

TO SAVE FACE SPF 30 PLUS FACIAL SUNSCREEN- avobenzone, octocrylene, oxybenzone, phenylbenzimidazole sulfonic acid cream

Mecca Brands Pty Ltd

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.

Drug Facts

Active Ingredients

Avobenzone 1%, Octocrylene 5%, Oxybenzone 1.5%, Phenylbenzimidazole sulfonic 2%

Purpose

Sunscreen

Uses

- Helps prevent sunburn
- Higher SPF gives more sun protection
- 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

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown to help only prevent sunburn, not skin cancer or early skin aging.

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 or irritation develops and lasts.

Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally and evenly to face and neck 15 minutes before sun exposure and as needed
- Reapply at least every 2 hours
- Use a water resistant sunscreen if swimming or sweating
- Reapply as needed or after towel drying, swimming, or sweating
- May be worn alone or under makeup
- 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 sun, especially from 10am-2pm
 - Wear long-sleeve shirts, pants, hats and sunglasses
- Children under 6 months of age: ask a doctor

Other Information

- Sun alert: Limiting sun exposure, wearing protective clothing and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.
- Protect this product from excessive heat and direct sun
- Store below 30 degrees C/86 degrees F

Inactive Ingredients

Hyaluronic acid, Parabens, Phenoxyethanol, Punica granatum (Pomegranate) Fruit Extract, Tocopherol (Vitamin E)

Questions or comments?

In Australia at www.mecca.com.au

In the USA at J Crew customer relations 24 hours, 7 days a week at +1 434 385 5575

SUN SERIES

TO SAVE FACE

SPF30+ FACIAL SUNSCREEN

MECCA COSMETICA

WEIGHTLESS HYDRATING FORMULA

UVA and UVB PROTECTION

PERFECT MAKEUP BASE

NET WT 3.53 OZ. (100G)

SUN SERIES

TO SAVE FACE
SPF30+ FACIAL SUNSCREEN

**MECCA
COSMETICA**

WEIGHTLESS HYDRATING FORMULA
UVA & UVB PROTECTION
PERFECT MAKEUP BASE

AUST L 144082
1000E3.52FL.OZ

NET WT 3.53 OZ. (100g)

Drug Facts

Active Ingredients

Avoberzone 1%, Octocrylene 5%,
Oxybenzone 1.5%, Phenylbenzimidazole
sulfonic 2%

Purpose

Sunscreen

Uses

- Helps prevent sunburn
- Higher SPF gives more sun protection
- Provides high protection against 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

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown to help only prevent sunburn, not skin cancer or early skin aging.

For external use only
Do not use



When using this product keep out of eyes.
Rinse with water to remove.
Stop use and ask a doctor if rash or irritation develops and lasts.
Keep out of reach of children.
If swallowed get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally and evenly to face and neck 15 minutes before sun exposure and as needed
- Reapply at least every 2 hours
- Use a water resistant sunscreen if swimming or sweating
- Reapply as needed or after towel drying, swimming, or sweating
- May be worn alone or under makeup
- **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 10am-2pm
 - Wear long-sleeve shirts, pants, hats and sunglasses
 - Children under 6 months of age: ask a doctor

Other Information

- Sun alert: Limiting sun exposure, wearing protective clothing and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.
- Protect this product from excessive heat and direct sun
- Store below 30°C/86°F

Inactive Ingredients Hyaluronic acid, Parabens, Phenoxyethanol, Punica granatum (Pomegranate) Fruit Extract, Tocopherol (Vitamin E)

Questions or comments?

In Australia at www.mecca.com.au
In the USA at J Crew customer relations
24 hours, 7 days a week at: +1 434 385 5775

TO SAVE FACE SPF 30 PLUS FACIAL SUNSCREEN

avobenzone, octocrylene, oxybenzone, phenylbenzimidazole sulfonic acid cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69505-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1 g in 100 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	1.5 g in 100 g
ENSULIZOLE (UNII: 9YQ9D11W42) (ENSULIZOLE - UNII:9YQ9D11W42)	ENSULIZOLE	2 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	5 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
HYALURONIC ACID (UNII: S270N0TRQY)	
PHENOXYETHANOL (UNII: H1E492ZZ3T)	
POMEGRANATE (UNII: 56687D1Z4D)	
TOCOPHEROL (UNII: R0ZB2556P8)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69505-001-01	1 in 1 CARTON		
1		100 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/29/2014	

Labeler - Mecca Brands Pty Ltd (890708373)

Establishment			
Name	Address	ID/FEI	Business Operations
Delta Laboratories Pty Limited		751231564	manufacture(69505-001)