

**ESTEE LAUDER MULTI-DEFENSE AQUA UV GEL BROAD SPECTRUM SPF 50-  
avobenzene, homosalate, octisalate, octocrylene, and oxybenzone lotion  
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.*

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**ESTÉE LAUDER MULTI-DEFENSE AQUA UV GEL BROAD SPECTRUM SPF 50**

**Drug Facts**

<b>Active ingredients</b>	<b>Purpose</b>
Avobenzene 3.0%	Sunscreen
Homosalate 5.0%	Sunscreen
Octisalate 4.5%	Sunscreen
Octocrylene 2.8%	Sunscreen
Oxybenzone 3.0%	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 • alcohol denat. • butylene glycol • tocopheryl acetate • sodium hyaluronate • camellia sinensis (green tea) leaf extract • anthemis nobilis (chamomile) flower extract • algae extract • triticum vulgare (wheat) germ extract • laminaria ochroleuca extract • polygonum cuspidatum root extract • squalane • hordeum vulgare (barley) extract\extrait d'orge • lillium tigrinum extract • opuntia tuna extract • caffeine • acrylates copolymer • caprylic/capric triglyceride • caprylyl glycol • cholesterol • ergothioneine • glycerin • sucrose • alcaligenes polysaccharides • thermus thermophilus ferment • sorbitan sesquiisostearate • tetrahexyldecyl ascorbate • hexylene glycol • acrylates/ beheneth-25 methacrylate copolymer • sodium hydroxide • dehydroxanthan gum • dipropylene glycol • carbomer • ppg-8-ceteth-20 • dextrin palmitate • cyclodextrin • acrylates/c10-30 alkyl acrylate crosspolymer • sorbeth-30 tetrastearate • glyceryl stearate • polymethylsilsesquioxane • ammonium acryloyldimethyltaurate/vp copolymer • bht • ethylbisiminomethylguaiacol manganese chloride • disodium edta • phenoxyethanol  
<iln47518>

### **Other information**

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

### **PRINCIPAL DISPLAY PANEL - 30 ml Tube Carton**

ESTÉE LAUDER

Perfectionist Pro  
Multi-Defense Aqua UV Gel  
Broad Spectrum SPF 50  
8 Anti-Oxidants

All Skintypes

1 FL. OZ. LIQ./30 ml e

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**Drug Facts**

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**Directions**

For sunscreen use:

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- 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/aqua/eau • alcohol denat. • butylene glycol • tocopheryl acetate •

**Drug Facts (continued)**

sodium hyaluronate • camellia sinensis (green tea) leaf extract • anthemis nobilis (chamomile) flower extract • algae extract • triticum vulgare (wheat) germ extract • laminaria ochroleuca extract • polygonum cuspidatum root extract • squalane • hordeum vulgare (barley) extract/extrait d'orge • lillium tigrinum extract • opuntia tuna extract • caffeine • acrylates copolymer • caprylic/capric triglyceride • caprylyl glycol • cholesterol • ergothioneine • glycerin • sucrose • alcaligenes polysaccharides • thermus thermophilus ferment • sorbitan sesquiossearate • tetrahexyldecyl ascorbate • hexylene glycol • acrylates/beheneth-25 methacrylate copolymer • sodium hydroxide • dehydroxanthan gum • dipropylene glycol • carbomer • ppg-8-ceteth-20 • dextrin palmitate • cyclodextrin • acrylates/c10-30 alkyl acrylate crosspolymer • sorbeth-30 tetraiossearate • glyceryl stearate • polymethylsilsesquioxane • ammonium acryloyldimethyltaurate/vp copolymer • bht • ethylbisiminomethylgualacol manganese chloride • disodium edta • phenoxyethanol <ln47518>

**Other information**

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



ESTÉE LAUDER

Perfectionist Pro  
Multi-Defense Aqua UV Gel  
Broad Spectrum SPF 50  
8 Anti-Oxidants

All Skintypes

1 FL. OZ. LIQ./30ml e

**Multi-Defense Aqua UV Gel Broad Spectrum SPF 50 For All Skintypes**

Professionally inspired next-generation protection: this powerful treatment helps safeguard the healthy beauty of your skin with a hybrid 3-in-1 defense for our most comprehensive, holistic protection ever. This Multi-Defense formula fights the visible effects of indoor and outdoor environmental assaults:

**Inhibits UV Damage:** Creates an invisible veil with SPF 50 to help protect against broad spectrum UVA/UVB exposure. This patent-pending formula, also featuring Tiger Lily Extract, helps skin continue to maintain its natural firmness.

