

**CELESTY COLORS SPECIAL EDITION WITH ALIX AVIEN CC CREAM- octinoxate, octocrylene, benzophenone-3, avobenzone, octisalate cream  
MABA KOZMETIK LIMITED SIRKETI**

*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.*

-----

**Celesty colors special edition with ALIX AVIEN™ CC CREAM SPF 15**

**Drug Facts:**

**Active ingredients**

Octinoxate: 3%  
Octocrylene: 2%  
Benzophenone-3: 1.6%  
Avobenzone: 2%  
Octisalate: 1.2%

**Purpose:**

Sunscreen

**Use**

- Helps prevent sunburn.

**Warnings**

**For external use only**

**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 only to help prevent sunburn, **not skin cancer or early skin aging.**

- **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.**

**Directions**

- Apply generously 15 minutes before the sun exposure • Children under 6 months of

age: ask a doctor. • 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.

### **Other information**

- Protect the product in this container from excessive heat and direct sunlight.
- Store at room temperature: 15C - 30C

### **Inactive ingredients**

Aqua/Water/Eau, Cyclopentasiloxane, Glycerin, Zinc Oxide, Dimethicone, Isopropyl Myristate, PEG-10 Dimethicone, Sorbitan Olivatate, Sodium Chloride, Phenoxyethanol, Cera Alba/Beeswax/Cire D'abeille, Euphorbia Cerifera (Candelilla) Wax/Candelilla Cera/Cire De Candelilla, Parfum/Fragrance, Silica Dimethyl Silylate, N,N,N-(2-Trimethylammonio) Ethyl Methacrylate Chloride, Triethyl Citrate, Ethylhexylglycerin, Linalool, Citronellol, Alpha-Isomethyl Ionone, Butylphenyl Methylpropional, Limonene **May Contain (+/-)** Titanium Dioxide (CI 77891), Iron Oxides (CI 77491, CI 77492), FD&C Blue No.1 (CI 42090), D&C Yellow 10 (CI 47005)

CC CREAM

SPF 15

COLOR CORRECTING SKIN PROTECTOR BRIGHTENER

Evens out skin tone and provides a natural, radiant appearance. Protects the skin from the harmful rays of the sun with SPF 15. Easy dermal absorption and ensures moisture throughout the day. Offers medium level of coverage. Suitable for all sensitive skin.

### **ALIX AVIEN PARIS**

34 Rue du l'Escouvrier 95200  
Sarcelles PARIS / FRANCE

### **ALIX AVIEN KOZMETİK San. Tic. A.Ş.**

Gazitepe Mah. Aybar Sk. No:7  
ISTANBUL / TURKEY

**www.celesty.com**

Distributed by **CELESTY LLC**  
3970 NW 167<sup>TH</sup> ST. MIAMI GARDENS,  
FL 33054 - USA  
info@celesty.com

MADE IN TURKEY

# Packaging

COLOR CORRECTING  
SKIN PROTECTÖR  
BRIGHTENER

### CC CREAM

Evens out skin tone and provides a natural, radiant appearance. Protects the skin from the harmful rays of the sun with SPF 15. Easy dermal absorption and ensures moisture throughout the day. Offers medium level of coverage. Suitable for all sensitive skin.

### CRÈME CC

Unifie le teint et procure une apparence radieuse et naturelle. Protège votre peau contre les rayons nocifs du soleil avec un indice de protection solaire de 15. Elle pénètre facilement dans la peau et assure une hydratation tout au long de la journée. Offre un niveau de couverture moyen. Convient à toutes les peaux sensibles.

### CREMA CC

Unifica el tono de la piel y proporciona una apariencia radiante y natural. Protege la piel de los efectos nocivos de la radiación solar con Protección Solar Factor 15. Se absorbe fácilmente por la piel y garantiza hidratación durante todo el día. Ofrece un nivel de cobertura medio. Apto para todas las pieles sensibles.

celesty  
colors!

CC CREAM  
SPF 15

special edition with  
ALIX AVIEN™  
P A R I S

40 ml e 1.35 fl.oz.

## Drug Facts: (continued)

### Directions

• Apply generously 15 minutes before the sun exposure • Children under 6 months of age: ask a doctor. • 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.

