

LONG LAST MAKEUP 00- octinoxate cream
LONG LAST MAKEUP 01- octinoxate cream
LONG LAST MAKEUP 05- octinoxate cream
LONG LAST MAKEUP 03- 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.

Long Last Makeup

Drug Facts:

Active Ingredient: Ethylhexyl methoxycinnamate 6% Purpose: Sunscreen

Inactive Ingredient

Aqua [water], isohexadecane, cyclopentasiloxane, butylene glycol, tricaprylin, cetyl PEG/PPG-10/1 dimethicone, silica, cyclohexasiloxane, saccharide isomerate, dicaprylyl carbonate, polyglyceryl-4, isostearate, panthenol, lauroyl lysine, hydrogenated castor oil, disteardimonium hectorite, lecithin, ascorbyl palmitate, BHT, tocopherol, sodium chloride, cera microcristallina [microcrystalline wax], disodium EDTA, propylene carbonate, citric acid, parfum [fragrance], benzyl salicylate, hydroxyisohexyl 3-cyclohexene carboxaldehyde, hydroxycitronellal, limonene, alpha-isomethyl ionone, coumarin, linalool, phenoxyethanol, methylparaben, ethylparaben, propylparaben, butylparaben, isobutylparaben, CI 77 891 [titanium dioxide], CI 77 491 [iron oxides], CI 77 492 [iron oxides], CI 77 499 [iron oxides]

Ask Doctor Section

Discontinue use if signs of irritation or rash appear. If irritation or rash persists, consult a doctor

Purpose of Use

For external use only. Not to be swallowed. Avoid contact with the eyes. If contact occurs, rinse eyes thoroughly with water

Keep out of reach

Keep out of reach of children

Long Last Make UP 00 30ml bottle - 8300

Faltschachtel Spender Megaplast Mirco 30ml VK - #C-830
Druck: 2-farbig; Pantone 8920 / Pantone 431

