

DAYWEAR MULTI-PROTECTION ANTI-OXIDANT 24H-MOISTURE CREME BROAD SPECTRUM SPF 15 NORMAL/COMBINATION SKIN- avobenzone and octisalate 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.

DAYWEAR MULTI-PROTECTION ANTI-OXIDANT 24H-MOISTURE CREME BROAD SPECTRUM SPF 15 NORMAL/COMBINATION SKIN

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
Avobenzone 3.00%	Sunscreen
Octisalate 5.00%	Sunscreen

Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (see Directions) decreases the risk of skin cancer and early skin aging caused by the sun

Warnings

For external use only

Do not use on damaged or broken skin

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

For sunscreen use:

- apply liberally and evenly 15 minutes before sun exposure
- reapply at least every two hours
- use a water resistant sunscreen if swimming or sweating
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
 - limit time in the sun, especially from 10 a.m. - 2 p.m.
 - wear long-sleeved shirts, pants, hats and sunglasses

- children under 6 months of age: ask a doctor

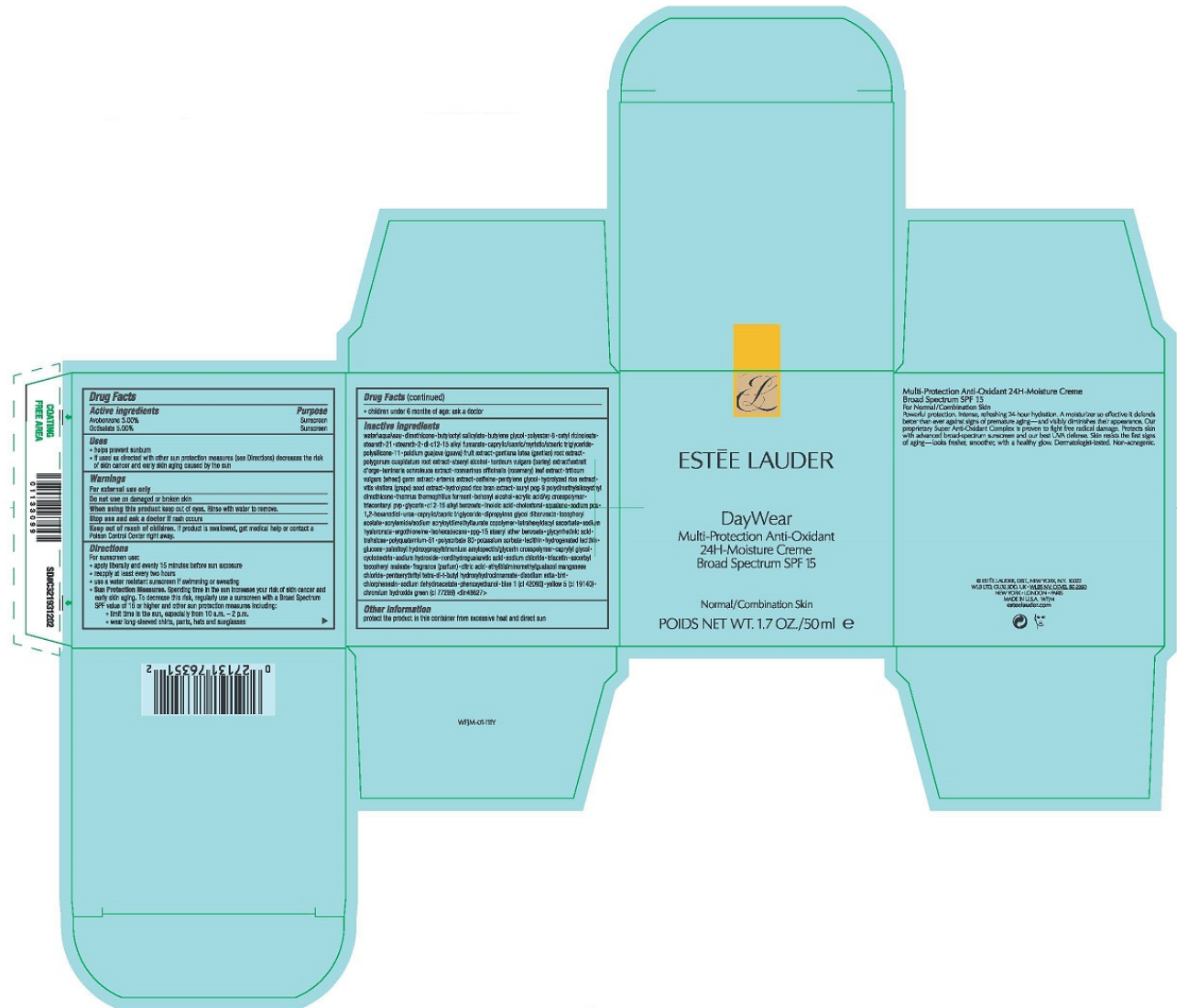
Inactive ingredients

water\aquaeau • dimethicone • butyloctyl salicylate • butylene glycol • polyester-8 • cetyl ricinoleate • steareth-21 • steareth-2 • di-c12-15 alkyl fumarate • caprylic/capric/myristic/stearic triglyceride • polysilicone-11 • psidium guajava (guava) fruit extract • gentiana lutea (gentian) root extract • polygonum cuspidatum root extract • stearyl alcohol • hordeum vulgare (barley) extract\extrait d'orge • laminaria ochroleuca extract • rosmarinus officinalis (rosemary) leaf extract • triticum vulgare (wheat) germ extract • artemia extract • caffeine • pentylene glycol • hydrolyzed rice extract • vitis vinifera (grape) seed extract • hydrolyzed rice bran extract • lauryl peg-9 polydimethylsiloxylethyl dimethicone • thermus thermophilus ferment • behenyl alcohol • acrylic acid/vp crosspolymer • triacontanyl pvp • glycerin • c12-15 alkyl benzoate • linoleic acid • cholesterol • squalane • sodium pca • 1,2-hexanediol • urea • caprylic/capric triglyceride • dipropylene glycol dibenzoate • tocopheryl acetate • acrylamide/sodium acryloyldimethyltaurate copolymer • tetrahexyldecyl ascorbate • sodium hyaluronate • ergothioneine • isohexadecane • ppg-15 stearyl ether benzoate • glycyrrhetic acid • trehalose • polyquaternium-51 • polysorbate 80 • potassium sorbate • lecithin • hydrogenated lecithin • glucose • palmitoyl hydroxypropyltrimonium amylopectin/glycerin crosspolymer • caprylyl glycol • cyclodextrin • sodium hydroxide • nordihydroguaiaretic acid • sodium chloride • triacetin • ascorbyl tocopheryl maleate • fragrance (parfum) • citric acid • ethylbisiminomethylguaiacol manganese chloride • pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate • disodium edta • bht • chlorphenesin • sodium dehydroacetate • phenoxyethanol • blue 1 (ci 42090) • yellow 5 (ci 19140) • chromium hydroxide green (ci 77289) <iln48627>

