

TINTED LIP CONDITIONER SPF 15 PLUS LAVENDER- octinoxate, octisalate gel
MAKEUP ART COSMETICS

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.

ACTIVE INGREDIENTS: OCTINOXATE 7.50% [] OCTISALATE 5.00%

INACTIVE INGREDIENTS: PETROLATUM [] RICINUS COMMUNIS (CASTOR) SEED OIL [] POLYBUTENE [] MICROCRYSTALLINE WAX\CERA MICROCRISTALLINA\CIRE MICROCRISTALLINE [] ETHYLENE/PROPYLENE/STYRENE COPOLYMER [] HYDROGENATED POLYISOBUTENE [] SILICA [] TOCOPHERYL ACETATE [] SQUALANE [] LECITHIN [] PRUNUS AMYGDALUS DULCIS (SWEET ALMOND) OIL [] BUTYROSPERMUM PARKII (SHEA BUTTER) [] PERSEA GRATISSIMA (AVOCADO) OIL UNSAPONIFIABLES [] LAVANDULA ANGUSTIFOLIA (LAVENDER) FLOWER WAX [] ASTROCARYUM MURUMURU SEED BUTTER [] POLYDECENE [] CHOLESTEROL [] TRITICUM VULGARE (WHEAT) GERM OIL [] POLYETHYLENE [] BUTYLENE/ETHYLENE/STYRENE COPOLYMER [] TRIETHOXYCAPRYLYLSILANE [] CALCIUM ALUMINUM BOROSILICATE [] TIN OXIDE [] FLAVOR (AROMA) [] SACCHARIN [] LINALOOL [] GERANIOL [] BHT [] TETRAHEXYLDECYL ASCORBATE [] [+/- MICA [] TITANIUM DIOXIDE (CI 77891) [] IRON OXIDES (CI 77491, CI 77492, CI 77499) [] BLUE 1 LAKE (CI 42090) [] RED 6 (CI 15850) [] RED 7 LAKE (CI 15850) [] RED 28 LAKE (CI 45410) [] RED 30 LAKE (CI 73360) [] RED 33 LAKE (CI 17200) [] YELLOW 5 LAKE (CI 19140) [] YELLOW 6 LAKE (CI 15985)

WARNING: STOP USE IF IRRITATION OCCURS.

PRINCIPAL DISPLAY PANEL:

