

**TENDERTONE LIP BALM SPF 12- octinoxate, octisalate, and avobenzone lipstick
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.

**MAC
TENDERTONE
LIP BALM SPF 12**

ACTIVE INGREDIENTS

OCTINOXATE 7.50%, OCTISALATE 2.00%, AVOBENZONE 1.50%

WARNING

STOP USE IF IRRITATION OCCURS.

INGREDIENTS

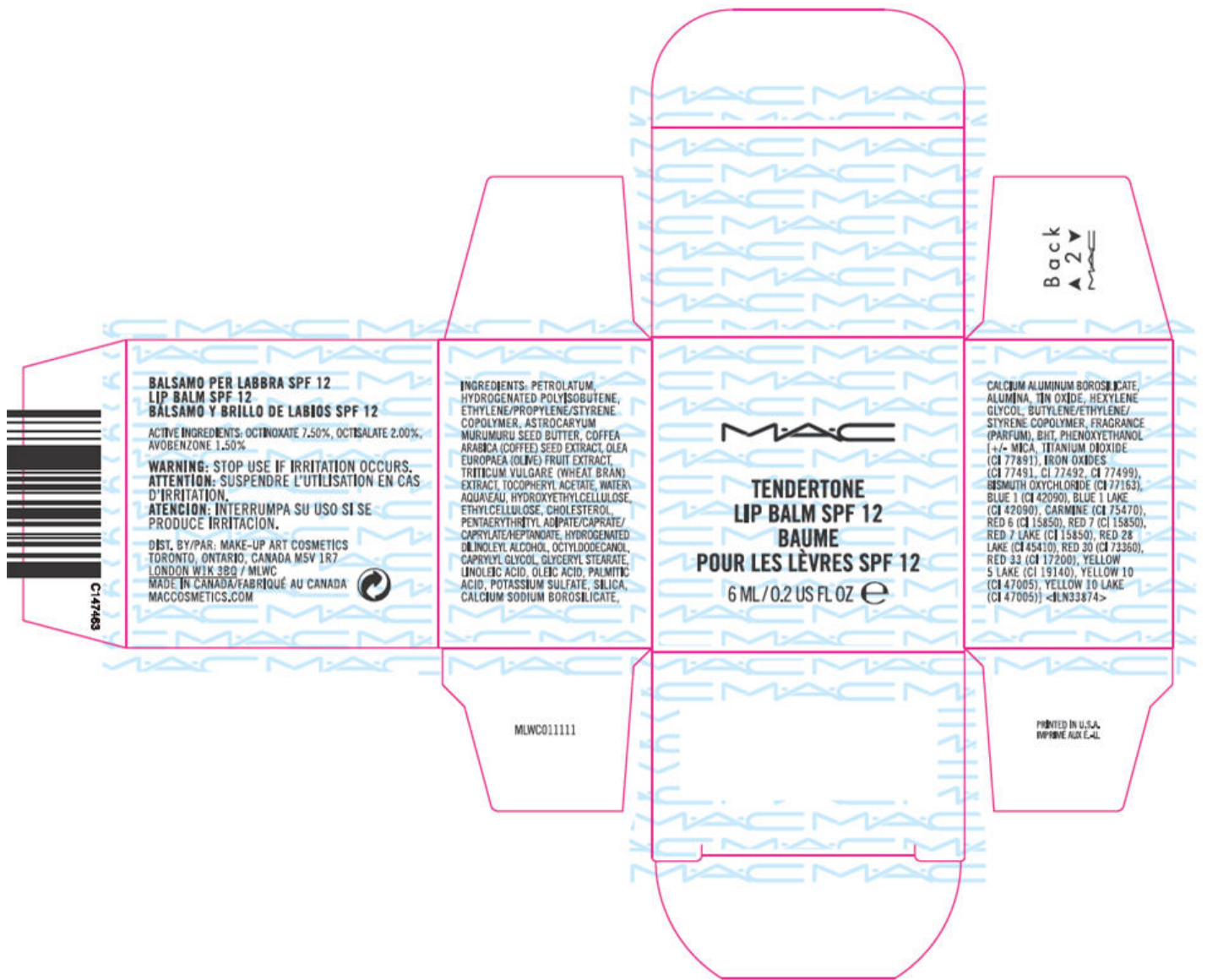
PETROLATUM, HYDROGENATED POLYISOBUTENE, ETHYLENE/PROPYLENE/STYRENE COPOLYMER, ASTROCARYUM MURUMURU SEED BUTTER, COFFEA ARABICA (COFFEE) SEED EXTRACT, OLEA EUROPAEA (OLIVE) FRUIT EXTRACT, TRITICUM VULGARE (WHEAT BRAN) EXTRACT, TOCOPHERYL ACETATE, WATER, HYDROXYETHYLCELLULOSE, ETHYLCELLULOSE, CHOLESTEROL, PENTAERYTHRITYL ADIPATE/CAPRATE/CAPRYLATE/HEPTANOATE, HYDROGENATED DILINOLEYL ALCOHOL, OCTYLDODECANOL, CAPRYLYL GLYCOL, GLYCERYL STEARATE, LINOLEIC ACID, OLEIC ACID, PALMITIC ACID, POTASSIUM SULFATE, SILICA, CALCIUM SODIUM BOROSILICATE, CALCIUM ALUMINUM BOROSILICATE, ALUMINA, TIN OXIDE, HEXYLENE GLYCOL, BUTYLENE/ETHYLENE/STYRENE COPOLYMER, FRAGRANCE, BHT, PHENOXYETHANOL [+/- MICA, TITANIUM DIOXIDE (CI 77891), IRON OXIDES (CI 77491, CI 77492, CI 77499), BISMUTH OXYCHLORIDE (CI 77163), BLUE 1 (CI 42090), BLUE 1 LAKE (CI 42090), CARMINE (CI 75470), RED 6 (CI 15850), RED 7 (CI 15850), RED 7 LAKE (CI 15850), RED 28 LAKE (CI 45410), RED 30 (CI 73360), RED 33 (CI 17200), YELLOW 5 LAKE (CI 19140), YELLOW 10 (CI 47005), YELLOW 10 LAKE (CI 47005)] <ILN33874>

