# COLOR CORRECTING SWIRL FOUNDATION BROAD SPECTRUM SPF 25 LIGHToctocrylene avobenzone octisalate cream LAURA GELLER MAKE UP INC.

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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# **Drug Facts**

# **Active Ingredients**

Octocrylene 5%

Avobenzone 3%

Octisalate 3%

# **Purpose**

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 generously 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.

# Other Information

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

# **Inactive Ingredients**

Isostearyl Neopentanoate, Isohexadecane, C12-15 Alkyl Benzoate, Butylene Glycol Cocoate, Titanium Dioxide, Hydrogenated Castor Oil, Polymethyl Methacrylate, Cetearyl Ethylhexanoate, Mica, Silica, Ceresin, Silica Dimethyl Silylate, Ascorbyl Tetraisopalmitate, Tocopheryl Acetate, PPG-15 Stearyl Ether, Pentaerythrityl Tetra-Di-T-Butyl Hydroxyhydrocinnamate, Caprylic/Capric Triglyceride, Isopropyl Myristate, Plankton Extract, Glycine Soja Oil (Glycine Soja (Soybean) Oil), Tribehenin, Retinyl Palmitate, Carthamus Tinctorius Seed Oil (Carthamus Tinctorius (Safflower) Seed Oil),Linoleic Acid, Ceramide 2, PEG-10 Rapeseed Sterol, Palmitoyl Oligopeptide

MAY CONTAIN: Titanium Dioxide, Iron Oxide, Iron Oxide, Ultramarines, Yellow 5 Lake, Yellow 6 Lake

# Questions?

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

# **Principal Display Panel**

LAURA GELLER

**BEAUTY INGENUITY** 

cc creme compact

color correcting swirl foundation

braod spectrum

**SPF 25** 

with sponge

LIGHT

Net Wt. 0.37 oz/10.5 g

# CC Crème Foundation Broad Spectrum SPF 25 - Light

# **Drug Facts**

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## Use

 Helps prevent sunburn.
 If used as directed with other sun protection measures (see <u>Directions</u>), 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

Isostearyl Neopentanoate, Isohexadecane, C12-15 Alkyl Benzoate, Butylene Glycol Cocoate, Titanium Dioxide, Hydrogenated Castor Oil, Polymethyl Methacrylate, Cetearyl Ethylhexanoate, Mica, Silica, Ceresin, Silica Dimethyl Silylate, Ascorbyl Tetraisopalmitate, Tocopheryl Acetate, PPG-15 Stearyl Ether, Pentaerythrityl Tetra-Di-T-Butyl Hydroxyhydrocinnamate, Caprylic/Capric Triglyceride, Isopropyl Myristate, Plankton Extract, Glycine Soja Oil (Glycine Soja (Soybean) Oil), Tribehenin, Retinyl Palmitate, Carthamus Tinctorius Seed Oil (Carthamus Tinctorius (Safflower) Seed Oil),

# LIGHT

# LAURA GELLER

# Drug Facts (continued)

Linoleic Acid, Ceramide 2, PEG-10 Rapeseed Sterol, Palmitoyl Oligopeptide MAY CONTAIN: Titanium Dioxide, Iron Oxide, Iron Oxide, Ultramarines, Yellow 5 Lake, Yellow 6 Lake

# Other Information

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

Questions? Call Laura Geller Beauty, LLC 1 (800) MAKE UP4 **BEAUTY INGENUITY** 

# cc crème compact

color correcting swirl foundation broad spectrum SPF 25

with sponge

LIGHT Net Wt. 0.37 oz./10.5 g

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

Made in Italy

Sponge: Made in Korea



www.laurageller.com

00-70393-02

FPO/UPC 849154001484

# COLOR CORRECTING SWIRL FOUNDATION BROAD SPECTRUM SPF 25 LIGHT

octocrylene avobenzone octisalate cream

<b>Product Information</b>	duct Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51389-119			
Route of Administration	TOPICAL					

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	5 g in 100 g		
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g		
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	3 g in 100 g		

Inactive Ingredients	
Ingredient Name	Strength
ISOSTEARYL NEO PENTANO ATE (UNII: 411THY156 Q)	
ISO HEXADECANE (UNII: 918 X10 UF1E)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
CETEARYL ETHYLHEXANO ATE (UNII: 9 M6 4UO 4C25)	
MICA (UNII: V8A1AW0880)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
CERESIN (UNII: Q1LS2UJO3A)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
ASCORBYL TETRAISOPALMITATE (UNII: 47143LT58A)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
<b>PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDRO XYPHENYL)PRO PIO NATE)</b> (UNII: 255PIF62MS)	
TRICAPRIN (UNII: O1PB8EU98M)	
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)	
SOYBEAN OIL (UNII: 241ATL177A)	
TRIBEHENIN (UNII: 8OC9U7TQZ0)	
VITAMIN A PALMITATE (UNII: 1D1K0 N0 VVC)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
LINOLEIC ACID (UNII: 9KJL21T0QJ)	
CERAMIDE 2 (UNII: C04977SRJ5)	
RAPESEED STEROL (UNII: B46B6DD20U)	
PALMITOYL OLIGOPEPTIDE (UNII: HO4ZT5S86C)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

F	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:51389-119-01	10.5 g in 1 CONTAINER				

# Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/02/2013	

# Labeler - LAURA GELLER MAKE UP INC. (199474524)

Revised: 5/2013 LAURA GELLER MAKE UP INC.