

**LAURA GELLER BEAUTY SUN KISSED COLOR LIP BALM TRIO BROAD SPECTRUM
SPF 15 PINK - CORAL - BERRY- octisalate, avobenzone, octinoxate, octocrylene
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.

**LAURA GELLER BEAUTY SUN KISSED COLOR LIP BALM TRIO BROAD SPECTRUM
SPF 15 Pink - Coral - Berry**

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SPF 15 Pink - Coral - Berry**

Active Ingredients

Octisalate 5%
Avobenzone 2.5%
Octinoxate 2%
Octocrylene 1.5%

Purpose

Sunscreen

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

Berry: Caprylic/Capric Triglyceride, C12-15 Alkyl Benzoate, Polyethylene, Pentaerythrityl Tetraistearate, Mica, Microcrystalline Wax, Helianthus Annuus (Sunflower) Seed Wax, Silica Silylate, Stearalkonium Bentonite, Dicalcium Phosphate, Tocopheryl Acetate, Propylene Carbonate, Ethyl Vanillin, Pentaerythrityl Tetra-Di-T-Butyl Hydroxyhydrocinnamate, 1,2-Hexanediol, Caprylyl Glycol, Mangifera Indica (Mango) Seed Butter, Ethylhexyl Cocoate, Cocos Nucifera (Coconut) Oil. **May Contain:** Titanium Dioxide, Red 7 Lake, Iron Oxides, Blue 1 Lake **Coral, Pink:** Caprylic/Capric Triglyceride, C12-15 Alkyl Benzoate, Polyethylene, Pentaerythrityl Tetraistearate, Mica, Microcrystalline Wax, Helianthus Annuus (Sunflower) Seed Wax, Dicalcium Phosphate, Silica Silylate, Stearalkonium Bentonite, Tocopheryl Acetate, Propylene Carbonate, Ethyl Vanillin, Pentaerythrityl Tetra-Di-T-Butyl Hydroxyhydrocinnamate, 1,2-Hexanediol, Caprylyl Glycol, Mangifera Indica (Mango) Seed Butter, Ethylhexyl Cocoate, Cocos Nucifera (Coconut) Oil. **May Contain:** Titanium Dioxide, Red 28 Lake, Red 6

Other Information

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

Questions or comments?

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

LAURA GELLER BEAUTY SUN KISSED COLOR LIP BALM TRIO BROAD SPECTRUM SPF 15 Pink - Coral - Berry (51389-122-03)

LAURA GELLER Sun Kissed Lip Balm broad spectrum SPF 15 PINK 2.5g (51389-123-01)

LAURA GELLER Sun Kissed Lip Balm broad spectrum SPF 15 CORAL 2.5g (51389-124-01)

LAURA GELLER Sun Kissed Lip Balm broad spectrum SPF 15 BERRY 2.5g (51389-125-01)





FRONT



BACK

LAURA GELLER BEAUTY

Infused with *Mango Butter, Vitamin E and Coconut Oil*, this trio of SPF 15 nourishing lip balms delivers a sheer wash of moisturizing color for a fresh, natural look.

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

Berry: Caprylic/Capric Triglyceride, C12-15 Alkyl Benzoate, Polyethylene, Pentaerythrityl Tetraistearate, Mica, Microcrystalline Wax, Helianthus Annuus (Sunflower) Seed Wax, Silica Silylate, Stearalkonium Bentonite, Dicalcium Phosphate, Tocopheryl Acetate, Propylene Carbonate, Ethyl Vanillin, Pentaerythrityl Tetra-Di-T-Butyl Hydroxyhydrocinnamate, 1,2-Hexanediol, Caprylyl Glycol, Mangifera Indica (Mango) Seed Butter, Ethylhexyl Cocoate, Cocos Nucifera (Coconut) Oil **May Contain:** Titanium Dioxide, Red 7 Lake, Iron Oxides, Blue 1 Lake **Coral, Pink:** Caprylic/Capric Triglyceride, C12-15 Alkyl Benzoate, Polyethylene, Pentaerythrityl Tetraistearate, Mica, Microcrystalline Wax, Helianthus Annuus (Sunflower) Seed Wax, Dicalcium Phosphate, Silica Silylate, Stearalkonium Bentonite, Tocopheryl Acetate, Propylene Carbonate, Ethyl Vanillin, Pentaerythrityl Tetra-Di-T-Butyl Hydroxyhydrocinnamate, 1,2-Hexanediol, Caprylyl Glycol, Mangifera Indica (Mango) Seed Butter, Ethylhexyl Cocoate, Cocos Nucifera (Coconut) Oil **May Contain:** Titanium Dioxide, Red 28 Lake, Red 6

Other Information

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

Questions or comments?

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

DISTRIBUTED BY LAURA GELLER BEAUTY, LLC NEW YORK, NY 10022
EU Distribution – Naritaweg 165, 1043 B W Amsterdam, The Netherlands
www.laurageller.com

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.

