

DAYWEAR ADVANCED MULTI-PROTECTION ANTIOXIDANT CREME SPF 15 FOR DRY SKIN- octisalate, avobenzone, homosalate 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% [] HOMOSALATE 2.00%

INACTIVE INGREDIENTS: WATER\AQUA\EAU [] BUTYLOCTYL SALICYLATE []
POLYESTER-8 [] PETROLATUM [] BUTYLENE GLYCOL [] CETYL RICINOLEATE []
OCTYLDODECYL MYRISTATE [] STEARETH-21 [] STEARETH-2 []
CAPRYLIC/CAPRIC/MYRISTIC/STEARIC TRIGLYCERIDE [] DI-C12-15 ALKYL FUMARATE []
DIMETHICONE [] PSIDIUM GUAJAVA (GUAVA) FRUIT EXTRACT [] GENTIANA LUTEA
(GENTIAN) ROOT EXTRACT [] POLYGONUM CUSPIDATUM ROOT EXTRACT [] HORDEUM
VULGARE (BARLEY) EXTRACT\EXTRAIT D'ORGE [] LAMINARIA OCHROLEUCA EXTRACT
[] TRITICUM VULGARE (WHEAT) GERM EXTRACT [] FUMARIA OFFICINALIS
FLOWER/LEAF/STEM EXTRACT [] CITRUS MEDICA LIMONUM (LEMON) FRUIT EXTRACT []
HYDROLYZED RICE BRAN EXTRACT [] HYDROLYZED RICE EXTRACT [] ARTEMIA
EXTRACT [] ROSMARINUS OFFICINALIS (ROSEMARY) LEAF EXTRACT [] VITIS VINIFERA
(GRAPE) SEED EXTRACT [] STEARYL ALCOHOL [] BUTYROSPERMUM PARKII (SHEA
BUTTER) [] THERMUS THERMOPHILLUS FERMENT [] SORBITAN OLIVATE [] CAFFEINE []
PENTYLENE GLYCOL [] LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE []
BEHENYL ALCOHOL [] PANTETHINE [] TRIACONTANYL PVP [] ACRYLIC ACID/VP
CROSSPOLYMER [] ETHYLHEXYLGLYCERIN [] GLYCERIN [] LINOLEIC ACID []
POLYQUATERNIUM-51 [] CHOLESTEROL [] CETEARYL OLIVATE [] SQUALANE [] SODIUM
PCA [] UREA [] CAPRYLIC/CAPRIC TRIGLYCERIDE [] TOCOPHERYL ACETATE []
TETRAHEXYLDECYL ASCORBATE [] CITRIC ACID [] SODIUM HYALURONATE []
ERGOTHIONEINE [] GLYCYRRHETINIC ACID [] TREHALOSE [] LECITHIN []
HYDROGENATED LECITHIN [] PALMITOYL HYDROXYPROPYLTRIMONIUM
AMYLOPECTIN/GLYCERIN CROSSPOLYMER [] CYCLODEXTRIN []
NORDIHYDROGUAIARETIC ACID [] ASCORBYL TOCOPHERYL MALEATE [] SODIUM
HYDROXIDE [] FRAGRANCE (PARFUM) [] FUMARIC ACID [] PENTAERYTHRITYL TETRA-
DI-T-BUTYL HYDROXYHYDROCINNAMATE [] ETHYLBISIMINOMETHYLGUAIACOL
MANGANESE CHLORIDE [] DISODIUM EDTA [] BHT [] PHENOXYETHANOL [] BENZYL
SALICYLATE [] HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXALDEHYDE []
BUTYLPHENYL METHYLPROPIONAL [] LINALOOL [] MICA [] YELLOW 5 (CI 19140) [] BLUE
1 (CI 42090) [] CHROMIUM HYDROXIDE GREEN (CI 77289)

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

KEEP OUT OF REACH OF CHILDREN.

PRINCIPAL DISPLAY PANEL

ESTEE LAUDER

DAYWEAR

ADVANCED MULTI-PROTECTION ANTI-OXIDANT CREME

SPF 15

FOR DRY SKIN

1.7 FL OZ/50 ML
 ESTÉE LAUDER DISTR
 NY NY 10022



DAYWEAR ADVANCED MULTI-PROTECTION ANTIOXIDANT CREME SPF 15 FOR DRY SKIN
 octisalate, avobenzone, homosalate cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11559-007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
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	2.0 mL in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0K00R)			
PETROLATUM (UNII: 4T6H12BN9U)			
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)			
DIMETHICONE (UNII: 92RU3N3Y1O)			
SHEA BUTTER (UNII: K49155WL9Y)			
GLYCERIN (UNII: PDC6A3C0OX)			
CHOLESTEROL (UNII: 97C5T2UQ7J)			
SQUALANE (UNII: GW89575KF9)			
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)			
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)			
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)			
PHENOXYETHANOL (UNII: HIE492ZZ3T)			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11559-007-01	1 in 1 CARTON		
1	NDC:11559-007-02	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	09/01/2010	

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: 12/2010

ESTEE LAUDER INC