Other information

protect the product in this container from excessive heat and direct sun

PRINCIPAL DISPLAY PANEL - 50 ml Jar Carton



ESTÉE LAUDER

DayWear

Multi-Protection

Anti-Oxidant

24H-Moisture Creme

Broad Spectrum SPF 15

NORMAL/COMBINATION SKIN

POIDS NET WT. 1.7 OZ. / 50 ml e

DAYWEAR MULTI-PROTECTION ANTI-OXIDANT 24H-MOISTURE CREME BROAD SPECTRUM SPF 15 NORMAL/COMBINATION SKIN

avobenzone and octisalate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11559-049
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
BUTYLENE GLYCOL (UNII: 3XUS85KORA)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)	
CETYL RICINOLEATE (UNII: 1P677500YD)	
STEARETH-21 (UNII: 53J3F32P58)	
STEARETH-2 (UNII: V56DFE46J5)	
DI-C12-15 ALKYL FUMARATE (UNII: A1CB3Z898P)	
CAPRYLIC/CAPRIC/PALMITIC/STEARIC TRIGLYCERIDE (UNII: ZF29F7IK5I)	
GUAVA (UNII: 74O70D6VG0)	
GENTIANA LUTEA ROOT (UNII: S72O3284MS)	
REYNOUTRIA JAPONICA ROOT (UNII: 7TRV45YZF7)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
BARLEY (UNII: 5PVM7YLI7R)	
LAMINARIA OCHROLEUCA (UNII: 4R2124HE76)	
ROSEMARY (UNII: IJ67X351P9)	
WHEAT GERM (UNII: YR3G369F5A)	
FUMARIA OFFICINALIS FLOWERING TOP (UNII: VH659J61ZL)	
CAFFEINE (UNII: 3G6A5W338E)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
RICE GERM (UNII: 7N2B70SFEZ)	
VITIS VINIFERA SEED (UNII: C34U15ICXA)	
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)	
THERMUS THERMOPHILUS LYSATE (UNII: 775R692494)	
DOCOSANOL (UNII: 9G1OE216XY)	
TRICONTANYL POVIDONE (UNII: N0SS3Q238D)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
LINOLEIC ACID (UNII: 9KJL21T0QJ)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
SQUALANE (UNII: GW89575KF9)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
UREA (UNII: 8W8T17847W)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	

DIPROPYLENE GLYCOL DIBENZOATE (UNII: 60A5ZDY41O)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
ERGOTHIONEINE (UNII: BDZ3DQM98W)
ISOHEXADECANE (UNII: 918X1OUF1E)
PPG-15 STEARYL ETHER BENZOATE (UNII: 80D2J6361M)
ENOXOLONE (UNII: P540XA09DR)
TREHALOSE (UNII: B8WCK70T7I)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
SODIUM HYDROXIDE (UNII: 55X04QC32I)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
ASCORBYL TOCOPHERYL MALEATE (UNII: D2G6259XR5)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
ETHYLBISIMINOMETHYLGUAIACOL MANGANESE CHLORIDE (UNII: SM5YJ88LTU)
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
SODIUM DEHYDROACETATE (UNII: 8W46YN971G)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
CHROMIUM HYDROXIDE GREEN (UNII: RV8FT8XF5R)
CHLORPHENESIN (UNII: I670DAL4SZ)
TRIACETIN (UNII: XHX3C3X673)
NORDIHYDROGUAIARETIC ACID, (+/-)- (UNII: 7PZ73W4ZNR)
.BETA.-CYCLODEXTRIN SULFOBUTYL ETHER (UNII: H1HJ8WR7WG)
TRIMETHYLPENTANEDIOL/ADIPIC ACID/GLYCERIN CROSSPOLYMER (25000 MPA.S) (UNII: 587WKM3S9Q)
GLUCOSE 1,6-BISPHOSPHATE (UNII: DRX17R6AM2)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
POLYQUATERNIUM-51 (2-METHACRYLOYLOXYETHYL PHOSPHORYLCHOLINE/N-BUTYL METHACRYLATE; 3:7) (UNII: EL9825H96J)
ACRYLAMIDE (UNII: 20R035KLCI)
ACRYLIC ACID (UNII: J94PBK7X8S)
RICE BRAN (UNII: R60QEP13IC)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11559-049-01	1 in 1 CARTON	12/01/2017	
1		50 mL in 1 JAR; Type 0: Not a Combination Product		
2	NDC:11559-049-02	1 in 1 CARTON	12/01/2022	
3		15 mL in 1 JAR; Type 0: Not a Combination		

2		Product	
3	NDC:11559-049-03	30 mL in 1 JAR; Type 0: Not a Combination Product	12/01/2022
4	NDC:11559-049-04	7 mL in 1 JAR; Type 0: Not a Combination Product	12/01/2022

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	12/01/2017	

Labeler - ESTEE LAUDER INC (005914387)

Registrant - Estee Lauder Companies Inc. (790802086)

Establishment

Name	Address	ID/FEI	Business Operations
PALC		078364654	pack(11559-049) , label(11559-049)

Establishment

Name	Address	ID/FEI	Business Operations
The Estee Lauder Inc		802599436	manufacture(11559-049) , pack(11559-049) , label(11559-049)

Establishment

Name	Address	ID/FEI	Business Operations
Northtec LLC		943871157	pack(11559-049) , label(11559-049)

Establishment

Name	Address	ID/FEI	Business Operations
PADC 1		949264774	pack(11559-049) , label(11559-049)

Revised: 8/2023

ESTEE LAUDER INC