

**LAURA GELLER SPACKLE BROAD SPECTRUM SPF 30 PROTECTIVE UNDER MAKE-UP PRIMER - 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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**LAURA GELLER spackle Broad Spectrum SPF 30 protective under make-up primer**

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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, 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 spackle Broad Spectrum SPF 30 protective under make-up primer 59ml (51389-210-00)**

## LAURA GELLER BEAUTY

Prime, perfect and protect!  
We've infused our beloved primer with Broad Spectrum SPF 30 to protect skin from the sun's aging rays while priming it to a flawless canvas for long wearing make-up application. The lightweight—never greasy!—texture glides on with a soft pearl finish for a glowing, healthy look. Formulated with good-for-skin antioxidants *Centella Asiatica*, *White Tea* and *Ginkgo Biloba Extracts*, toning *Witch Hazel* and *Aloe Leaf Extract* to soothe, Spackle® SPF 30 is your single solution for protected, primed and pretty, healthy skin.

### Spackle® SPF 30

#### Drug Facts

Active Ingredients	Purpose
Avobenzone 3.00%	Sunscreen
Octinoxate 7.50%	Sunscreen
Octisalate 5.00%	Sunscreen

#### Use

- 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.
- 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, Glycerin, Mica, Octyldodecyl Neopentanoate, Butylene Glycol, Cyclopentasiloxane, Titanium Dioxide (CI 77891), Dimethicone, Camellia Sinensis Leaf Extract, Ginkgo Biloba Leaf Extract, Aloe Barbadosensis Leaf Extract, Hamamelis Virginiana (Witch Hazel) Water, Centella Asiatica Extract, Lens Esculenta (Lentil) Seed Extract, Dimethiconol, Glyceryl Acrylate/Acrylic Acid Copolymer, PEG/PPG-12/18 Dimethicone, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, 1,2-Hexanediol, Decylene Glycol, Sodium Hydroxide, Disodium EDTA, Phenoxethanol, Iron Oxides (CI 77491, CI 77492, CI 77499).

## LAURA GELLER

### BEAUTY INGENUITY

spackle®  
Broad Spectrum  
SPF 30  
protective  
under make-up  
primer

Net Wt.  
2 oz./59 ml

#### Other Information

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

#### Questions or comments?

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

Made in USA

DIST. BY LAURA GELLER BEAUTY, LLC  
NY, NY 10022

Naritaweg 165, 1043 R W Amsterdam,

The Netherlands

[laurageller.com](http://laurageller.com)

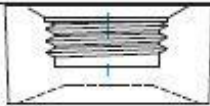
spackle®

SPF 30

protective  
under make-up  
primer

LAURA GELLER  
BEAUTY INGENUITY

Net Wt.  
2 oz./56 g/59 ml



**DIRECTIONS:**

Apply a thin layer of Spackle  
SPF 30. Follow with  
foundation.

*Active Ingredients...Purpose*  
Octinoxate...7.5%...Sunscreen  
Octisalate...5%...Sunscreen  
Avobenzone...3%...Sunscreen

*See carton for complete  
Drug Facts information*

**WARNING:** For external use only. Keep out of  
eyes, rinse with water to remove. Stop use  
and see a doctor if irritation  
develops and lasts.

**KEEP OUT OF REACH OF CHILDREN.**

Made in USA

DISTRIBUTED BY  
LAURA GELLER BEAUTY, LLC  
NEW YORK, NY 10022

EU Distribution  
Naritaweg 165, 1043 B W Amsterdam,  
The Netherlands

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



BACK

## LAURA GELLER SPACKLE BROAD SPECTRUM SPF 30 PROTECTIVE UNDER MAKE-UP PRIMER

avobenzone, octinoxate, octisalate cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51389-210
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: 0THF5PCI0R)	
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: S57M60MI88)	
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:51389-210-00	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	05/14/2014	

**Labeler** - Laura Geller Beauty, LLC (199474524)

## Establishment

Name	Address	ID/FEI	Business Operations
MANA Products, Inc.		078870292	manufacture(51389-210)