

**LAURA MERCIER FLAWLESS SKIN REPAIR DAY BROAD SPECTRUM SPF 15  
SUNSCREEN- avobenzone, octinoxate, oxybenzone cream  
Gurwitch Products, 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 Mercier Flawless Skin Repair Day Creme Broad Spectrum SPF 15 Sunscreen**

***Drug Facts***

***Active ingredients***

Avobenzone (0.80%)

Octinoxate (3.50%)

Oxybenzone (0.50%)

***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 swallowed, get medical help or contact a Poison Control Center right away.

***Directions***

- For sunscreen use:
- 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

**Other information**

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

**Inactive Ingredients**

Water, Sea Water, Glycerin, Polymethylsilsesquioxane, Trehalose, Dimethicone, Squalane, Butylene Glycol, Polyglyceryl-10 Isostearate, Dicaprylyl Carbonate, Cetearyl Alcohol, Beeswax, Vitis Vinifera (Grape) Seed Oil, Hydrolyzed Xylan, Argania Spinosa Kernel Oil, Camellia Sinensis Leaf powder, Phenoxyethanol, Polyacrylamide, Carbomer, C13-14 Isoparaf n, Tocopheryl Acetate, PVM/MA Decadiene Crosspolymer, Disodium EDTA, Potassium Hydroxide, Pyrus Cydonia Seed Extract, Laureth-7, Glycosphingolipids, Glycerylamidoethyl Methacrylate/Stearyl Methacrylate Copolymer, Sodium Polyacrylate, Synthetic Fluorphlogopite, Aluminum Hydroxide, Hydrolyzed Collagen, Ethyl Oleate, Dipotassium Glycyrrhizate, Caprylic/Capric Triglyceride, Zinc Oxide, Tocopherol, Yeast Extract, Yeast Beta-Glucan, Sodium Ascorbyl Phosphate, Hydrogen Dimethicone, Oligopeptide-6, Tripeptide-3, Hexapeptide-3, Linalool.

**Questions or comments?**

Call 1-888-637-2437, M – F 9am – 5pm CST.

**Package Labeling:**

indicate obligatory manufacturing batch number

**3 DAY CREME  
OZ. CARTON - USA**

**Drug Facts (continued)**

**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 swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

**Drug Facts (continued)**

**For sunscreen use:**

- 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

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

**REPAIR DAY CRÈME BROAD SPECTRUM SPF 15 SUNSCREEN**  
This advanced anti-aging daily moisturizer helps repair skin for a smoother, radiant, younger looking complexion while providing environmental protection. Repair Day Crème Broad Spectrum SPF 15 Sunscreen helps:  
- Prevent and diminish the appearance of fine lines and wrinkles with Green Tea Extract  
- Smooth skin texture with Hydrolyzed Xylan and boost hydration with Argan Oil  
- Repair the lipid barrier with Deep Sea Water minerals.  
**Directions for use:** Apply every morning to cleansed skin after a Flawless Skin serum.  
DERMATOLOGIST TESTED. NON-COMEDOGENIC.

**Drug Facts**

Active ingredients	Purpose
Azelaic Acid (1.00%)	Sunscreen
Octinoxate (3.50%)	Sunscreen
Oxybenzone (0.50%)	Sunscreen

**Drug Facts (continued)**

**Inactive Ingredients** Water, Sea Water, Glycerin, Polymethylsilsesquioxane, Trehalose, Dimethicone, Squalane, Butylene Glycol, Polyglyceryl-10 Isostearate, Dicaprylyl Carbonate, Cetearyl Alcohol, Beeswax, Vitis Vinifera (Grape) Seed Oil, Hydrolyzed Xylan, Argania Spinosa Kernel Oil, Camellia Sinensis Leaf powder, Phenoxyethanol, Polyacrylamide, Carbomer, C13-14 Isoparaf n, Tocopheryl Acetate, PVM/MA Decadiene Crosspolymer, Disodium EDTA, Potassium Hydroxide, Pyrus Cydonia Seed Extract, Laureth-7, Glycosphingolipids, Glycerylamidoethyl Methacrylate/Stearyl Methacrylate Copolymer, Sodium Polyacrylate, Synthetic Fluorphlogopite, Aluminum Hydroxide, Hydrolyzed Collagen, Ethyl Oleate, Dipotassium Glycyrrhizate, Caprylic/Capric Triglyceride, Zinc Oxide, Tocopherol, Yeast Extract, Yeast Beta-Glucan, Sodium Ascorbyl Phosphate, Hydrogen Dimethicone, Oligopeptide-6, Tripeptide-3, Hexapeptide-3, Linalool.

