

**SUNTINTS LIQUID LIP BALM SPF 20- octinoxate, octisalate, avobenzone, homosalate, octocrylene 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.

ACTIVE INGREDIENTS: OCTINOXATE 7.50% [] OCTISALATE 5.00% [] AVOBENZONE 3.00%
[] HOMOSALATE 2.90% [] OCTOCRYLENE 2.70%

INACTIVE INGREDIENTS: OCTYLDODECANOL [] NEOPENTYL GLYCOL DIHEPTANOATE []
ETHYLCELLULOSE [] DIISOSTEARYL MALATE [] BUTYLOCTYL SALICYLATE []
DICAPRYLYL CARBONATE [] TOCOPHERYL ACETATE [] POLYGONUM CUSPIDATUM
ROOT EXTRACT [] DEXTRIN PALMITATE [] CALCIUM ALUMINUM BOROSILICATE []
CALCIUM SODIUM BOROSILICATE [] CAPRYLYL GLYCOL [] HEXYLENE GLYCOL [] SILICA
[] TIN OXIDE [] LINOLEIC ACID [] HYDROGENATED DILINOLEYL ALCOHOL [] VANILLIN []
PHENOXYETHANOL [] [+/- MICA [] IRON OXIDES (CI 77491, CI 77492, CI 77499) [] TITANIUM
DIOXIDE (CI 77891) [] BISMUTH OXYCHLORIDE (CI 77163) [] BLUE 1 LAKE (CI 42090) []
CARMINE (CI 75470) [] 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.

MAC

SUNTINTS SPF 20

LIQUID BALM

10 ML/ .33 FL OZ LIQ

MAKE UP ART COSMETICS, DIST

NY,NY 10022



SUNTINTS LIQUID LIP BALM SPF 20

octinoxate, octisalate, avobenzone, homosalate, octocrylene lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:40046-0034
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
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3.0 mL in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	2.9 mL in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2.7 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
OCTYLDODECANOL (UNII: 461N1O614Y)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
ETHYLCELLULOSES (UNII: 7Z8S9VYZ4B)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
POLYGONUM CUSPIDATUM ROOT (UNII: 7TRV45YZF7)	
CALCIUM ALUMINOSILICATE (UNII: 3L00JH8411)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STANNIC OXIDE (UNII: KM7N50LOS6)	
LINOLEIC ACID (UNII: 9KJL21T0QJ)	
VANILLIN (UNII: CHI530446X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:40046-0034-1	1 in 1 CARTON		
1	NDC:40046-0034-2	10 mL in 1 VIAL		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/01/2009	

Labeler - MAKEUP ART COSMETICS (010597206)

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
Estee Lauder Inc		042918826	manufacture

Establishment

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

Establishment

Name	Address	ID/FEI	Business Operations
Northtec Bristol		959338336	manufacture, relabel, repack

Establishment

Name	Address	ID/FEI	Business Operations
Northtec Keystone		943871157	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.		205952385	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Cosmetics, Ltd.		244669714	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 Centre		208579636	repack, relabel

Establishment

Name	Address	ID/FEI	Business Operations
ELGC K.K.		712808195	relabel, repack

Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder N.V.		370151326	manufacture

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
Pennsylvania Logistics Center (PALC)		078364654	repack, relabel

Revised: 4/2012

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