

MARIO BADESCU SPF 17- avobenzone, octinoxate, octocrylene lotion
Bentley Laboratories 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.

Bentley Mario Badescu - 135

Drug Facts

Active ingredients

Avobenzone 2.0%

Octinoxate 5%

Octocrylene 6%

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 aging caused by the sun.

Warnings

For external use only.

Do not use on damaged or broken skin.

Stop use and ask a doctor if rash occurs.

When using this product keep out of eyes. Rinse with water to remove

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
- children under 6 months: Ask a doctor

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.

Inactive ingredients

Aqua (Water, Eau), Dimethicone, Cetearyl Alcohol, Aluminum Starch Octenylsuccinate, Glycerin, PPG-2 Myristyl Ether Propionate, Ethylhexyl Methoxycrylene, C12-15 Alkyl Benzoate, Cetareth-20, Sorbitan Oleate, Aloe Barbadensis Leaf Juice, Styrene/Acrylates Copolymer, PEG-100 Stearate, Carbomer, Tetrasodium Glutamate Diacetate, Ethylhexylglycerin, PEG-8 Laurate, Sodium Hydroxide, Caprylyl Glycol, Phenoxyethanol

Other information

Protect this product from excessive heat and direct sun.

Questions or comments?

Call 1-800-223-3728 M - F 9 a.m. - 5 p.m. EST or visit mariobadescu.com

Mario Badescu Oil Free Moisturizer SPF 17 product label

MARIO

BADESCU

SKIN CARE

Established 1967

MB

OIL FREE

MOISTURIZER

BROAD SPECTRUM

SPF 17 SUNSCREEN

SKIN TYPES - C, O, S,

1 fl oz (29 ml)

Made in the USA. 71849-J001

CRUELTY FREE | PARABEN FREE

Mario Badescu Skin Care, New York, NY • (800) BADESCU

Leceur Plaza 1 Salford M50 3UB, UK

order online at mariobadescu.com

**MARIO
BADESCU**
SKIN CARE
Established 1967
MB

SKIN
TYPES
C, O, S

**OIL FREE
MOISTURIZER**
BROAD SPECTRUM
SPF 17 SUNSCREEN

1 fl.oz. e (29 ml)

Moisturize oily, congested, or problem skin without clogging pores. This fast-absorbing formulation sinks in quickly to deliver lightweight hydration and broad spectrum sun protection.

Store in a cool, dry place. Made in USA. 71850-S001
CRUELTY FREE | PARABEN FREE
Mario Badescu Skin Care, New York, NY • (800) BADESCU
Leicester Plaza 1 Salford, M50 3UB, UK

order online at mariobadescu.com

Drug Facts

Active ingredients: Purpose:
Octocrylene 6%, Octinoxate 5%,
Avobenzone 2%, Sunscreen

FOR DRUG FACTS, LEFT HERE

Back

Drug Facts (continued)

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Warnings: For external use only. Do not use on damaged or broken skin. Stop use and ask a doctor if rash occurs. When using this product keep out of eyes. Rinse with water to remove. 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 • children under 6 months: Ask a doctor • **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.

Base

Drug Facts (continued)

Inactive ingredients: Aqua (Water, Eau), Dimethicone, Cetearyl Alcohol, Aluminum Starch Octenylsuccinate, Glycerin, PPG-2 Myristyl Ether Propionate, Ethylhexyl Methoxycrylene, C12-15 Alkyl Benzoate, Cetearth-20, Sorbitan Oleate, Aloe Barbadensis Leaf Juice, Styrene/Acrylates Copolymer, PEG-100 Stearate, Carbomer, Tetrasodium Glutamate Diacetate, Ethylhexylglycerin, PEG-8 Laurate, Sodium Hydroxide, Caprylyl Glycol, Phenoxyethanol

Other information: Protect this product from excessive heat and direct sun.

Questions or comments?: Call 1-800-223-3728 M – F 9 a.m.–5 p.m. EST or visit mariobadescu.com

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MARIO BADESCU SPF 17

avobenzone, octinoxate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54111-135
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1.0 g in 29 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2.5 g in 29 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	3.0 g in 29 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
GLYCERIN (UNII: PDC6A3C0OX)	
PPG-2 MYRISTYL ETHER PROPIONATE (UNII: 88R97D8U8A)	
ETHYLHEXYL METHOXYCRYLENE (UNII: S3KFG6Q5X8)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
SORBITAN MONOLEATE (UNII: 06XEA2VD56)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
STYRENE/ACRYLAMIDE COPOLYMER (MW 500000) (UNII: 5Z4DPO246A)	
PEG-100 STEARATE (UNII: YD01N1999R)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PEG-8 LAURATE (UNII: 762O8IWA10)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54111-135-51	29 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/01/2017	
2	NDC:54111-135-50	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/01/2017	