150.50 mm



216.60 mm

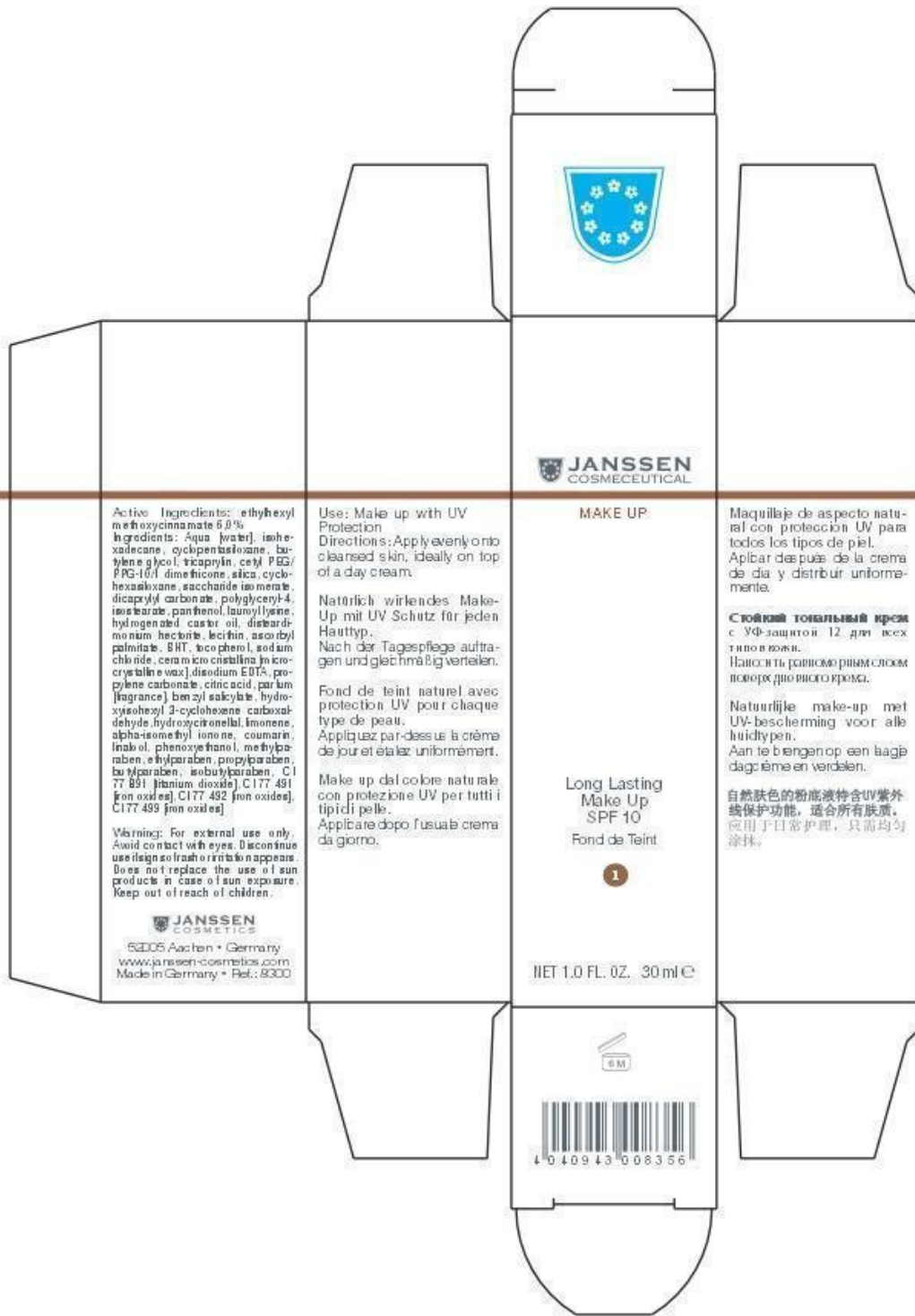


Long Lasting Makeup 01 30ml pump bottle -8301

Faltschachtel Spender Megaplast Mirco 30ml VK - #C-830
Druck: 2-farbig; Pantone 89 20 / Pantone 431