DRUG FACTS

Active Ingredients	Purpose
Octisalate 5%	Sunscreen
Avobenzone 2.5%	Sunscreen
Octinoxate 2%	Sunscreen
Octocrylene 1.5%	Sunscreen

LAURA GELLER
BEAUTY

SUN KISSED COLOR LIP BALM TRIO



BROAD SPECTRUM SPF 15
Pink • Coral • Berry
Net Wt 0.09 oz./2.5 g

Sun Kissed Color Lip Balm SPF 15—Berry, Coral, Pink
Ingredients: Caprylic/Capric Triglyceride, C12-15 Alkyl Benzoate, Polyethylene, Pentaerythrityl Tetraistearate, Mica, Cera Microcrystallina (Microcrystalline Wax), Helianthus Annuus Seed Cera (Helianthus Annuus (Sunflower) Seed Wax), Dicalcium Phosphate, Silica Silylate, Stearalkonium Bentonite, Tocopheryl Acetate, Propylene Carbonate, Ethyl Vanillin, Pentaerythrityl Tetra-Di-T-Butyl Hydroxyhydrocinnamate, 1,2-Hexanediol, Caprylyl Glycol, Mangifera Indica Seed Butter (Mangifera Indica (Mango) Seed Butter), Ethylhexyl Cocoate, Cocos Nucifera Oil (Cocos Nucifera (Coconut) Oil) **May Contain:** CI 77891 (Titanium Dioxide), CI 77491 (Iron Oxides), CI 15850 (Red 7 Lake), CI 45410 (Red 28 Lake), CI 19140 (Yellow 5 Lake), CI 15850 (Red 6), CI 77492 (Iron Oxides), CI 42090 (Blue 1 Lake)
Made in Italy

LAURA GELLER BEAUTY SUN KISSED COLOR LIP BALM TRIO BROAD SPECTRUM SPF 15 PINK - CORAL - BERRY

octisalate, avobenzone, octinoxate, octocrylene kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51389-122
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51389-122-03	1 in 1 KIT; Type 1: Convenience Kit of Co-Package	12/09/2013	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	2.5 g
Part 2	1 TUBE	2.5 g
Part 3	1 TUBE	2.5 g

Part 1 of 3

LAURA GELLER SUN KISSED LIP BALM BROAD SPECTRUM SPF 15 PINK

octisalate, avobenzone, octinoxate, octocrylene lipstick

Product Information

Item Code (Source) NDC:51389-123

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 g in 100 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2.5 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	1.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
PENTAERYTHRITYL TETRAISO STEARATE (UNII: 9D7IK5483F)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
ETHYL VANILLIN (UNII: YC9ST449YJ)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
MANGIFERA INDICA SEED BUTTER (UNII: 4OXD9M35X2)	
ETHYLHEXYL COCOATE (UNII: IIMPW273QS)	
COCONUT OIL (UNII: Q9L0O73W7L)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
D&C RED NO. 6 (UNII: 481744A14O)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51389-123-01	1 in 1 PACKAGE		

1	2.5 g in 1 TUBE; Type 0: Not a Combination Product	
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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/06/2013	

Part 2 of 3

LAURA GELLER SUN KISSED LIP BALM BROAD SPECTRUM SPF 15 CORAL

octisalate, avobenzone, octinoxate, octocrylene lipstick

Product Information

Item Code (Source)	NDC:51389-124
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2.5 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	1.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
PENTAERYTHRITYL TETRAISO STEARATE (UNII: 9D7IK5483F)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
ETHYL VANILLIN (UNII: YC9ST449YJ)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
MANGIFERA INDICA SEED BUTTER (UNII: 4OXD9M35X2)	
ETHYLHEXYL COCOATE (UNII: IIMPW273QS)	
COCONUT OIL (UNII: Q9L0O73W7L)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

D&C RED NO. 28 (UNII: 767IP0Y5NH)

D&C RED NO. 6 (UNII: 481744A14O)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51389-124-01	1 in 1 PACKAGE		
1		2.5 g 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	12/06/2013	

Part 3 of 3

LAURA GELLER SUN KISSED LIP BALM BROAD SPECTRUM SPF 15 BERRY

octisalate, avobenzone, octinoxate, octocrylene lipstick

Product Information

Item Code (Source)	NDC:51389-125
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2.5 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	1.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
PENTAERYTHRITYL TETRAISO STEARATE (UNII: 9D7IK5483F)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
ETHYL VANILLIN (UNII: YC9ST449YJ)	

PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
MANGIFERA INDICA SEED BUTTER (UNII: 40XD9M35X2)	
ETHYLHEXYL COCOATE (UNII: IIMPW273QS)	
COCONUT OIL (UNII: Q9L0O73W7L)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51389-125-01	1 in 1 PACKAGE		
1		2.5 g 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	12/06/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/09/2013	

Labeler - LAURA GELLER MAKE UP INC. (199474524)

Establishment

Name	Address	ID/FEI	Business Operations
Gotha Cosmetics SRL		378071679	manufacture(51389-125, 51389-124, 51389-123, 51389-122)

Revised: 12/2019

LAURA GELLER MAKE UP INC.