DIST. BY: MAKE-UP ART COSMETICS
TORONTO, ONTARIO, CANADA M5V 1R7
LONDON W1K 3BQ / MLWC

PRINCIPAL DISPLAY PANEL - 6 ML Jar Carton

**MAC
TENDERTONE
LIP BALM SPF 12**

6 ML/0.2 US FL OZ e



TENDERTONE LIP BALM SPF 12

octinoxate, octisalate, and avobenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:40 46-00 30
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	2 mL in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1.5 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
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Petrolatum (UNII: 4T6H12BN9U)	
Astrocaryum Murumuru Seed Butter (UNII: 12V64UPU6R)	
Arabica Coffee Bean (UNII: 3SW678MX72)	
Black Olive (UNII: 2M6QWV94OC)	
Wheat Bran (UNII: 6L966A1IMR)	
Alpha-Tocopherol Acetate (UNII: 9E8X80D2L0)	
Water (UNII: 059QF0KO0R)	
Ethylcelluloses (UNII: 7Z8S9VYZ4B)	
Cholesterol (UNII: 97C5T2UQ7J)	
Octyldodecanol (UNII: 461N1O614Y)	
Caprylyl Glycol (UNII: 00YIU5438U)	
Glyceryl Monostearate (UNII: 230OU9XXE4)	
Linoleic Acid (UNII: 9KJL21T0QJ)	
Oleic Acid (UNII: 2UM9U37CP)	
Palmitic Acid (UNII: 2V16EO95H1)	
Potassium Sulfate (UNII: 1K573LC5TV)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Aluminum Oxide (UNII: LM26O6933)	
Stannic Oxide (UNII: KM7N50LOS6)	
Hexylene Glycol (UNII: KEH0A3F75J)	
Butylated Hydroxytoluene (UNII: 1P9D0Z171K)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Mica (UNII: V8A1AW0880)	
Titanium Dioxide (UNII: 15FIX9V2JP)	
Ferric Oxide Red (UNII: 1K09F3G675)	
Ferric Oxide Yellow (UNII: EX438O2MRT)	
Ferrosoferric Oxide (UNII: XM0M87F357)	
Bismuth Oxychloride (UNII: 4ZR792I587)	
FD&C Blue No. 1 (UNII: HBR47K3TBD)	
Cochineal (UNII: TZ8Z31B35M)	
D&C Red No. 6 (UNII: 481744AI4O)	
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)	
D&C Yellow No. 10 (UNII: 35SW5USQ3G)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:40046-0030-1	1 in 1 CARTON		
1		6 mL in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	01/01/2007	

Labeler - MAKEUP ART COSMETICS (010597206)**Establishment**

Name	Address	ID/FEI	Business Operations
ELGC Kabushiki Kaisha		712808195	RELABEL(40046-0030) , REPACK(40046-0030)

Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Pennsylvania Distribution Center 2 (PADC 2)		828534516	MANUFACTURE(40046-0030) , RELABEL(40046-0030) , REPACK(40046-0030)

Establishment

Name	Address	ID/FEI	Business Operations
ARAMIS, INC		042918826	MANUFACTURE(40046-0030)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS DISTRIBUTION CENTER		208579636	RELABEL(40046-0030) , REPACK(40046-0030)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		253616536	MANUFACTURE(40046-0030)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		255175580	MANUFACTURE(40046-0030)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		205952385	MANUFACTURE(40046-0030)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(40046-0030)

Establishment

Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(40046-0030)

Establishment

Name	Address	ID/FEI	Business Operations
NORTEC KEYSTONE		787336577	MANUFACTURE(40046-0030) , RELABEL(40046-0030) , REPACK(40046-0030)

Establishment

Name	Address	ID/FEI	Business Operations
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NORTHTEC BRISTOL		949264774	MANUFACTURE(40046-0030) , RELABEL(40046-0030) , REPACK(40046-0030)
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Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC KEYSTONE		618107429	MANUFACTURE(40046-0030) , RELABEL(40046-0030) , REPACK(40046-0030)

Establishment

Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(40046-0030)

Establishment

Name	Address	ID/FEI	Business Operations
Aveda Corporation		071352058	MANUFACTURE(40046-0030)

Revised: 1/2012

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