

**OPTIMAL TINTED COMPLEXION- ethylhexyl methoxycinnamate cream**  
**Janssen Cosmetics GmbH**

*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.*

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**Optimal Tinted Complexion Cream**

**Drug Facts**

Active Ingredients: ethylhexyl methoxycinnamate 7.0% Purpose: Sunscreen

**Inactive Ingredients**

**Inactive Ingredients:** Aqua [water], caprylic/capric triglyceride, butylene glycol, dicaprylyl carbonate, C12-15 alkyl benzoate, cetearyl

alcohol, methyl glucose sesquistearate, CI 77891 [titanium dioxide], glyceryl stearate, nylon-12, saccharide isomerate, ascorbyl

palmitate, BHT, tocopherol, lauroyl lysine, lecithin, disodium EDTA, citric acid, parfum [fragrance], hexyl cinnamal, hydroxyisohexyl 3-cyclohexene carboxaldehyde, butylphenyl methylpropional, alpha-isomethylionone, benzyl salicylate, citronellol, linalool, limonene, benzyl benzoate, phenoxyethanol, methylparaben, propylparaben, butylparaben, ethylparaben, isobutylparaben, CI 77 492 [iron oxides], CI 77 491 [iron oxides], CI 77 499 [iron oxides]

**Warning Section**

Avoid contact with eyes. Keep out of reach of children. For External use only. Does not replace the use of sun products in care of sun exposure

**Ask Doctor Section**

Discontinue use and consult a doctor if signs of rash or irritation develops and persists

**Direction:**

Apply evenly onto cleansed skin in the morning. Ideal foundation for make-up

**Principal Display**

Innenseite - Farb + Lackfrei halten  
Inside - Non Print Area

**Active Ingredients:** ethylhexyl methoxycinnamate 6,99 %

**Ingredients:** Aqua [water], caprylic/capric triglyceride, butylene glycol, dicaprylyl carbonate, C12-15 alkyl benzoate, cetearyl alcohol, methyl glucose sesquistearate, Cl 77 891 [tinium dioxide], glyceryl stearate, nylon-12, saccharide isomerase, ascorbyl palmitate, BH-T, tocopherol, lauroyl lysine, lecithin, disodium EDTA, citric acid, perfume [fragrance], hexyl cinnamal, hydroxysheoxy 3-cyclohexene carboxaldehyde, butylphenyl methylpropional, alpha-isomethyl ionone, benzyl salicylate, citronellol, linalool, limonene, benzyl benzoate, phenoxyethanol, methylparaben, propylparaben, butylparaben, ethylparaben, isobutylparaben, Cl 77 482 [iron oxides], Cl 77 481 [iron oxides], Cl 77 489 [iron oxides]

**Warning:** For external use only. Not to be swallowed. Avoid contact with the eyes. If contact occurs, rinse eyes thoroughly with water. Discontinue use if signs of irritation or rash appear. If irritation or rash persists, consult a doctor. **Keep out of reach of children.**



**JANSSEN**  
COSMETICS

52005 Aachen • Germany  
[www.janssen-cosmetics.com](http://www.janssen-cosmetics.com)  
Made in Germany • Ref.: 012



**Tinted day protection cream with SPF for demanding skin.**  
Leaves the complexion looking fresh and youthful. With moisture retention complex obtained from natural sugars.

**Directions:** Apply evenly onto cleansed skin in the morning. Ideal foundation for make-up.

**Getönte Tagesschutzcreme mit LSF für die anspruchsvolle Haut.**  
Sorgt für einen frischen, jugendlichen Teint. Mit einem Feuchtigkeitskomplex aus natürlichen Zuckern gewonnen.  
Morgens auf die gereinigte Haut auftragen. Ideale Make-up-Unterlage.

**Crème de jour teinté avec protection solaire FPS pour la peau exigeante.**  
Procure un teint frais et resplendissant de jeunesse. Contient un complexe d'agents hydratants à base de sucre naturel.  
Appliquez le matin sur la peau bien nettoyée. Base idéale pour le maquillage.