150.50 mm

216.60 mm

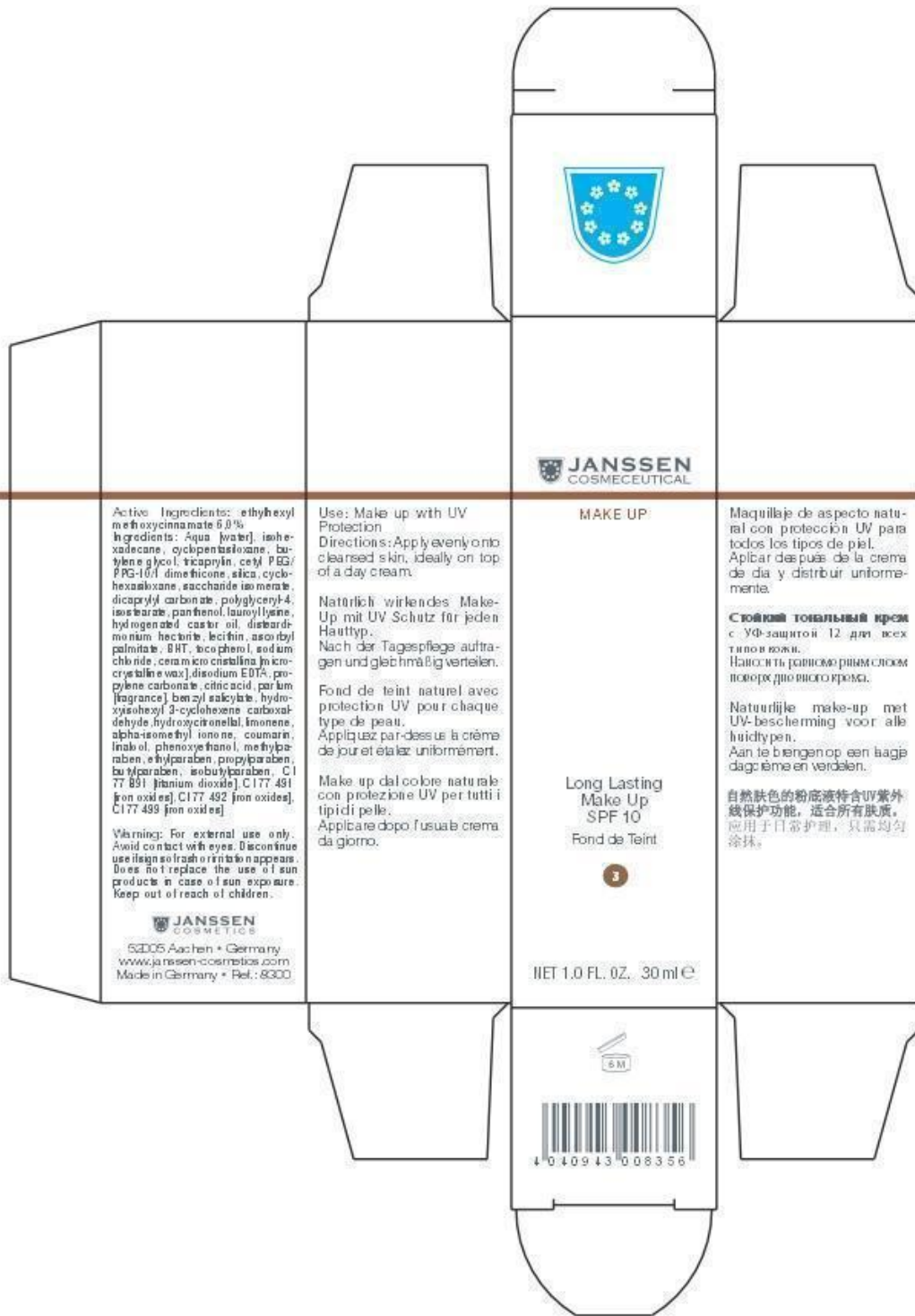


K:12755-1

Long Lasting Makeup 03 -30ml pump bottle -8303

150.50 mm

216.60 mm



K:12755-1

150.50 mm

216.60 mm



Active Ingredients: ethylhexyl methoxycinnamate 5.0 %
 Ingredients: Aqua [water], isohexadecane, cyclopentasiloxane, butylene glycol, tricaprylin, cetyl PEG/PPG-10/1 dimethicone, silica, cyclohexaoloxane, saccharide isomerate, dicaprylyl carbonate, polyglyceryl-4 isoparate, panthenol, lauryllysene, hydrogenated castor oil, distardimonium hecтонite, lecithin, ascorbyl palmitate, BHT, tocoopherol, sodium chloride, ceramico cristallina [microcrystalline wax], disodium EDTA, propylene carbonate, citric acid, parfum [fragrance], benzyl salicylate, hydroxyisohexyl 3-cyclohexene carboxaldehyde, hydroxyacetone, limonene, alpha-isomethyl ionone, coumarin, linoleol, phenoxethanol, methylparaben, ethylparaben, propylparaben, butylparaben, isobutylparaben, CI 77 891 [titanium dioxide], CI 177 491 [iron oxides], CI 177 492 [iron oxides], CI 177 493 [iron oxides]

Warning: For external use only. Avoid contact with eyes. Discontinue use if skin sores or irritation appears. Does not replace the use of sun products in case of sun exposure. Keep out of reach of children.

JANSSEN COSMETICS
 SEDOS Aachen • Germany
 www.janssen-cosmetics.com
 Made in Germany • Ref.: 8300

Use: Make up with UV Protection
 Directions: Apply evenly on to cleansed skin, ideally on top of a day cream.

Natürlich wirkendes Make-Up mit UV Schutz für jeden Hauttyp.
 Nach der Tagespflege auftragen und gleichmäßig verteilen.

