

**1000 ROSES DAILY SHADE FACIAL SPF 18- octisalate, octocrylene, and avobenzone lotion**  
**Andalou naturals**

*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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**1000 Roses® Daily Shade Facial Lotion SPF 18**

**Drug Facts**

<b>Active Ingredients</b>	<b>Purpose</b>
Octisalate 5.0%	Sunscreen
Octocrylene 5.0%	Sunscreen
Avobenzone 2.5%	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.
- When using this product keep out of eyes. Rinse with water to remove.
- Stop use and ask a doctor if rash or irritation develops and lasts.

**Directions**

- Daily, alone or under make-up.
- Apply liberally 15-30 minutes before sun exposure and as needed.
- Reapply at least every 2 hours.
- Use water resistant sunscreen if swimming or sweating.
- **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 of 15 or higher and other sun protection measures including: limit time in the sun, especially from 10am-2pm, wear long sleeve shirts, pants and sunglasses.
- Children under 6 months: ask a doctor.

**Inactive Ingredients**

Aloe Barbadensis Leaf Juice<sup>1</sup>, Purified Water (Aqua), Vegetable Glycerin, Cetyl Alcohol, Stearic Acid, Stearyl Alcohol, Helianthus Annuus (Sunflower) Seed Oil<sup>1</sup>, Plant Stem Cells (Alpine Rose, Malus Domestica, Solar Vitis) and BioActive 8 Berry Complex<sup>1</sup>, Dimethicone, Lecithin, Tocopherol, Soothing Complex: [Sodium Hyaluronate, Magnolia Officinalis Bark Extract, Boswellia Serrata (Boswellin) Extract], Panthenol, Allantoin, Rosa Damascena (Rose) Flower Distillate<sup>1</sup>, Magnesium Ascorbyl Phosphate (Vitamin C), Chamomilla Recutita (Chamomile) Flower Extract<sup>1</sup>, Calendula Officinalis Flower Extract<sup>1</sup>, Rosa Canina (Rosehip) Fruit Oil<sup>1</sup>, Punica Granatum (Pomegranate) Seed Oil<sup>1</sup>, Camellia Sinensis (White Tea) Leaf Extract<sup>12</sup>, Aspalathus Linearis (Rooibos) Extract<sup>12</sup>, Hibiscus Sabdariffa Flower Extract<sup>12</sup>, Phenethyl Alcohol, Ethylhexylglycerin, Rose Isolates, Vanilla Isolates, Pelargonium Graveolens (Rose Geranium) Flower Oil<sup>1</sup>, Citrus Aurantium Dulcis (Orange) Peel Oil<sup>1</sup>

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**1 Certified Organic**

**2 Fair Trade Ingredients**

### **Other Information**

- Protect the product in this container from excessive heat and direct sun.

### **Questions**

Call (888) 898-6955 or visit [www.Andalou.com](http://www.Andalou.com)

Dist. by Andalou Naturals

Novato, CA 94945 USA

## **PRINCIPAL DISPLAY PANEL - 80 mL Tube Carton**

**NEW LOOK**

**ANDALOU**  
NATURALS

**NON**  
**GMO**

1000 Roses®  
**DAILY SHADE**

Facial Lotion  
SPF 18

with Rose Stem Cells  
Soothing Resilience

Broad Spectrum Protection

**FRUIT**  
**STEM**  
**CELL**

**SCIENCE®**

**SENSITIVE**

2.7 fl oz e 80 mL

NATURE'S INTELLIGENCE®

FRUIT  
STEM  
CELL  
SCIENCE®

NEW LOOK

ANDALOU  
NATURALS

NON  
GMO

ANDALOU  
NATURALS

1000 Roses®



GMO



1000 Roses®  
**DAILY SHADE**

Lotion Visage

Facial Lotion  
SPF 18

with Rose Stem Cells  
Soothing Resilience

Broad Spectrum Protection



SCIENCE®

**SENSITIVE**

2.7 fl oz e 80 mL



8 59975 02008 3

**DAILY SHADE**

Lotion Visage

Facial Lotion  
SPF 18

with Rose Stem Cells  
Soothing Resilience

**FRUIT  
STEM  
CELL**

SCIENCE®

**SENSITIVE**

## SENSITIVE SOLUTIONS FOR

- Delicate & Dry Skin
- Easily Irritated
- Uneven & Blotchy
- Over-Exposed

Perfect for sensitive skin, this ultra-sheer SPF 18 facial lotion with alpine rose stem cells, provides essential hydration and dermal vitality with easy to wear sun protection for a flawless looking complexion.

Skin's truest self is fully realized with a portfolio of nature's most potent bioactives and the innovation that captures it all, Fruit Stem Cell Science®.



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Octocrylene 5.0% .....	Sunscreen
Avobenzone 2.5% .....	Sunscreen

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**Inactive Ingredients** Aloe Barbadosensis Leaf Juice\*, Purified Water (Aqua), Vegetable Glycerin, Cetyl Alcohol,

K

- Sheer, lightweight coverage
- Comfortable for everyday
- Alone or under make-up

**To Use:** Daily. For best protection apply 30 minutes prior to sun exposure. Reapply as needed.

For external use only. Avoid direct contact with eyes. pH balanced and hypoallergenic.

