

**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 [] TOCOPHERYL ACETATE [] LECITHIN [] SQUALANE [] PRUNUS AMYGDALUS DULCIS (SWEET ALMOND) OIL [] BUTYROSPERMUM PARKII (SHEA BUTTER) [] PERSEA GRATISSIMA (AVOCADO) OIL UNSAPONIFIABLES [] LAVANDULA ANGUSTIFOLIA (LAVENDER) FLOWER WAX [] ASTROCARYUM MURUMURU SEED BUTTER [] TRITICUM VULGARE (WHEAT) GERM OIL [] POLYDECENE [] CHOLESTEROL [] SILICA [] POLYETHYLENE [] BUTYLENE/ETHYLENE/STYRENE COPOLYMER [] TRIETHOXYCAPRYLYLSILANE [] SACCHARIN [] LINALOOL [] GERANIOL [] FLAVOUR (AROMA) [] BHT [] TETRAHEXYLDECYL ASCORBATE [] TITANIUM DIOXIDE (CI 77891)

WARNING: STOP USE IF IRRITATION OCCURS.

PRINCIPAL DISPLAY PANEL:

MAC

LIP CONDITIONER SPF 15

+ LAVENDER

15 ML/0.5 US FL OZ.

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



LIP CONDITIONER SPF 15 PLUS LAVENDER

octinoxate, octisalate gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:40046-0040
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: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5.0 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
CASTOR OIL (UNII: D5340Y2I9G)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:40046-0040-1	1 in 1 CARTON		
1	NDC:40046-0040-2	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

