

**TIME ZONE LINE AND WRINKLE REDUCING CREME SPF 15 NORMAL COMBO SKIN-
octinoxate, octisalate, avobenzone cream
ESTEE LAUDER INC**

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%

INACTIVE INGREDIENTS: WATER [] BUTYLENE GLYCOL [] OCTYLDODECYL MYRISTATE [] GLYCERIN [] NEOPENTYL GLYCOL DIHEPTANOATE [] DIMETHICONE [] CETYL ALCOHOL [] PENTYLENE GLYCOL [] GLYCERYL STEARATE [] BEHENYL ALCOHOL [] YEAST EXTRACT\FAEX\EXTRAIT DE LEVURE [] PUNICA GRANATUM (POMEGRANATE) JUICE EXTRACT [] CUCUMIS SATIVUS (CUCUMBER) FRUIT EXTRACT [] HUMULUS LUPULUS (HOPS) EXTRACT [] SELAGINELLA TAMARISCINA (SPIKE MOSS) EXTRACT [] POLYGONUM CUSPIDATUM ROOT EXTRACT [] VITIS VINIFERA (GRAPE) SEED EXTRACT [] ROSMARINUS OFFICINALIS (ROSEMARY) EXTRACT [] CITRUS RETICULATA (TANGERINE) PEEL EXTRACT [] OLEA EUROPAEA (OLIVE) FRUIT EXTRACT [] TRITICUM VULGARE (WHEAT BRAN) EXTRACT [] HORDEUM VULGARE (BARLEY) EXTRACT\EXTRAIT D'ORGE [] TAMARINDUS INDICA SEED EXTRACT [] ARGANIA SPINOSA LEAF EXTRACT [] LAMINARIA SACCHARINA EXTRACT [] LARIX SIBIRICA WOOD EXTRACT [] CENTAURIUM ERYTHRAEA (CENTAURY) EXTRACT [] PADINA PAVONICA THALLUS EXTRACT [] HYDROLYZED RICE EXTRACT [] CAPRYLIC/CAPRIC/MYRISTIC/STEARIC TRIGLYCERIDE [] SIGESBECKIA ORIENTALIS EXTRACT [] CHOLESTEROL [] POLYETHYLENE [] PENTAERYTHRITYL TETRAETHYLHEXANOATE [] CAFFEINE [] LINOLEIC ACID [] HYDROGENATED LECITHIN [] LINOLENIC ACID [] PEG-100 STEARATE [] PHYTANTRIOL [] TREHALOSE [] PVP/HEXADECENE COPOLYMER [] ACETYL GLUCOSAMINE [] CREATINE [] HDI/PPG/POLYCAPROLACTONE CROSSPOLYMER [] CAPRYLYL GLYCOL [] ACRYLAMIDE/SODIUM ACRYLOYLDIMETHYLTAURATE COPOLYMER [] POLYSILICONE-11 [] HYALURONIC ACID [] ISOHEXADECANE [] ACETYL HEXAPEPTIDE-8 [] PROPYLENE GLYCOL DICAPRATE [] SODIUM PCA [] ADENOSINE PHOSPHATE [] HELIANTHUS ANNUUS (SUNFLOWER) SEEDCAKE [] POLYSORBATE 80 [] SODIUM HYALURONATE [] SILICA [] HEXYLENE GLYCOL [] NORDIHYDROGUAIARETIC ACID [] CYCLODEXTRIN [] POTASSIUM CARBOMER [] CARBOMER [] FRAGRANCE (PARFUM) [] ETHYLBISIMINOMETHYLGUAIACOL MANGANESE CHLORIDE [] DISODIUM EDTA [] PHENOXYETHANOL

WARNING: KEEP OUT OF EYES. STOP USE IF IRRITATION OCCURS.

KEEP OUT OF REACH OF CHILDREN

PRINCIPAL DISPLAY PANEL:

ESTEE LAUDER

TIME ZONE

LINE AND WRINKLE REDUCING CREAM

SPF 15

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
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3.0 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
SACCHAROMYCES LYSATE (UNII: R85W246Z1C)	
CUCUMBER (UNII: YY7C30VXJT)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
BARLEY (UNII: 5PWM7YLI7R)	
TAMARIND SEED (UNII: 6AHP8A7OML)	
SACCHARINA LATISSIMA WHOLE (UNII: RTR3OGP8ET)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
LINOLEIC ACID (UNII: 9KJL21T0QJ)	
TREHALOSE (UNII: B8WCK70T7I)	
CREATINE (UNII: MU72812GK0)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11559-737-01	1 in 1 CARTON		
1	NDC:11559-737-02	50 mL in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/01/2009	

Labeler - ESTEE LAUDER INC (005914387)**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

Revised: 7/2011

ESTEE LAUDER INC