

LAURA GELLER BEAUTY TUSCAN SUN SPACKLE SPF 30 PROTECTIVE UNDER MAKE-UP PRIMER MEDIUM - avobenzone, octinoxate, octisalate cream

Laura Geller Beauty, 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.

LAURA GELLER BEAUTY TUSCAN SUN SPACKLE SPF 30 PROTECTIVE UNDER MAKE-UP PRIMER MEDIUM

LAURA GELLER BEAUTY TUSCAN SUN SPACKLE SPF 30 PROTECTIVE UNDER MAKE-UP PRIMER MEDIUM

Active Ingredients

Avobenzone 3.00%

Octinoxate 7.50%

Octisalate 5.00%

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.

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 liberally 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 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 10 a.m. - 2 p.m.
- ○ wear long-sleeved shirts, pants, hats and sunglasses.
- Children under 6 months of age: Ask a doctor.

INACTIVE INGREDIENTS

Water (Aqua), Glycerin, Mica, Octyldodecyl Neopentanoate, Butylene Glycol, Cyclopentasiloxane, Titanium Dioxide (CI 77891), Dimethicone, Camellia Sinensis Leaf Extract, Ginkgo Biloba Leaf Extract, Aloe Barbadensis Leaf Extract, Hamamelis Virginia (Witch Hazel) Water, Centella Asiatica Extract, Lens Esculenta (Lentil) Seed Extract, Dimethiconol, Glyceryl Acrylate/Acrylic Acid Copolymer, PEG/PPG-18 Dimethicone, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, 1,2-Hexandiol, Decylene Glycol, Sodium Hydroxide, Disodium EDTA, Phenoxyethanol, Iron Oxides (CI 77491, CI 77492, CI 77499).

Other Information

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

Questions or comments?

Call Laura Gellar Beauty, LLC, 1 (800) MAKE UP4

LAURA GELLER BEAUTY TUSCAN SUN SPACKLE SPF 30 PROTECTIVE UNDER MAKE-UP PRIMER MEDIUM 59ml (51389-202-00)

SPACKLE® SPF 30 PROTECTIVE UNDER MAKE-UP PRIMER									
<p>DRUG FACTS</p> <table border="0"> <tr> <td>Active Ingredients</td> <td style="text-align: right;">Purpose</td> </tr> <tr> <td>Avobenzone 3.00%</td> <td>Sunscreen</td> </tr> <tr> <td>Octinoxate 7.50%</td> <td>Sunscreen</td> </tr> <tr> <td>Octisalate 5.00%</td> <td>Sunscreen</td> </tr> </table>	Active Ingredients	Purpose	Avobenzone 3.00%	Sunscreen	Octinoxate 7.50%	Sunscreen	Octisalate 5.00%	Sunscreen	<p>DIRECTIONS</p> <ul style="list-style-type: none"> • Apply liberally 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 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: <ul style="list-style-type: none"> • limit time in the sun, especially from 10 a.m. – 2 p.m. • wear long-sleeved shirts, pants, hats, and sunglasses. • Children under 6 months of age: Ask a doctor.
Active Ingredients	Purpose								
Avobenzone 3.00%	Sunscreen								
Octinoxate 7.50%	Sunscreen								
Octisalate 5.00%	Sunscreen								
<p>USES</p> <ul style="list-style-type: none"> • 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. 	<p>INACTIVE INGREDIENTS</p> <p>Water (Aqua), Glycerin, Mica, Octyldodecyl Neopentanoate, Butylene Glycol, Cyclopentasiloxane, Titanium Dioxide (CI 77891), Dimethicone, Camellia Sinensis Leaf Extract, Ginkgo Biloba Leaf Extract, Aloe Barbadensis Leaf Extract, Hamamelis Virginiana (Witch Hazel) Water, Centella Asiatica Extract, Lens Esculenta (Lentil) Seed Extract, Dimethiconol, Glyceryl Acrylate/Acrylic Acid Copolymer, PEG/PPG-18/18 Dimethicone, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, 1,2-Hexandiol, Decylene Glycol, Sodium Hydroxide, Disodium EDTA, Phenoxyethanol, Iron Oxides (CI 77491, CI 77492, CI 77499).</p>								
<p>WARNINGS</p> <p>For external use only.</p> <hr/> <p>Do not use on damaged or broken skin.</p> <hr/> <p>When using this product keep out of eyes. Rinse with water to remove.</p> <hr/> <p>Stop use and ask a doctor if rash occurs.</p> <hr/> <p>Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.</p>	<p>Other Information</p> <ul style="list-style-type: none"> • Protect the product in this container from excessive heat and direct sun. <p>Questions or comments? Call Laura Gellar Beauty, LLC, 1 (800) MAKE UP4</p>								

BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
GINKGO (UNII: 19FUJ2C58T)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
HAMAMELIS VIRGINIANA TOP WATER (UNII: NT00Y05A2V)	
CENTELLA ASIATICA (UNII: 7M867G6T1U)	
LENTIL (UNII: 6O38V6B52O)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
DECYLENE GLYCOL (UNII: S57M60M88)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51389-202-00	1 in 1 PACKAGE		
1		59 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/10/2014	

Labeler - Laura Geller Beauty, LLC (199474524)

Establishment

Name	Address	ID/FEI	Business Operations
MANA Products, Inc.		078870292	manufacture(51389-202)

Revised: 3/2014

Laura Geller Beauty, LLC