

TINTED LIP CONDITIONER SPF 15- 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 [] FRAGRANCE (PARFUM) [] SILICA []
BUTYROSPERMUM PARKII (SHEA BUTTER) [] PERSEA GRATISSIMA (AVOCADO) OIL
UNSAAPONIFIABLES [] TRITICUM VULGARE (WHEAT) GERM OIL [] CHAMOMILLA
RECUTITA (MATRICARIA) FLOWER OIL [] ASTROCARYUM MURUMURU BUTTER []
PRUNUS AMYGDALUS DULCIS (SWEET ALMOND) OIL [] TOCOPHERYL ACETATE []
RETINYL PALMITATE [] CHOLESTEROL [] LECITHIN [] SQUALANE [] POLYETHYLENE []
POLYDECENE [] BUTYLENE/ETHYLENE/STYRENE COPOLYMER []
TRIETHOXYCAPRYLYLSILANE [] TETRAHEXYLDECYL ASCORBATE [] SACCHARIN []
VANILLIN [] BHT

WARNING: STOP USE IF IRRITATION OCCURS.

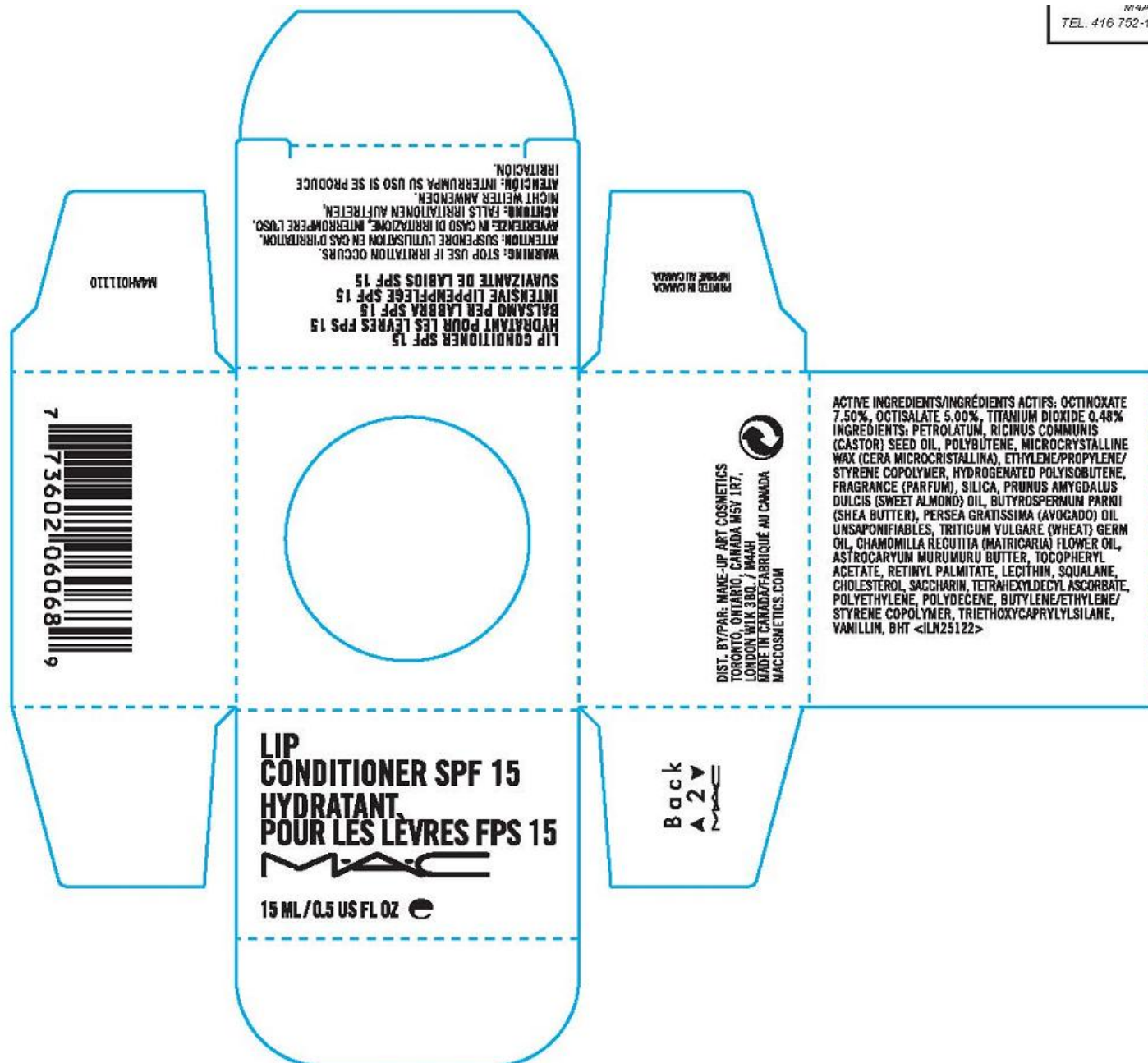
PRINCIPAL DISPLAY PANEL:

MAC

LIP CONDITIONER SPF 15

15 ML/0.5 US FL OZ.

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



TINTED LIP CONDITIONER SPF 15

octinoxate, octisalate gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:40046-0049
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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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: 4T6 H12BN9 U)	
CASTOR OIL (UNII: D5340 Y2I9 G)	
MICROCRYSTALLINE WAX (UNII: XOF59 7Q3KY)	
SILICON DIOXIDE (UNII: ETJ7Z6 XBU4)	
POLYISOBUTYLENE (35000 MW) (UNII: 98553S1MHQ)	
LECITHIN, SOYBEAN (UNII: 1DI56 QDM62)	
ALMOND OIL (UNII: 66YXD4DKO9)	
SHEA BUTTER (UNII: K49 155WL9 Y)	
ASTROCARYUM MURUMURU SEED BUTTER (UNII: 12V64UPU6R)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
WHEAT GERM OIL (UNII: 14C97E680P)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
STANNIC OXIDE (UNII: KM7N50LOS6)	
SACCHARIN (UNII: FST467XS7D)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0 Z171K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:40046-0049-1	1 in 1 CARTON		
1	NDC:40046-0049-2	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
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Len-Ron Manufacturing Division of Aramis Inc.		809771152	manufacture
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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