

**FLORMAR BB SHEER TINTED BEAUTY SUNSCREEN BROAD SPECTRUM SPF 15 01
LIGHT- octinoxate cream**

Kosan Kozmetik Sanayi ve Ticaret A.S.

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.

flormar BB Cream Sheer Tinted Beauty Sunscreen Broad Spectrum SPF 15 01 Light

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Active ingredient

Octinoxate 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

- Wear alone or under foundation.
- Shake well before use.
- Apply liberally 15 minutes before sun exposure.
- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.
- **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.
- Keep the product cool.
- After use, close the tube properly with cap.

Inactive ingredients

water, cyclopentasiloxane, butylene glycol, ethylhexyl methoxycinnamate, polysilicone-11, cetyl PEG/PPG-10/1 dimethicone, dimethicone, PEG-10 dimethicone, trimethylsiloxysilicate, disteardimonium hectorite, glycerin, SD alcohol 40-B, polymethylsilsesquioxane, phenoxyethanol, methy methacrylate cross-polymer, sodium chloride, fragrance, sodium PCA, ethylhexylglycerin, urea, triethoxycaprylylsilane, algae extract, laureth-12, soluble collagen, aluminum hydroxide, trehalose, leuconostoc/radish root ferment filtrate, polyquaternium-51, sodium hyaluronate, chlorphenesin, propylene glycol, fig (Ficus carica) fruit extract, cotton (Gossypium hirsutum) seed extract, linseed (Linum usitatissimum) seed extract, sodium dehydroacetate, caprylyl glycol, hexyl cinnamal, benzyl salicylate, butylphenyl methylpropional, alpha-isomethyl ionone, linalool.
may contain: titanium dioxide, iron oxides.

**flormar BB Cream Sheer Tinted Beauty Sunscreen Broad Spectrum SPF 15 01 Light 40ml
(61722-001-00)**



BB Cream

Sheer Tinted
Beauty Sunscreen
Broad Spectrum SPF 15

SPF 15

1.3 fl oz (40 ml)

Drug Facts

| Active ingredient | Purpose |
|-------------------|-----------|
| Octinoxate 5% | 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

- Wear alone or under foundation.
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- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.
- **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.
- Keep the product cool.
- After use, close the tube properly with cap.

Inactive ingredients

water, cyclopentasiloxane, butylene glycol, ethylhexyl methoxycinnamate, polysilicone-11, cetyl PEG/PPG-10/1 dimethicone, dimethicone, PEG-10 dimethicone, trimethylsiloxysilicate, disteardimonium hectorite, glycerin, SD alcohol 40-8, polymethylsilsesquioxane, phenoxyethanol, methyl methacrylate cross-polymer, sodium chloride, fragrance, sodium PCA, ethylhexyl glycerin, urea, triethoxycaprylylsilane, algae extract, laureth-12, soluble collagen, aluminum hydroxide, trehalose, leuconostoc/radish root ferment filtrate, polyquaternium-51, sodium hyaluronate, chlorphenesin, propylene glycol, fig (Ficus carica) fruit extract, cotton (Gossypium hirsutum) seed extract, linseed (Linum usitatissimum) seed extract, sodium dehydroacetate, caprylyl glycol, hexyl cinnamal, benzyl salicylate, butylphenyl methylpropional, alpha-isomethyl ionone, Inalcol, may contain: titanium dioxide, iron oxides.

Kosan Kozmetik Sanayi ve
Ticaret A.S., Gebze Organize
Sanayi Bölgesi
İnsan Dede Cad,900,SK NO:133
Gebze, Kocaeli 41480
Turkey

Made in Turkey

To report a serious adverse
event contact (917) 768-7350.



www.flormar.com
info@flormar.com.de
ITEM: 1097.04

Beauty Cream with
moisturizers for
natural effect.
Wear alone or
under foundation.
Shake well before use.

This Unit Not Labeled For Retail Sale
THIS UNIT IS PACKAGED IN AN OUTER CONTAINER.
PLEASE SEE OUTER CONTAINER FOR COMPLETE
DRUG FACTS INFORMATION.



BB Cream

Sheer Tinted
Beauty Sunscreen
Broad Spectrum SPF 15

SPF 15

1.3 fl oz (40 ml)

n

Active ingredient: Octinoxate 5%

Warnings:

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Kosan Kozmetik Sanayi ve Ticaret A.S.,
Gebze Organize Sanayi Bolgesi

Made in Turkey

www.flormar.com

To report a serious adverse event contact
(917) 768-7350.



FLORMAR BB SHEER TINTED BEAUTY SUNSCREEN BROAD SPECTRUM SPF 15 01 LIGHT

octinoxate cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:61722-001

Route of Administration TOPICAL

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 50 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| WATER (UNII: 059QF0KO0R) | |
| CYCLOMETHICONE 5 (UNII: 0THF5PCI0R) | |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2) | |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) | |
| UREA (UNII: 8W8T17847W) | |
| TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E) | |
| LAURETH-12 (UNII: OAH19558U1) | |
| ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) | |
| TREHALOSE (UNII: B8WCK70T7I) | |
| LEUCONOSTOC/RADISH ROOT FERMENT FILTRATE (UNII: D2QHA03458) | |
| HYALURONATE SODIUM (UNII: YSE9PPT4TH) | |
| CHLORPHENESIN (UNII: I670DAL4SZ) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| FIG (UNII: TGD87RII2U) | |
| COTTON SEED (UNII: DI0ZRJ0MXN) | |
| FLAX SEED (UNII: 4110YT348C) | |
| SODIUM DEHYDROACETATE (UNII: 8W46YN971G) | |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | |
| .ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I) | |
| BENZYL SALICYLATE (UNII: WAO5MKN9TU) | |
| BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69) | |
| ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B) | |
| LINALOOL, (+/-)- (UNII: D81QY6I88E) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:61722-001-00 | 1 in 1 BOX | 06/16/2014 | |
| 1 | | 40 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 | 06/16/2014 | |

Labeler - Kosan Kozmetik Sanayi ve Ticaret A.S. (644090409)

Revised: 10/2019

Kosan Kozmetik Sanayi ve Ticaret A.S.