Fond de teint naturel avec protection UV pour chaque type de peau.
 Appliquez par-dessus la crème de jour et étalez uniformément.

Make up dal colore naturale con protezione UV per tutti i tipi di pelle.
 Applicare dopo l'usuale crema da giorno.

JANSSEN COSMECEUTICAL

MAKE UP

Long Lasting Make Up SPF 10
 Fond de Teint

5

11ET 1.0 FL. OZ. 30 ml e



Maquillaje de aspecto natural con protección UV para todos los tipos de piel.
 Aplicar después de la crema de día y distribuir uniformemente.

Стойкий тональный крем с УФ-защитой 12 для всех типов кожи.
 Нанести ровным слоем поверх дневного крема.

Natuurlijke make-up met UV-bescherming voor alle huidtypen.
 Aan te brengen op een laagje dagcrème en verdelen.

自然肤色的粉底液特含UV紫外线保护功能，适合所有肤质，适用于日常护理，只需均匀涂抹。

K:12755-1

LONG LAST MAKEUP 00

octinoxate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24653-800
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1.8 g in 30 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
CYCLOMETHICONE 5 (UNII: 0TH5PC10R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
TRICAPRYLIN (UNII: 6P92858988)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 1.5) (UNII: V2W71V8T0X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
SACCHARIDE ISOMERATE (UNII: W8K377W98I)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
PANTHENOL (UNII: WV9CM0O67Z)	
LAUROYL LYSINE (UNII: 113171Q70B)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
DISTEARYLDIMONIUM CHLORIDE (UNII: OM9573ZX3X)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
TOCOPHEROL (UNII: R0ZB2556P8)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
BENZYL SALICYLATE (UNII: WAO5MKN9TU)	
HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXYALDEHYDE (UNII: QUE43B9Z2Q)	
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
ISOMETHYL- α -IONONE (UNII: 9XP4LC555B)	
COUMARIN (UNII: A4VZ22K1WT)	
LINALOOL, (+)- (UNII: F4VNO44C09)	

PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
ETHYL PARABEN (UNII: 14255EXE39)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
BUTYL PARABEN (UNII: 3QP1IU3FV8)	
ISOBUTYL PARABEN (UNII: 0QJ25X58G)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24653-800-02	1 in 1 CARTON		
1	NDC:24653-800-01	30 mL in 1 BOTTLE, PUMP		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/05/2012	

LONG LAST MAKEUP 01

octinoxate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24653-801
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1.8 g in 30 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISOHEXADECANE (UNII: 918X10UF1E)	
CYCLOMETHICONE 5 (UNII: 0TH5PCI0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
TRICAPRYLIN (UNII: 6P92858988)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 1.5) (UNII: V2W71V8T0X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	

SACCHARIDE ISOMERATE (UNII: W8K377W98I)
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
PANTHENOL (UNII: WV9CM0O67Z)
LAUROYL LYSINE (UNII: 113171Q70B)
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)
DISTEARYLDIMONIUM CHLORIDE (UNII: OM9573ZX3X)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
ASCORBYL PALMITATE (UNII: QN83US2B0N)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
TOCOPHEROL (UNII: R0ZB2556P8)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
EDETATE DISODIUM (UNII: 7FLD91C86K)
PROPYLENE CARBONATE (UNII: 8D08K3S51E)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
BENZYL SALICYLATE (UNII: WAO5MNK9TU)
HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXYALDEHYDE (UNII: QUE43B9Z2Q)
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
COUMARIN (UNII: A4VZ22K1WT)
LINALOOL, (+)- (UNII: F4VNO44C09)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
METHYL PARABEN (UNII: A2I8C7HI9T)
ETHYL PARABEN (UNII: 14255EXE39)
PROPYL PARABEN (UNII: Z8IX2SC1OH)
BUTYL PARABEN (UNII: 3QPIIU3FV8)
ISOBUTYL PARABEN (UNII: 0QQJ25X58G)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24653-801-02	1 in 1 CARTON		
1	NDC:24653-801-01	30 mL in 1 BOTTLE, PUMP		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/10/2008	