### Other information

• Protect the product in this container from excessive heat and direct sunlight. • Store at room temperature: 15C - 30C

### Inactive ingredients

Aqua/Water/Eau, Cyclopentasiloxane, Glycerin, Zinc Oxide, Dimethicone, Isopropyl Myristate, PEG-10 Dimethicone, Sorbitan Olivale, Sodium Chloride, Phenoxyethanol, Cera Alba/Beeswax/Cire D'abeille, Euphorbia Cerifera (Candelilla) Wax/Candelilla Cera/Cire De Candelilla, Parfum/Fragrance, Silica Dimethyl Silylate, N,N,N-(2-Trimethylammonio) Ethyl Methacrylate Chloride, Triethyl Citrate, Ethylhexylglycerin, Linalool, Citronellol, Alpha-Isomethyl Ionone, Butylphenyl Methylpropional, Limonene **May Contain (+/-)** Titanium Dioxide (CI 77891), Iron Oxides (CI 77491, CI 77492), FD&C Blue No.1 (CI 42090), D&C Yellow 10 (CI 47005)



## Drug Facts:

### Active Ingredients

Ocinoxate: 3%  
Octocrylene: 2%  
Benzophenone-3: 1.6%  
Avobenzone: 2%  
Octisalate: 1.2%

**Purpose:** Sunscreen

**Use** • Helps prevent sunburn.

### Warnings

**For external use only**  
**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 only to help prevent sunburn, **not skin cancer or early skin aging.**  
• **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.**

### ALIX AVIEN PARIS

34 Rue du l'Escouvrier 95200  
Sarcelles PARIS / FRANCE

ALIX AVIEN KÖZMETİK San. Tic. A.Ş.  
Gaztepe Mah. Aybar Sk. No:7  
İSTANBUL / TURKEY

[www.celesty.com](http://www.celesty.com)

Distributed by CELESTY LLC  
3970 NW 167TH ST. MIAMI GARDENS,  
FL 33054 - USA  
info@celesty.com

MADE IN TURKEY

# CELESTY COLORS SPECIAL EDITION WITH ALIX AVIEN CC CREAM

octinoxate, octocrylene, benzophenone-3, avobenzene, octisalate cream

## Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:81120-115 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

## Active Ingredient/Active Moiety

| <b>Ingredient Name</b>  | <b>Basis of Strength</b> | <b>Strength</b> |
|---|--------------------------|-----------------|
| <b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)   | OCTINOXATE               | 30 mg in 1 mL   |
| <b>OCTOCRYLENE</b> (UNII: 5A68WGF6VM) (OCTOCRYLENE - UNII:5A68WGF6VM) | OCTOCRYLENE              | 20 mg in 1 mL   |
| <b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)   | OXYBENZONE               | 16 mg in 1 mL   |
| <b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)   | AVOBENZONE               | 20 mg in 1 mL   |
| <b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)   | OCTISALATE               | 12 mg in 1 mL   |

## Inactive Ingredients

| <b>Ingredient Name</b>  | <b>Strength</b> |
|---|-----------------|
| <b>WATER</b> (UNII: 059QF0KO0R)   |                 |
| <b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)                                      |                 |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)  |                 |
| <b>ZINC OXIDE</b> (UNII: SOI2LOH54Z)  |                 |
| <b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)   |                 |
| <b>ISOPROPYL MYRISTATE</b> (UNII: 0RE8K4LNJS)                                   |                 |
| <b>PEG-10 DIMETHICONE (600 CST)</b> (UNII: 8PR7V1SVM0)                          |                 |
| <b>SORBITAN OLIVATE</b> (UNII: MDL271E3GR)                                      |                 |
| <b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)                                       |                 |
| <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)  |                 |
| <b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)  |                 |
| <b>CANDELILLA WAX</b> (UNII: VL0328HX19)  |                 |
| <b>SILICA DIMETHYL SILYLATE</b> (UNII: EU2PSP0G0W)                              |                 |
| <b>N,N,N-(2-TRIMETHYLAMMONIO)ETHYL METHACRYLATE CHLORIDE</b> (UNII: PP88R88K3O) |                 |
| <b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)                                      |                 |
| <b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)                                    |                 |
| <b>LINALOOL, (+/-)-</b> (UNII: D81QY6I88E)                                      |                 |
| <b>.BETA.-CITRONELLOL, (R)-</b> (UNII: P01OUT964K)                              |                 |
| <b>ISOMETHYL-.ALPHA.-IONONE</b> (UNII: 9XP4LC555B)                              |                 |
| <b>BUTYLPHENYL METHYLPROPIONAL</b> (UNII: T7540GJV69)                           |                 |
| <b>LIMONENE, (+)-</b> (UNII: GFD7C86Q1W)  |                 |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)                                      |                 |
| <b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)                                      |                 |
| <b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)                                   |                 |
| <b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)                                   |                 |
| <b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)                                 |                 |

## Packaging

| # | Item Code        | Package Description                                | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:81120-115-01 | 1 in 1 CARTON                                      | 03/19/2021           |                    |
| 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                                  | 03/19/2021           |                    |

**Labeler** - MABA KOZMETIK LIMITED SIRKETI (503001418)

## Establishment

| Name                          | Address | ID/FEI    | Business Operations    |
|-------------------------------|---------|-----------|------------------------|
| MABA KOZMETIK LIMITED SIRKETI |         | 503001418 | manufacture(81120-115) |

Revised: 3/2021

MABA KOZMETIK LIMITED SIRKETI