

LAURA MERCIER TINTED MOISTURIZER - ILLUMINATING BROAD SPECTRUM SPF 20 SUNSCREEN - BRONZE RADIANCE- avobenzone, octinoxate cream

Gurwitch Products, L.L.C.

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 Mercier Tinted Moisturizer - Illuminating Broad Spectrum SPF 20 Sunscreen - Bronze Radiance

Drug Facts

Active Ingredient

Avobenzone (2.0%), Octinoxate (7.5%)

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, dimethicone, cetearyl alcohol, hydrogenated polyisobutene, xylitylglucoside, PEG-40 castor oil, polyglyceryl-4 isostearate, cyclopentasiloxane, potassium cetyl phosphate, hexyl laurate, anhydroxylitol, mica, tocopheryl acetate, cetyl PEG/PPG-10/1 dimethicone, xylitol, polysorbate 60, phenoxyethanol, butylene glycol, tribhenin, sodium dehydroacetate, sodium hyaluronate, allantoin, camellia sinensis leaf extract, copper gluconate, carbomer, hydrogenated olive oil, butyrospermum parkii (shea) butter, aminomethyl propanol, tetrasodium EDTA, magnesium aluminum silicate, sodium ascorbate, dipotassium glycyrrhizate, may contain: titanium dioxide, iron oxides, copper powder.

Questions or comments?

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

Product Labels



laura mercier[®]
 DIST. GURWITCH PRODUCTS, L.L.C.
 PO BOX 7568,
 NEW YORK, NY 10150
 MADE IN USA lauramercier.com 001



Drug Facts (continued)

parkii (shea) butter, aminomethyl propanol, tetrasodium EDTA, magnesium aluminum silicate, sodium ascorbate, dipotassium glycyrrhizate. may contain: titanium dioxide, iron oxides, copper powder.

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

1.7 FL. OZ./50 ml

tinted moisturizer • illuminating
 BROAD SPECTRUM SPF 20 SUNSCREEN
 LIGHTWEIGHT FLAWLESS COVERAGE
 laura mercier

BRONZE RADIANCE

Drug Facts

Active ingredients

Avobenzone 2.0%
 Octinoxate 7.5%

Purpose

Sunscreen
 Sunscreen

Uses • helps prevent sunburn

Drug Facts (continued)

• 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.

Drug Facts (continued)

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

Drug Facts (continued)

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, dimethicone, cetearyl alcohol, hydrogenated polyisobutene, xylitylglucoside, PEG-40 castor oil, polyglyceryl-4 isostearate, cyclopentasiloxane, potassium cetyl phosphate, hexyl laurate, anhydroxylitol, mica, tocopheryl acetate, cetyl PEG/PPG-10/1 dimethicone, xylitol, polysorbate 60, phenoxyethanol, butylene glycol, tribehenin, sodium dehydroacetate, sodium hyaluronate, allantoin, camellia sinensis leaf extract, copper gluconate, carbomer, hydrogenated olive oil, butyrospermum

tinted moisturizer • illuminating

BROAD SPECTRUM SPF 20 SUNSCREEN
LIGHTWEIGHT FLAWLESS COVERAGE

laura mercier

LAURA MERCIER'S TINTED MOISTURIZER - ILLUMINATING IS A PERFECT BLEND OF SKINCARE AND MAKEUP. IT HYDRATES SKIN WITH BARELY-THERE COLOUR FOR A LUMINOUS RADIANT GLOW, THIS LIGHTWEIGHT FORMULA PROVIDES IDEAL PROTECTION FROM THE SUN'S HARMFUL AND DAMAGING RAYS WITH BROAD SPECTRUM UVB/UVA SPF 20 SUNSCREEN. PERFECT FOR ALL SKIN TYPES.

The Technique: Apply to clean skin with Laura's foundation sponge or with fingertips. Blend with foundation for an instant boost. DERMATOLOGIST TESTED. NON COMEDOGENIC.

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.

Active ingredients: Avobenzone: 2.0%, Octinoxate: 7.5%

laura mercier®

DIST. GURWITCH PRODUCTS, L.L.C.
PO BOX 7568, NEW YORK, NY 10150

MADE IN USA

lauramercier.com

001

1.7 FL.OZ./50 ml

BRONZE RADIANCE

LAURA MERCIER TINTED MOISTURIZER - ILLUMINATING BROAD SPECTRUM SPF 20 SUNSCREEN - BRONZE RADIANCE

avobenzone, octinoxate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65342-1394
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	20 mg in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	

XYLITYLGLUCOSIDE (UNII: O0IEZ166FB)
PEG-40 CASTOR OIL (UNII: 4ERD2076EF)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)
HEXYL LAURATE (UNII: 4CG9F9W01Q)
ANHYDROXYLITOL (UNII: 8XWR7NN42F)
MICA (UNII: V8A1AW0880)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
XYLITOL (UNII: VCQ006KQ1E)
POLYSORBATE 60 (UNII: CAL22UVI4M)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
SODIUM DEHYDROACETATE (UNII: 8W46YN971G)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
ALLANTOIN (UNII: 344S277G0Z)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
HYDROGENATED OLIVE OIL (UNII: 53839415GI)
SHEANUT OIL (UNII: O88E196QRF)
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)
EDETATE SODIUM (UNII: MP1J8420LU)
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)
SODIUM ASCORBATE (UNII: S033EH8359)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
COPPER (UNII: 789U1901C5)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65342-1394-0	50 mL in 1 TUBE; 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	11/29/2010	

Labeler - Gurwitch Products, L.L.C. (884875246)

Establishment

Name	Address	ID/FEI	Business Operations
Atlantis Laboratories, Inc.		194673984	manufacture(65342-1394)

Establishment

Name	Address	ID/FEI	Business Operations
Beauty Manufacturing Solutions Corp.		783200723	pack(65342-1394)