Dermatologist Tested

Made in USA with domestic and imported materials.

Comments or Questions?  
Talk to Us at [andalou.com](http://andalou.com)

Dist. by Andalou Naturals  
Novato, CA 94945 USA

Stearic Acid, Stearyl Alcohol, Helianthus Annuus (Sunflower) Seed Oil\*, Plant Stem Cells (Alpine Rose, Malus Domestica, SolarVitis) and BioActive 8 Berry Complex\*, Dimethicone, Lecithin, Tocopherol, Soothing Complex (Sodium Hyaluronate, Magnolia Officinalis Bark Extract, Boswellia Serrata (Boswellin) Extract, Panthenol, Allantoin, Rosa Damascena (Rose) Flower Distillate\*, Magnesium Ascorbyl Phosphate (Vitamin C), Chamomilla Recutita (Chamomile) Flower Extract\*, Calendula Officinalis Flower Extract\*, Rosa Canina (Rosehip) Fruit Oil\*, Punica Granatum (Pomegranate) Seed Oil\*, Camellia Sinensis (White Tea) Leaf Extract\*, Aspalathus Linearis (Rooibos) Extract\* †, Hibiscus Sabdariffa Flower Extract\* †, Phenethyl Alcohol, Ethylhexylglycerin, Rose Isolates, Vanilla Isolates, Pelargonium Graveolens (Rose Geranium) Flower Oil\*, Citrus Aurantium Dulcis (Orange) Peel Oil\*

\* Certified Organic † Fair Trade Ingredients

**Other Information** ■ Protect the product in this container from excessive heat and direct sun.

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2537355 v6

octisalate, octocrylene, and avobenzone lotion

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55560-0103
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	50 mg in 1 mL
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	25 mg in 1 mL

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)	
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)	
<b>ROSA RUGOSA FLOWER</b> (UNII: 969IQC5YJU)	
<b>APPLE</b> (UNII: B423VGH5S9)	
<b>VITIS VINIFERA SEED</b> (UNII: C34U15ICXA)	
<b>ACAI</b> (UNII: 46AM2VJ0AW)	
<b>ARONIA MELANOCARPA FRUIT JUICE</b> (UNII: D2EVP827PJ)	
<b>ARCTOSTAPHYLOS UVA-URSI LEAF</b> (UNII: 3M5V3D1X36)	
<b>VACCINIUM MYRTILLUS ANTHOCYANOSIDES</b> (UNII: R911H793SU)	
<b>EUROPEAN ELDERBERRY JUICE</b> (UNII: Z4IFJ0AK1E)	
<b>LYCIUM BARBARUM FRUIT</b> (UNII: 930626MWDL)	
<b>ROSA CANINA FRUIT</b> (UNII: 3TNW8D08V3)	
<b>HIPPOPHAE RHAMNOIDES FRUIT</b> (UNII: AVL0R9111T)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>LECITHIN, SUNFLOWER</b> (UNII: 834K0WOS5G)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)	
<b>MAGNOLIA OFFICINALIS BARK</b> (UNII: 5M609NV974)	
<b>INDIAN FRANKINCENSE</b> (UNII: 4PW41QCO2M)	
<b>PANTHENOL</b> (UNII: WW9CM0067Z)	
<b>ALLANTOIN</b> (UNII: 344S277G0Z)	
<b>ROSA X DAMASCENA FLOWER</b> (UNII: JWB78P295A)	
<b>MAGNESIUM ASCORBYL PHOSPHATE</b> (UNII: 0R822556M5)	
<b>CHAMOMILE</b> (UNII: FGL3685T2X)	
<b>CALENDULA OFFICINALIS FLOWER</b> (UNII: P0M7O4Y7YD)	
<b>ROSA CANINA FRUIT OIL</b> (UNII: CR7307M3QZ)	
<b>POMEGRANATE SEED OIL</b> (UNII: 0UI45XV0T6)	



<b>WHITE TEA</b> (UNII: O0M3396E09)	
<b>ASPALATHUS LINEARIS WHOLE</b> (UNII: O17JQA1A9Z)	
<b>HIBISCUS SABDARIFFA FLOWER</b> (UNII: 45TGG6IU6M)	
<b>PHENYLETHYL ALCOHOL</b> (UNII: ML9LGA7468)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>GERANIOL</b> (UNII: L837108USY)	
<b>VANILLIN</b> (UNII: CHI530446X)	
<b>GERANIUM OIL, ALGERIAN TYPE</b> (UNII: 5Q1I94P4WG)	
<b>ORANGE OIL, COLD PRESSED</b> (UNII: AKN3KSD11B)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55560-0103-1	1 in 1 CARTON	03/01/2014	
1		80 mL 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 FINAL	part352	03/01/2014	

**Labeler** - Andalou naturals (011472720)

### Establishment

Name	Address	ID/FEI	Business Operations
Sun Deep Inc		189788201	MANUFACTURE(55560-0103)

Revised: 7/2019

Andalou naturals