

**LIP CONDITIONER SPF 15- octinoxate, octisalate, titanium dioxide lipstick
MAKE UP 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% [] TITANIUM DIOXIDE 1.00%

INGREDIENTS: RICINUS COMMUNIS (CASTOR) SEED OIL [] CANOLA OIL\HUILE DE COLZA [] DIPENTAERYTHRITYL HEXAHYDROXYSTEARATE/HEXASTEARATE/HEXAROSINATE [] OZOKERITE [] GLYCERYL ROSINATE [] CETYL LACTATE [] EUPHORBIA CERIFERA (CANDELILLA) WAX\CANDELILLA CERA\CIRE DE CANDELILLA [] MYRISTYL LACTATE [] CETYL ACETATE [] BEESWAX\CERA ALBA\CIRE D'ABEILLE [] FRAGRANCE (PARFUM) [] SILICA [] ZEA MAYS (CORN) STARCH [] PERSEA GRATISSIMA (AVOCADO) OIL [] TRITICUM VULGARE (WHEAT) GERM OIL [] PRUNUS AMYGDALUS DULCIS (SWEET ALMOND) OIL [] BUTYROSPERMUM PARKII (SHEA BUTTER) [] HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL [] ANTHEMIS NOBILIS (CHAMOMILE) FLOWER EXTRACT [] ASTROCARYUM MURUMURU BUTTER [] TOCOPHEROL [] TOCOPHERYL ACETATE [] ASCORBYL PALMITATE [] RETINYL PALMITATE [] POLYDECENE [] SACCHARIN [] BISABOLOL

WARNINGS: KEEP OUT OF EYES. STOP USE IF IRRITATION OCCURS. KEEP OUT OF REACH OF CHILDREN.

PRINCIPAL DISPLAY PANEL:

MAC

LIP CONDITIONER STICK

SPF 15

4.8 g/0.16 oz

distr make up art cosmetics

Toronto, Ontario

Canada m5v 1r7

**LIPPENPFLEGESTIFT
SPF 15
BALSAM LABIAL
EN STICK SPF 15**

ACTIVE INGREDIENTS:
OCTINOXATE 7.50%,
OCTISALATE 5.00%,
TITANIUM DIOXIDE 1.00%

**WARNING: STOP USE IF
IRRITATION OCCURS.**

DIST. BY/PAR:
MAKE-UP ART COSMETICS
TORONTO, ONTARIO,
CANADA M5V 1R7
LONDON W1K 3BQ. / M6H1-01
MADE IN U.S.A./
FABRIQUÉ AUX É.-U.
MACCOSMETICS.COM



**INGREDIENTS: RICINUS
COMMUNIS (CASTOR) SEED
OIL, CANOLA OIL/HAILE DE
COLZA, DIPENTAERYTHRITYL
HEXAHYDROXYSTEARATE/
HEXASTEARATE/HEXAROSINATE,
OZOKERITE, GLYCERYL
ROSINATE, CETYL LACTATE,
EUPHORBIA CERIFERA
(CANDELILLA) WAX/CANDELILLA
CERACIRE DE CANDELILLA,
MYRISTYL LACTATE, GETYL
ACETATE, BEESWAX/CERA
ALBA/CIRE D'ABEILLE,
FRAGRANCE (PARFUM),
SILICA, ZEA MAYS (CORN)
STARCH, PERSEA GRATISSIMA
(AVOCADO) OIL, TRITICUM
VULGARE (WHEAT) GERM OIL,
PRUNUS AMYGDALUS DULCIS
(SWEET ALMOND) OIL,
BUTYROSPERMUM PARKII
(SHEA BUTTER), HELIANTHUS
ANNUUS (SUNFLOWER) SEED
OIL, ANTHEMIS NOBILIS
(CHAMOMILE) FLOWER EXTRACT,
ASTROCARYUM MURUMURU
BUTTER, TOCOPHEROL,
TOCOPHERYL ACETATE,
ASCORBYL PALMITATE, RETINYL
PALMITATE, POLYDECENE,
SACCHARIN, BISABOLOL
<ILN3115>**



**LIP
CONDITIONER STICK
SPF 15
HYDRATANT
POUR LES LÈVRES
FPS 15 EN BÂTON
4.8 g / 0.16 US OZ**



LIP CONDITIONER SPF 15

octinoxate, octisalate, titanium dioxide lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:40046-0053
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5.0 g in 100 g
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	1.0 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CASTOR OIL (UNII: D5340 Y2I9G)	
CERESIN (UNII: Q ILS2UJO3A)	

CANDELILLA WAX (UNII: WL0328HX19)	
MYRISTYL LACTATE (UNII: 1D822OC34X)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
WHEAT GERM OIL (UNII: 14C97E680P)	
ALMOND OIL (UNII: 66YXD4DKO9)	
SHEA BUTTER (UNII: K49155WL9Y)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
CHAMAEMELUM NOBILE FLOWER (UNII: O2T154T6OG)	
ASTROCARYUM MURUMURU SEED BUTTER (UNII: 12V64UPU6R)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
SACCHARIN (UNII: FST467XS7D)	
LEVOMENOL (UNII: 24WE03BX2T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:40046-0053-1	1 in 1 CARTON		
1	NDC:40046-0053-2	4.8 g in 1 CARTRIDGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/01/2005	

Labeler - MAKE UP ART COSMETICS (010597206)

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
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Northtec Bristol		949264774	manufacture, relabel, repack
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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

Establishment

Name	Address	ID/FEI	Business Operations
MANA COSMETICS INC		078870292	manufacture