

RICH NUTRIENT SKIN REFINER- octyl methoxycinnamate, octocrylene cream 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.

Drug Facts

Active Ingredients : Ethylhexyl Methoxycinnamate 7.494% , Octocrylene 3.0 - Purpose:
Sunscreen

Inactive Ingredients: AQUA [WATER], CAPRYLIC/CAPRIC TRIGLYCERIDE, ISOSTEARYL ISOSTEARATE, METHYL GLUCOSE SESQUISTEARATE, BUTYLENE GLYCOL, SQUALANE, DECYL OLEATE, CETEARYL ALCOHOL, HYDROGENATED COCO-GLYCERIDES, GLYCERYL STEARATE, OCTYLDODECANOL, PENTYLENE GLYCOL, ETHYLHEXYL TRIAZONE, SACCHARIDE ISOMERATE, STEARETH-21, AVENA SATIVA (OAT) KERNEL EXTRACT, SODIUM HYALURONATE, DIMETHICONE, GLYCERYL CAPRYLATE, LECITHIN, ASCORBYL PALMITATE, BHT, TOCOPHEROL, TETRASODIUM GLUTAMATE DIACETATE, CITRIC ACID, SODIUM CITRATE, SODIUM HYDROXIDE, BUTYLPHENYL METHYLPROPIONAL, LINALOOL, HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXYLATE, ALPHA-ISOMETHYL IONONE, BENZYL BENZOATE, PHENOXYETHANOL, SODIUM BENZOATE

Ask Doctor Section

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

Warning Section

Avoid contact with eyes. If contact occurs rinse eye thoroughly with water

Keep out of reach of children

For External use only. Not be be swallowed

Directions

Apply to cleansed skin

Image of packaging

FS Tiegel 50ml - #0010
 Druck: 2-farbig; Pantone 431 / Silberfolienheißprägung (hier angelegt in Pantone 877)



RICH NUTRIENT SKIN REFINER

octyl methoxycinnamate, octocrylene cream cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24653-0 10
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2.25 g in 50 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	0.9 g in 50 mL

Inactive Ingredients

Ingredient Name	Strength
BUTYLPHENYL METHYLPROPIONAL, (+)- (UNII: WP1PPC4R9G)	
.ALPHA.-ISOMETHYLIONYL ACETATE, (2R)-(+)- (UNII: 53VC4S6U3E)	
BENZYL BENZOATE (UNII: N863NB338G)	
LINALOOL, (+)- (UNII: F4VNO44C09)	
HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXYALDEHYDE (UNII: QUE43B9Z2Q)	

ISOSTEARYL ISOBUTYRATE (UNII: 52MGR8MV2R)
PEG-20 METHYL GLUCOSE SESQUISTEARATE (UNII: 0345752X7U)
1,3-BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
SQUALANE (UNII: GW89575KF9)
CETYL ALCOHOL (UNII: 936JST6JCN)
HYDROGENATED COCO-GLYCERIDES (UNII: XDD37N2GPR)
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)
OCTYLDODECANOL (UNII: 461N1O614Y)
PENTYLENE GLYCOL (UNII: 50C1307PZG)
AVENA SATIVA WHOLE (UNII: 5P8D0Z74RG)
PEG-9 DIGLYCIDYL ETHER/SODIUM HYALURONATE CROSSPOLYMER (UNII: 788QAG3W8A)
STEARETH-21 (UNII: 53J3F32P58)
DIMETHICONE 1000 (UNII: MCU2324216)
CAPRYLIC/CAPRIC/LAURIC TRIGLYCERIDE (UNII: FJ1H6M2JG9)
WATER (UNII: 059QF0KO0R)
DECYL OLEATE (UNII: ZGR06DO97T)
ETHYLHEXYL TRIAZONE (UNII: XQN8R9SAK4)
SACCHARIDE ISOMERATE (UNII: W8K377W98I)
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)
ASCORBYL PALMITATE (UNII: QN83US2B0N)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
HYDROXYCITRIC ACID (UNII: 8W94T9026R)
SODIUM CITRATE (UNII: 1Q73Q2JULR)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
SODIUM BENZOATE (UNII: OJ245FE5EU)
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)
SODIUM HYDROXIDE (UNII: 55X04QC32I)
TOCOPHEROL (UNII: R0ZB2556P8)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24653-010-02	1 in 1 BOX		
1	NDC:24653-010-01	50 mL in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	08/03/2015	

Labeler - Janssen Cosmetics GmbH (499187946)

Registrant - Janssen Cosmetics GmbH (499187946)

Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 8/2015

Janssen Cosmetics GmbH