MAC

TINTED LIP CONDITIONER SPF 15

+ LAVENDER

15 ML/0.5 US FL OZ.

DISTR. BY MAKEUP ART COSMETICS
TORONTO, ONTARIO, CANADA, M5V 1R7

<p>IDRATANTE COLORATO PER LABBRA SPF 15 BETÖNTE LIPPENPFLEGE SPF 15 BÁLSAMO LABIAL CON COLOR SPF 15</p> <p>WARNING: STOP USE IF IRRITATION OCCURS. ATTENTION: SUSPENDRE L'UTILISATION EN CAS D'IRRITATION. AVVERTENZE: IN CASO DI IRRITAZIONE, INTERRUPELRE L'USO. ACHTUNG: FALLS IRRITATIONEN AUFRETEN, NICHT WEITER ANWENDEN. ATENCIÓN: INTERRUPTA SU USO SI SE PRODUCE IRRITACIÓN.</p> <p>DIST. BY/PAR: MAKE-UP ART COSMETICS TORONTO, ONTARIO, CANADA M5V 1R7 LONDON W1K 3BQ / M18K MADE IN CANADA/FABRIQUÉ AU CANADA MACCOSMETICS.COM</p> 	<p>ACTIVE INGREDIENTS: OCTINOXATE 7.50%, OCTISALATE 5.00%</p> <p>INGREDIENTS: PETROLATUM, RICINUS COMMUNIS (CASTOR) SEED OIL, POLYBUTENE, MICROCRYSTALLINE WAX, CERA MICROCRISTALLINACIRE MICROCRISTALLINE, ETHYLENE/ PROPYLENE/STYRENE COPOLYMER, HYDROGENATED POLYISOBUTENE, SILICA, TOCOPHERYL ACETATE, SQUALANE, LECITHIN, PRUNUS AMYGDALUS DULCIS (SWEET ALMOND) OIL, BUTYROSPERMIUM PARKII (SHEA BUTTER), PERSEA GRATISSIMA (AVOCADO) OIL UNSAPOHIFIABLES, LAVANDULA ANGUSTIFOLIA (LAVENDER) FLOWER WAX, ASTROCARYUM MURUMURU SEED BUTTER,</p>	 <p>TINTED LIP CONDITIONER SPF 15 + LAVENDER BAUME COLORE POUR LES LÈVRES SPF 15 15 ML/0.5 US FL OZ e</p>	<p>POLYDECENE, CHOLESTEROL, TRITICUM VULGARE (WHEAT) GERM OIL, POLYETHYLENE, BUTYLENE/ETHYLENE/ STYRENE COPOLYMER, TRIETHOXYCAPRYLSILANE, CALCIUM ALUMINUM BOROSILICATE, TIN OXIDE, FLAVOR (AROMA), SACCHARIN, LINALOOL, GERANIOL, BHT, TETRAHEXYLDECYL ASCORBATE [± MICA, TITANIUM DIOXIDE (CI 77891), IRON OXIDES (CI 77491, CI 77492, CI 77499), BLUE 1 LAKE (CI 42090), RED 6 (CI 15850), RED 7 LAKE (CI 15850), RED 28 LAKE (CI 45410), RED 30 LAKE (CI 73360), RED 33 LAKE (CI 17200), YELLOW 6 LAKE (CI 19140), YELLOW 6 LAKE (CI 15985)] <ILN37204></p>
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TINTED LIP CONDITIONER SPF 15 PLUS LAVENDER

octinoxate, octisalate gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:40046-0041
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 mL in 100 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5.0 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
CASTOR OIL (UNII: D5340 Y219G)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLYISOBUTYLENE (35000 MW) (UNII: 98553S1MHQ)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
ALMOND OIL (UNII: 66YXD4DKO9)	
SHEA BUTTER (UNII: K49155WL9Y)	
ASTROCARYUM MURUMURU SEED BUTTER (UNII: 12V64UPU6R)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	

WHEAT GERM OIL (UNII: 14C97E680P)
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
OCTYLTRIETHOXYSILANE (UNII: LDC331P08E)
STANNIC OXIDE (UNII: KM7N50LOS6)
SACCHARIN (UNII: FST467XS7D)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
D&C RED NO. 6 (UNII: 481744A140)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 28 (UNII: 767IP0Y5NH)
D&C RED NO. 30 (UNII: 2S42T2808B)
D&C RED NO. 33 (UNII: 9DBA0SBB0L)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)
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:40046-0041-1	1 in 1 CARTON		
1	NDC:40046-0041-2	15 mL in 1 JAR		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/01/2010	

Labeler - MAKEUP ART COSMETICS (010597206)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		205952385	manufacture

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	manufacture

Establishment			
Name	Address	ID/FEI	Business Operations
Len-Ron Manufacturing Division of Aramis Inc.		809771152	manufacture

Establishment			
Name	Address	ID/FEI	Business Operations
Aramis Inc.		042918826	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Northtec Bristol		949264774	manufacture, relabel, repack

Establishment

Name	Address	ID/FEI	Business Operations
Northtec Keystone		618107429	manufacture, relabel, repack

Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Pennsylvania Distribution Center 2		828534516	manufacture, relabel, repack

Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Cosmetics, Ltd.		255175580	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Cosmetics, Ltd		253616536	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Cosmetics Distribution Center		208579636	repack, relabel

Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Kabushiki Kaisha		712808195	relabel, repack

Establishment

Name	Address	ID/FEI	Business Operations
Whitman Laboratories Ltd.		216866277	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Aveda Corporation		071352058	manufacture