LONG LAST MAKEUP 05

octinoxate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24653-802
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1.8 g in 30 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISOHEXADECANE (UNII: 918X10UF1E)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
TRICAPRYLIN (UNII: 6P92858988)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 1.5) (UNII: V2W71V8T0X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
SACCHARIDE ISOMERATE (UNII: W8K377W98J)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
PANTHENOL (UNII: WV9CM0O67Z)	
LAUROYL LYSINE (UNII: 113171Q70B)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
DISTEARYLDIMONIUM CHLORIDE (UNII: OM9573ZX3X)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
TOCOPHEROL (UNII: R0ZB2556P8)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
BENZYL SALICYLATE (UNII: WAO5MKN9TU)	
HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXYALDEHYDE (UNII: QUE43B9Z2Q)	
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
COUMARIN (UNII: A4VZ22K1WT)	
LINALOOL, (+)- (UNII: F4VNO44C09)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
ETHYL PARABEN (UNII: 14255EXE39)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
BUTYL PARABEN (UNII: 3QP1U3FV8)	

ISOBUTYL PARABEN (UNII: 0QJ25X58G)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24653-802-02	1 in 1 CARTON		
1	NDC:24653-802-01	30 mL in 1 BOTTLE, PUMP		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	01/10/2012		

LONG LAST MAKEUP 03
octinoxate cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24653-803	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)		OCTINOXATE	1.8 g in 30 mL

Inactive Ingredients		
Ingredient Name		Strength
WATER (UNII: 059QF0KO0R)		
ISOHEXADECANE (UNII: 918X1OUF1E)		
CYCLOMETHICONE 5 (UNII: 0THF5PCI0R)		
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)		
TRICAPRYLIN (UNII: 6P92858988)		
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 1.5) (UNII: V2W71V8T0X)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
CYCLOMETHICONE 6 (UNII: XHK3U310BA)		
SACCHARIDE ISOMERATE (UNII: W8K377W98I)		
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)		
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)		
PANTHENOL (UNII: WV9CM0O67Z)		
LAUROYL LYSINE (UNII: 113171Q70B)		
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)		

DISTEARYLDIMONIUM CHLORIDE (UNII: OM9573ZX3X)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
ASCORBYL PALMITATE (UNII: QN83US2B0N)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
TOCOPHEROL (UNII: R0ZB2556P8)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
EDETATE DISODIUM (UNII: 7FLD91C86K)
PROPYLENE CARBONATE (UNII: 8D08K3S51E)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
BENZYL SALICYLATE (UNII: WAO5MKN9TU)
HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXYALDEHYDE (UNII: QUE43B9Z2Q)
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
COUMARIN (UNII: A4VZ22K1WT)
LINALOOL, (+)- (UNII: F4VNO44C09)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
METHYL PARABEN (UNII: A2I8C7HI9T)
ETHYL PARABEN (UNII: 14255EXE39)
PROPYL PARABEN (UNII: Z8IX2SC1OH)
BUTYL PARABEN (UNII: 3QP1I03FV8)
ISOBUTYL PARABEN (UNII: 0QQJ25X58G)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROUS FERRIC OXIDE (UNII: XM0M87F357)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24653-803-02	1 in 1 CARTON		
1	NDC:24653-803-01	30 mL in 1 BOTTLE, PUMP		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/10/2008	

Labeler - Janssen Cosmetics GmbH (499187946)

Registrant - Janssen Cosmetics GmbH (499187946)

Establishment

Name	Address	ID/FEI	Business Operations
Janssen Cosmetics GmbH		499187946	manufacture(24653-800)

Establishment

Name	Address	ID/FEI	Business Operations
Dr. Sacher Kosmetik GmbH		341926681	api manufacture(24653-800)

Revised: 10/2012

Janssen Cosmetics GmbH