

**TIME ZONE LINE AND WRINKLE REDUCING CREME SPF 15 FOR DRY SKIN- octsalate,
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: OCTISALATE 5.00% [] AVOBENZONE 3.00%

INGREDIENTS: WATER\AQUA\EAU [] DIMETHICONE [] BUTYROSPERMUM PARKII (SHEA BUTTER) [] POLYESTER-8 [] BUTYLENE GLYCOL [] DI-C12-15 ALKYL FUMARATE [] STEARETH-21 [] PENTAERYTHRITYL TETRAETHYLHEXANOATE [] SUCROSE [] CETYL ALCOHOL [] NEOPENTYL GLYCOL DIETHYLHEXANOATE [] HDI/PPG/POLYCAPROLACTONE CROSSPOLYMER [] GLYCERIN [] STEARETH-2 [] ACRYLAMIDE/SODIUM ACRYLOYLDIMETHYLAURATE COPOLYMER [] CUCUMIS SATIVUS (CUCUMBER) FRUIT EXTRACT [] ROSMARINUS OFFICINALIS (ROSEMARY) EXTRACT [] SELAGINELLA TAMARISCINA (SPIKE MOSS) EXTRACT [] CITRUS RETICULATA (TANGERINE) PEEL EXTRACT [] HUMULUS LUPULUS (HOPS) EXTRACT [] YEAST EXTRACT\FAEX\EXTRAIT DE LEVURE [] TRITICUM VULGARE (WHEAT BRAN) EXTRACT [] HORDEUM VULGARE (BARLEY) EXTRACT\EXTRAIT D'ORGE [] TAMARINDUS INDICA SEED EXTRACT [] ARGANIA SPINOSA LEAF EXTRACT [] HYDROLYZED RICE EXTRACT [] PADINA PAVONICA THALLUS EXTRACT [] LARIX SIBIRICA WOOD EXTRACT [] POLYGONUM CUSPIDATUM ROOT EXTRACT [] VITIS VINIFERA (GRAPE) SEED EXTRACT [] SIGESBECKIA ORIENTALIS (ST. PAUL'S WORT) EXTRACT [] PUNICA GRANATUM (POMEGRANATE) JUICE EXTRACT [] OLEA EUROPAEA (OLIVE) FRUIT EXTRACT [] CENTAURIUM ERYTHRAEA (CENTAURY) EXTRACT [] LAMINARIA SACCHARINA EXTRACT [] CHOLESTEROL [] CREATINE [] ADENOSINE PHOSPHATE [] HELIANTHUS ANNUUS (SUNFLOWER) SEEDCAKE [] CAFFEINE [] POLYETHYLENE [] PVP/HEXADECENE COPOLYMER [] CETYL DIMETHICONE [] ISOHEXADECANE [] DIPENTAERYTHRITYL TRI-POLYHYDROXYSTEARATE [] PPG-15 STEARYL ETHER [] POLYSILICONE-11 [] TOCOPHERYL ACETATE [] LINOLENIC ACID [] PHYTANTRIOL [] SODIUM HYALURONATE [] TREHALOSE [] ACETYL GLUCOSAMINE [] HYALURONIC ACID [] ETHYLHEXYLGLYCERIN [] ACETYL HEXAPEPTIDE-8 [] CAPRYLYL GLYCOL [] PROPYLENE GLYCOL DICAPRATE [] SODIUM PCA [] PROPYLENE GLYCOL HEPTANOATE [] POLYSORBATE 80 [] CYCLODEXTRIN [] LINOLEIC ACID [] ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER [] NEOPENTYL GLYCOL DIISOSTEARATE [] TROMETHAMINE [] HEXYLENE GLYCOL [] SILICA [] FRAGRANCE (PARFUM) [] NORDIHYDROGUAIARETIC ACID [] ETHYLBISIMINOMETHYLGUAIACOL MANGANESE CHLORIDE [] DISODIUM EDTA [] PHENOXYETHANOL [] POLYAMINOPROPYL BIGUANIDE [] MICA

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

Ingredient Name	Strength
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: HIE49ZZZ3T)	
MICA (UNII: V8A1AW0880)	
POLYAMINOPROPYL BIGUANIDE (UNII: 322U039GMF)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11559-728-01	1 in 1 CARTON		
1	NDC:11559-728-02	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