

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

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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 DEEP 59ml (51389-204-00)

SPACKLE® SPF 30 PROTECTIVE UNDER MAKE-UP PRIMER									
<p>DRUG FACTS</p> <table border="0"> <tr> <td style="text-align: left;">Active Ingredients</td> <td style="text-align: left;">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.
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Laura Geller Beauty Tuscan Sun Spackle SPF 30 Protective Under Make-Up Primer Deep

avobenzone, octinoxate, octisalate cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51389-204
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL	
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	50 mg in 1 mL	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
MICA (UNII: V8A1AW0880)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	

CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)
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)
FERROSO FERRIC OXIDE (UNII: XM0M87F357)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51389-204-00	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(51389-204)