**Crema protettiva da giorno colorata con SPF per pelli esigenti.**  
Lascia una carnagione fresca e giovane. A base di concentrato idratante derivato da zuccheri naturali.  
Applicare sulla pelle pulita del viso la mattina. Ideale come base per il trucco.

**JANSSEN**  
COSMECEUTICAL

**DEMANDING SKIN  
PEAU EXIGEANTE**

**Optimal Tinted  
Complexion Cream**

**SPF 10**

**Crème Teintée  
Éclat Optimal**

**NET WT. 1.7 OZ. 50 ml e**

**Crema de día con SPF y color para la piel exigente.** Deja un cutis radiante y fresco. Con ingredientes que retienen la humedad extraídos de azúcares naturales.  
Aplicar sobre la piel limpia por la mañana. Ideal como base de maquillaje.

**дневной крем с легким тонирующим эффектом для зрелой и сухой кожи.** Придает коже свежий, сияющий оттенок. С влагоудерживающим комплексом на основе натуральных сахара. Со средним фактором защиты.  
Наносите на очищенную кожу утром. Идеально подходит в качестве базы под макияж.

**Getinte en beschermende crème met zonnefilter, voor de veeleisende huid.** Laat de huid stralen met een frisse en jeugdige teint. Bevat een complex van vochtvasthoudende ingrediënten op basis van natuurlijke suikers.  
's Ochtends aanbrengen op de gereinigde huid. Ideale basis voor make-up.

**有色防护日霜。在防晒紫外线的同时  
修饰肤色，赋予皮肤青春光彩。  
富含从糖类中获取的保湿复合物。  
每天日间涂抹在洁净的皮肤上。  
是化妆前使用的理想产品。**

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DEMANDING SKIN  
PEAU EXIGEANTE

**Optimal Tinted  
Complexion Cream  
SPF 10**  
Crème Teintée

NET WT. 1.7 OZ. 50 ml e

Getönte Tagesscreme mit LSF.  
Auf die gereinigte Haut auftragen.

Tinted day cream with SPF.  
Apply onto cleansed skin.

Crème de jour teintée avec  
protection solaire FPS.

Appliquez sur la peau bien nettoyée.

Crema colorata da giorno  
con SPF.

Appicare dopo la deterzione sulla  
pelle del viso.

Crema de día con color y SPF.  
Aplicar sobre la piel limpia.

**Active Ingredients:** ethylhexyl  
methoxycinnamate 6,99 %

**Warning:** For external use only. Not to be swallowed.  
Avoid contact with the eyes. If contact occurs,  
rinse eyes thoroughly with water. Discontinue use  
if signs of irritation or rash appear. If irritation or rash  
persists, consult a doctor. Keep out of reach of  
children.



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**OPTIMAL TINTED COMPLEXION**

ethylhexyl methoxycinnamate cream

**Product Information**

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:24653-011

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3.5 g in 50 mL

**Inactive Ingredients**

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
CAPRYLIC/CAPRIC/LAURIC TRIGLYCERIDE (UNII: FJ1H6M2JG9)	
CETO STEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLUCAMETACIN (UNII: N1EXE5EHAN)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
NYLON-12 (UNII: 446U8J075B)	
SACCHARIDE ISOMERATE (UNII: W8K377W98I)	
LAUROYL LYSINE (UNII: 113171Q70B)	
EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
TOCOPHEROL (UNII: R0ZB2556P8)	
EDETA TE DISODIUM (UNII: 7FLD91C86K)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)	
HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXALDEHYDE (UNII: QUE43B9Z2Q)	
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
BENZYL SALICYLATE (UNII: WA05MNK9TU)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
BENZYL BENZOATE (UNII: N863NB338G)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
ETHYLPARABEN (UNII: 14255EXE39)	
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24653-011-02	1 in 1 BOX		
1	NDC:24653-011-01	50 mL in 1 TUBE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/20/2012	

**Labeler** - Janssen Cosmetics GmbH (499187946)

**Registrant** - Janssen Cosmetics GmbH (499187946)

## Establishment

Name	Address	ID/FEI	Business Operations
Janssen Cosmetics GmbH		499187946	manufacture(24653-011)

Revised: 9/2012

Janssen Cosmetics GmbH