

**OPTIMAL TINTED COMPLEXION- octinoxate 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

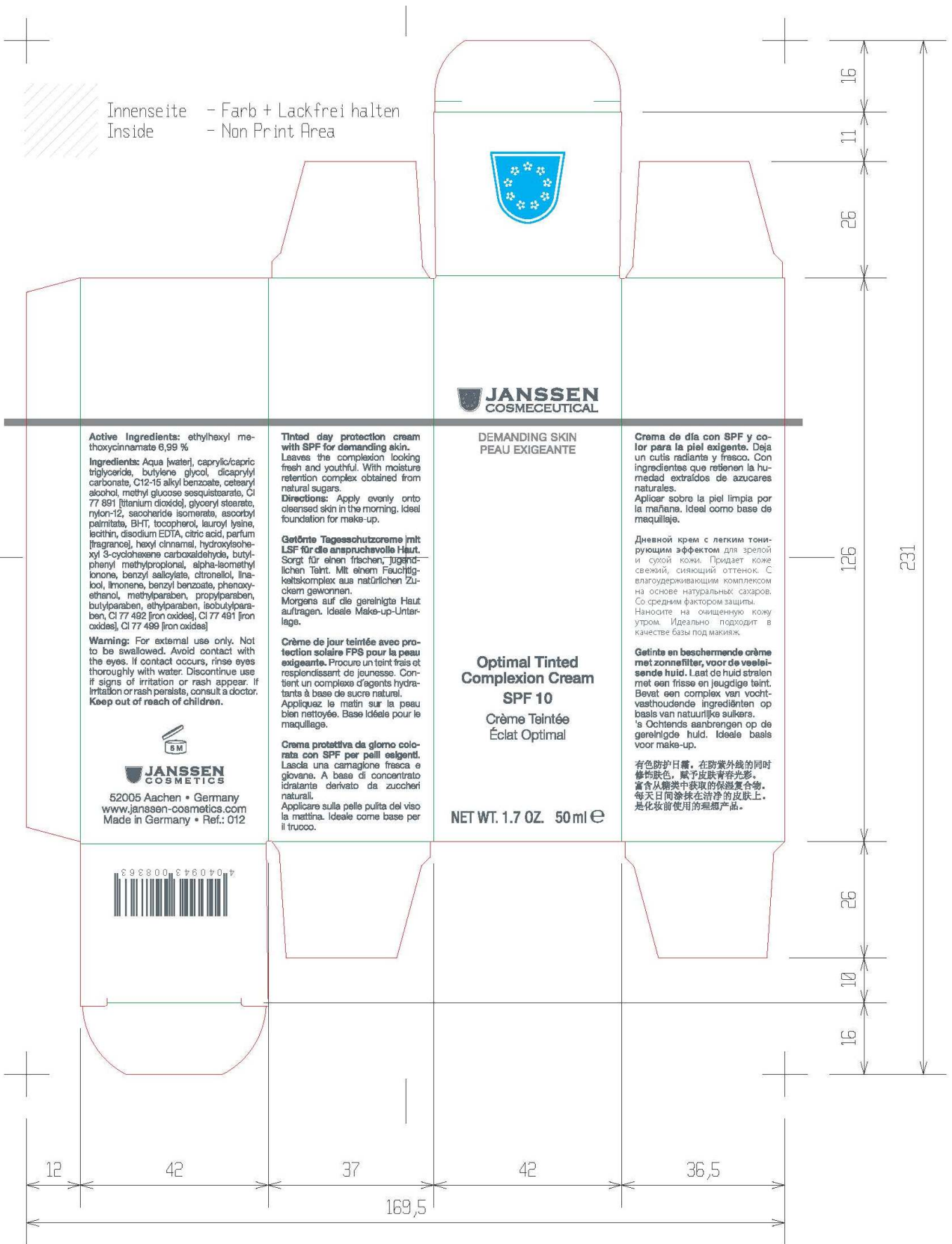
**Ask Doctor Section**

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**



**Principal Display Product Tube**



DEMANDING SKIN  
PEAU EXIGEANTE

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

NET WT. 1.7 OZ. 50 ml e

**Getönte Tagescreme 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.**  
Applicare dopo la detersione 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 LABEL

Item Code (Source)

NDC:24653-011

Route of Administration

TOPICAL

DEA Schedule

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (OCTINOXATE)	OCTINOXATE	3.5 g in 50 mL

**Inactive Ingredients**

Ingredient Name	Strength
WATER	
BUTYLENE GLYCOL	
DICAPRYLYL CARBONATE	
C12-15 ALKYL BENZOATE	
CAPRYLIC/CAPRIC/LAURIC TRIGLYCERIDE	
CETOSTEARYL ALCOHOL	
GLUCAMETACIN	
GLYCERYL MONOSTEARATE	
NYLON-12	
SACCHARIDE ISOMERATE	
LAUROYL LYSINE	
EGG PHOSPHOLIPIDS	
ASCORBYL PALMITATE	
BUTYLATED HYDROXYTOLUENE	
TOCOPHEROL	
EDETATE DISODIUM	
CITRIC ACID MONOHYDRATE	
.ALPHA.-HEXYLCINNAMALDEHYDE	
HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXYALDEHYDE	
BUTYLPHENYL METHYLPROPIONAL	
ISOMETHYL-.ALPHA.-IONONE	
BENZYL SALICYLATE	
.BETA.-CITRONELLOL, (R)-	
LINALOOL, (+/-)-	
BENZYL BENZOATE	
PHENOXYETHANOL	
METHYLPARABEN	
PROPYLPARABEN	
BUTYLPARABEN	
ETHYLPARABEN	
ISOBUTYLPARABEN	

**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