously

30  
SPF

100% MINERAL  
SUNSCREEN

tropical • hypoallergenic

BROAD SPECTRUM (UVA/UVB), NON NANO

DERMATOLOGICALLY TESTED

• EWG VERIFIED  
FOR YOUR HEALTH •  
EWG.ORG •™

WORRY-FREE

• INGREDIENTS •

NPN 80047088 • 150 g / 5.2 OZ.

© 2018 BD SPECTRA, MONTREAL, CANADA H2T 2A4 • 231, RUE SAINT-HONORE, PARIS, FRANCE 75001 / T: +33 (0)1 77 75 97 03 • MADE IN CANADA / FAIT AU CANADA

**DRUG FACTS / RENSEIGNEMENTS**

**Active ingredient / Ingrédient médicinal**      **Purpose / Utilisation**  
 Zinc oxide / Oxyde de zinc (20%).....Sunscreen / Crème solaire

**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. / **Utilisation :** ■ Aide à prévenir les coups de soleil ■ Si utilisé selon le mode d'emploi et avec d'autres mesures de protection (voir Mode d'emploi), diminue les risques de cancer de la peau et de vieillissement prématuré de la peau.

**Warnings / Attention :**  
**For external use only. / Pour usage externe seulement.**

**Do not use** on damaged or broken skin. If rash occurs, stop use and ask a doctor. **Ne pas utiliser** sur la peau endommagée ou présentant des lésions. En présence d'une éruption cutanée, cesser l'utilisation et consulter un professionnel de la santé.

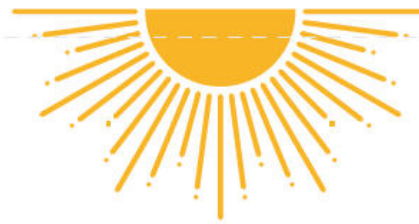
**When using this product** keep out of eyes. Rinse with water to remove. **Éviter tout contact avec les yeux.** Rincer à l'eau le cas échéant.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away. / **Garder hors de portée des enfants.** En cas d'ingestion, consulter un médecin immédiatement ou appeler un centre antipoison.

**DIRECTIONS:** ■ Apply liberally 15 minutes before sun exposure ■ Reapply: ■ At least every 2 hours ■ After 40 minutes of swimming or sweating ■ Immediately after towel drying ■ Ask a doctor for use on children under 6 months of age. **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 value of 15 or higher and other sun protection measures including: ■ Limit time in the sun, especially from 10am-2pm ■ Wear long-sleeved shirts, pants, hats, and sunglasses. / **Mode d'emploi :** ■ Appliquer généreusement et uniformément 15 minutes avant l'exposition au soleil. ■ Appliquer de nouveau au moins toutes les 2 heures. Utiliser un écran solaire résistant à l'eau lors d'une activité aquatique ou s'il y a transpiration. Pour les enfants âgés de moins de 6 mois, consulter un professionnel de la santé. **Mesures de protection contre le soleil :** Passer du temps au soleil augmente le risque de cancer de la peau et de vieillissement prématuré de la peau. Afin de diminuer ce risque, il convient d'utiliser régulièrement un écran solaire avec un F.P.S. à large spectre d'au moins 15 et d'appliquer d'autres mesures de protection contre le soleil, telles que : limiter le temps passé au soleil, notamment entre 10 et 14 heures; et porter des chemises à manches longues, des pantalons, un chapeau et des lunettes de soleil.

**Inactive or non-medicinal ingredients / Ingrédients non médicinaux :** Aqua, caprylic/capric triglyceride, cetearyl alcohol, cetearyl glucoside, glyceryl isostearate, glyceryl stearate, C10-18 triglycerides, glycerin, polyhydroxystearic acid, ethylhexylglycerin, caprylyl glycol, xanthan gum, sodium gluconate, triethyl citrate, gamma-undecalactone (sweet fruit).

**Other information / Autre information :**  
 Store at temperatures below 90°F. / Entreposer à une température inférieure à 32 °C.



**ATTITUDE**

live consciously



100% MINERAL

**SUNSCREEN**

tropical · hypoallergenic

BROAD SPECTRUM (UVA/UVB), NON NANO

DERMATOLOGICALLY TESTED

**CRÈME SOLAIRE**

100 % MINÉRALE

tropicale · hypoallergénique

LARGE SPECTRE (UVA/UVB), NON NANO

TESTÉ SOUS CONTRÔLE DERMATOLOGIQUE



**WORRY-FREE**  
 • INGREDIENTS •  
 RASSURANTS

NPN 80047088 · 150 g / 5.2 OZ.

**ATTITUDE 100% MINERAL SUNSCREEN - TROPICAL**

zinc oxide cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61649-011
<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	20 g in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
C10-18 TRIGLYCERIDES (UNII: 43AGM4PHPI)	
GLYCERIN (UNII: PDC6A3C0OX)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM GLUCONATE (UNII: R6Q3791S76)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
.GAMMA.-UNDECALACTONE (UNII: QB1T0AG2YL)	
.GAMMA.-OCTALACTONE (UNII: UHD6M52X0K)	

### Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61649-011-15	1 in 1 CARTON	07/01/2014	
1		150 g 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	07/01/2014	

**Labeler** - Bio Spectra (201137051)

### Establishment

Name	Address	ID/FEI	Business Operations
Fusion Solution inc		251948899	MANUFACTURE(61649-011)