**Neutralizes Indoor/Outdoor Pollution:** A precise combination of 8 potent antioxidants helps fight visible damage from unavoidable environmental aggressors like ozone, smoke, infrared (IR) and microdust.

**Strengthens Skin's Barrier:** Advanced fortifiers help seal in moisture, which can help prevent dehydration from external causes such as heating and air conditioning. Strengthens skin with all-day moisture.

The water-light gel emulsion applies with a refreshing burst of hydration. Absorbs quickly, leaving an invisible level of protection. Non-greasy, non-sticky. Won't clog pores. Leaves skin more radiant, smooth and protected, creating an ideal base for makeup.

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NEW YORK, N.Y. 10022  
WLS LTD. GU32 3DD, UK  
WLS NV, Oevel, BE-2260  
NEW YORK • LONDON • PARIS  
MADE IN BELGIUM P7X4  
estelauder.com



FPO/UPC

P7X4-01-1111

# ESTEE LAUDER MULTI-DEFENSE AQUA UV GEL BROAD SPECTRUM SPF 50

avobenzone, homosalate, octisalate, octocrylene, and oxybenzone lotion

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11559-060
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	50 mg in 1 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	45 mg in 1 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	28 mg in 1 mL
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	30 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>ETHYLBISIMINOMETHYLGUAIACOL MANGANESE CHLORIDE</b> (UNII: SM5YJ88LTU)	
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>1,2-BUTANEDIOL</b> (UNII: RUN0H01QEU)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)	
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)	
<b>CHAMAEMELUM NOBILE FLOWER</b> (UNII: O2T154T6OG)	
<b>SARGASSUM FILIPENDULA</b> (UNII: 55P66J5H7N)	
<b>WHEAT GERM</b> (UNII: YR3G369F5A)	
<b>LAMINARIA OCHROLEUCA</b> (UNII: 4R2124HE76)	
<b>REYNOUTRIA JAPONICA ROOT</b> (UNII: 7TRV45YZF7)	
<b>SQUALANE</b> (UNII: GW89575KF9)	
<b>HORDEUM VULGARE ROOT</b> (UNII: 790S39483Z)	
<b>LILIUM LANCIFOLIUM BULB</b> (UNII: 47Z05W73EZ)	
<b>OPUNTIA TUNA WHOLE</b> (UNII: DI94T5T0ZY)	
<b>CAFFEINE</b> (UNII: 3G6A5W338E)	
<b>BUTYL ACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID COPOLYMER (18000 MW)</b> (UNII: JZ1374NL9E)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>CHOLESTEROL</b> (UNII: 97C5T2UQ7J)	

<b>ERGOTHIONEINE</b> (UNII: BDZ3DQM98W)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>SUCROSE</b> (UNII: C151H8M554)
<b>ALCALIGENES FAECALIS</b> (UNII: 05KB30NGW2)
<b>THERMUS THERMOPHILUS LYSATE</b> (UNII: 775R692494)
<b>SORBITAN SESQUIISOSTEARATE</b> (UNII: VU97D01BF9)
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)
<b>HEXYLENE GLYCOL</b> (UNII: KEH0A3F75J)
<b>BEHENETH-25 METHACRYLATE</b> (UNII: 108R05PWG6)
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)
<b>DEHYDROXANTHAN GUM</b> (UNII: 63ZP7I1BQO)
<b>DIPROPYLENE GLYCOL</b> (UNII: E107L85C40)
<b>CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE</b> (UNII: 0A5MM307FC)
<b>PPG-2-CETETH-9</b> (UNII: 1OTA54V264)
<b>DEXTRIN PALMITATE (CORN; 20000 MW)</b> (UNII: 89B2BSF9I3)
<b>BETADEX</b> (UNII: JV039JZZ3A)
<b>CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED)</b> (UNII: 59TL3WG5CO)
<b>PEG-10 SORBITAN LAURATE</b> (UNII: 4Z93U4C2WN)
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)
<b>POLYMETHYLSILSESQUIOXANE (4.5 MICRONS)</b> (UNII: 59Z907ZB69)
<b>AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER</b> (UNII: W59H9296ZG)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11559-060-01	1 in 1 CARTON	05/08/2020	
1		30 mL in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	05/04/2020	

**Labeler** - ESTEE LAUDER INC (005914387)

**Registrant** - Estee Lauder Companies Inc. (790802086)

### Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder N.V.		370151326	manufacture(11559-060) , pack(11559-060) , label(11559-060)