**Questions or comments?**  
Call 1-888-637-2437, M – F 9am – 5pm CST.

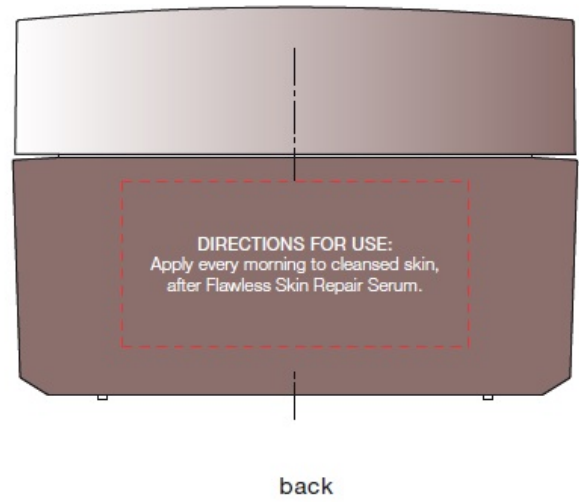
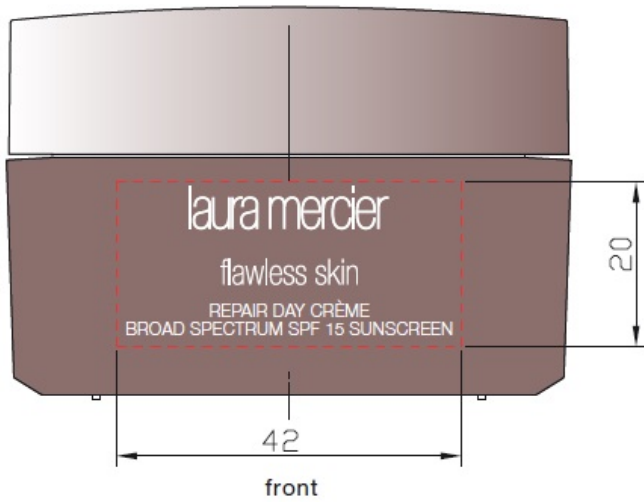
B8553

ICF2640C

laura mercier  
flawless skin  
REPAIR DAY CRÈME  
BROAD SPECTRUM SPF 15 SUNSCREEN  
50 g / NET WT. 1.7 OZ.

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REPAIR DAY CRÈME  
BROAD SPECTRUM SPF 15 SUNSCREEN  
50 g / NET WT. 1.7 OZ.

Front panel of unit carton



Rendering



bottom label - 1 3/8" diameter

TOP



bottom label - 1 3/8" diameter

TOP BACK



bottom label - 1 3/8" diameter

BOTTOM

## LAURA MERCIER FLAWLESS SKIN REPAIR DAY BROAD SPECTRUM SPF 15 SUNSCREEN

avobenzone, octinoxate, oxybenzone cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65342-7500
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	8 mg in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	35 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	5 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
GLYCERIN (UNII: PDC6A3C0OX)	
TREHALOSE (UNII: B8WCK70T7I)	
DIMETHICONE (UNII: 92RU3N3Y1O)	

SQUALANE (UNII: GW89575KF9)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
YELLOW WAX (UNII: 2ZA36H0S2V)
GRAPE SEED OIL (UNII: 930MLC8XGG)
ARGAN OIL (UNII: 4V59G5UW9X)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)
CYDONIA OBLONGA SEED (UNII: JXU526QH1V)
LAURETH-7 (UNII: Z95S6G8201)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
ETHYL OLEATE (UNII: Z2Z439864Y)
GLYCYRRHIZINATE DIPO TASSIUM (UNII: CA2Y0FE3FX)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
ZINC OXIDE (UNII: SOI2LOH54Z)
TOCOPHEROL (UNII: R0ZB2556P8)
YEAST, UNSPECIFIED (UNII: 3NY3SM6B8U)
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)
ACETYL HEXAPEPTIDE-8 (UNII: L4EL31FWIL)
LINALOOL, (+/-)- (UNII: D81QY6I88E)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65342-7500-1	1 in 1 CARTON	01/05/2017	
1		50 mL in 1 JAR; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/05/2017	

**Labeler** - Gurwitch Products, LLC (884875246)