

**BIO DAMASCENA ROSE OTTO FACE SUNSCREEN- zinc oxide lotion**  
**ALTEYA ORGANICS OOD**

*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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**BIO DAMASCENA ROSE OTTO FACE SUNSCREEN**

***Drug Facts***

**☐Active Ingredient:**

Non-Nano Uncoated Zinc Oxide 18%

**☐Purpose**

Sunscreen

**Use:** • Helps prevent sunburn • If used as directed with other sun protection measures (see **Directions**), decreases the chance 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 product is swallowed, get medical help or contact a Poison Control Center right away.

**Directions:** • Apply generously (2mg /cm<sup>2</sup> of skin) 15 minutes before sun exposure. • Reapply at least every 2 hours. Use a water-resistant sunscreen if swimming or sweating. • For children under 6 months: ask a doctor. • **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 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:** Distilled Thermal Water, Helianthus Annuus (Sunflower) Seed Oil\*, Cocos Nucifera (Coconut) Oil\*, Glycerin<sup>☐</sup>, Butyrospermum Parkii (Shea Butter)\*, Simmondsia Chinensis (Jojoba) Oil\*, Cucurbita Pepo (Pumpkin) Seed Oil<sup>☐</sup>, Copernicia Cerifera (Carnauba Wax)\*, Polyglyceryl-6 Stearate (and) Polyglyceryl-6 Behenate, Caprylic / Capric Triglycerides, Cera Alba (Beeswax)\*, Lecithin<sup>☐</sup>, Isoamyl Laurate, Macadamia Integrifolia (Macadamia) Oil\*, Glyceryl Caprylate, Glyceryl Undecylenate, Cyamopsis Tetragonoloba (Guar) Gum<sup>☐</sup>, Aloe Barbadensis (Aloe) Leaf Juice<sup>☐</sup>, Persea Gratissima (Avocado) Oil\*, Rosa Damascena (Rose) Flower Extract, Rosa Damascena (Rose) Flower Oil<sup>☐</sup>, Pistacia Lentiscus (Mastic) Gum, Oenothera Biennis (Evening Primrose) Oil\*, Rosa Canina (Rosehip) Seed Oil\*, Euterpe Oleracea (Acai) Fruit Oil<sup>☐</sup>, Iron Oxides (CI 77492, CI 77491, CI 77499), Tocopherol (Vitamin E), Hippophae Rhamnoides (Seabuckthorn) Fruit Extract\*, Calendula officinalis (Flower) Extract\*, Lavandula Angustifolia (Lavender) Oil\*, Cymbopogon Martini (Palmarosa) Oil\*, Anthemis Nobilis (Roman Chamomile) Flower Oil<sup>☐</sup>, Linalool\*\*, Geraniol\*\*, Citronellol\*\*, Eugenol\*\*

\* *Certified Organic Ingredients*

\*\* *Naturally occurring in essential oils*

**Other information:** • Store at temperatures between 70-90°F/21-32°C. Higher or lower temperatures may cause the product to separate or thicken. • May stain some fabrics.

BROAD SPECTRUM SPF 25

Sheer Tint

Ageless UVA/UVB Care

CERTIFIED ORGANIC

No harmful chemical ingredients

Not Tested on Animals

Manufactured by **Alteya Organics** LLC.

Yagoda 6167, Made in Bulgaria

[www.AlteyaOrganics.com](http://www.AlteyaOrganics.com)

## □ Packaging





## BIO DAMASCENA ROSE OTTO FACE SUNSCREEN

zinc oxide lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71330-104
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	18 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
SUNFLOWER OIL (UNII: 3W1JG795Y)	
COCONUT OIL (UNII: Q9L0O73W7L)	
GLYCERIN (UNII: PDC6A3C0OX)	
SHEA BUTTER (UNII: K49155WL9Y)	
JOJOBA OIL (UNII: 724GKU717M)	

PUMPKIN SEED OIL (UNII: 6E5QR5USSP)
CARNAUBA WAX (UNII: R12CBM0EIZ)
POLYGLYCERYL-6 STEARATE (UNII: ETY9Q81E2T)
POLYGLYCERYL-6 BEHENATE (UNII: 4T2L7QIB13)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
YELLOW WAX (UNII: 2ZA36H0S2V)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
ISOAMYL LAURATE (UNII: M1SLX00M3M)
MACADAMIA OIL (UNII: 515610SU8C)
GLYCERYL MONOCAPRYLATE (UNII: TM2TZD4G4A)
GLYCERYL 1-UNDECYLENATE (UNII: B68LJT9544)
GUAR GUM (UNII: E89I1637KE)
ALOE (UNII: V5VD430YW9)
AVOCADO OIL (UNII: 6VNO72PFC1)
ROSA X DAMASCENA FLOWER OIL (UNII: 18920M3T13)
PISTACIA LENTISCUS RESIN (UNII: 7446H202QW)
EVENING PRIMROSE OIL (UNII: 3Q9L08K71N)
ROSA CANINA SEED (UNII: 4503R1M9UT)
ACAI OIL (UNII: Z0W6766A2W)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERROSO FERRIC OXIDE (UNII: XM0M87F357)
TOCOPHEROL (UNII: R0ZB2556P8)
HIPPOPHAE RHAMNOIDES FRUIT (UNII: AVL0R9111T)
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)
LAVENDER OIL (UNII: ZBP1YXW0H8)
PALMAROSA OIL (UNII: 0J3G3O53ST)
CHAMAEMELUM NOBILE FLOWER OIL (UNII: UB27587839)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71330-104-50	1 in 1 BOX	04/01/2017	
1		50 mL in 1 BOTTLE; 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	04/01/2017	

**Labeler** - ALTEYA ORGANICS OOD (503572407)

### Establishment

Name	Address	ID/FEI	Business Operations
ALTEYA ORGANICS OOD		503572407	manufacture(71330-104)

