

**RE NUTRIV RADIANT UV BASE BROAD SPECTRUM SPF 50- homosalate , octyl salicylate, avobenzene, oxybenzone, octocrylene 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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**DRUG FACTS**

**ACTIVE INGREDIENTS:**

AVOBENZONE 3.00%  
HOMOSALATE 5.00%  
OCTOCRYLENE 2.70%  
OCTISALATE 5.00%  
OXYBENZONE 3.00%

**PURPOSE**

SUNSCREEN

**USE**

HELPS PREVENT SUNBURN

**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 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:

- o limit time in the sun, especially from 10 a.m.–2 p.m.
- o wear long-sleeved shirts, pants, hats and sunglasses
- \* children under 6 months of age: ask a doctor

## **INACTIVE INGREDIENTS**

WATER\AQUA\EAU [] BUTYLOCTYL SALICYLATE [] METHYL TRIMETHICONE []  
NEOPENTYL GLYCOL DIHEPTANOATE [] ALEURITES MOLUCCANA (KUKUI) SEED OIL []  
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE [] PEG-100 STEARATE []  
BUTYLENE GLYCOL [] DIPENTAERYTHRITYL TRI-POLYHYDROXYSTEARATE []  
GLYCERYL STEARATE [] ALGAE EXTRACT [] LAMINARIA OCHROLEUCA EXTRACT []  
LAMINARIA DIGITATA EXTRACT [] CETYL ALCOHOL [] CAFFEINE [] HYDROLYZED  
WHEAT PROTEIN [] VP/EICOSENE COPOLYMER [] PEARL POWDER [] GOLD [] SODIUM  
HYALURONATE [] ERGOTHIONEINE [] STEARIC ACID [] DEHYDROXANTHAN GUM []  
POTASSIUM CETYL PHOSPHATE [] ETHYLHEXYLGLYCERIN [] AMMONIUM  
ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER [] SACCHARIDE ISOMERATE []  
CAPRYLYL GLYCOL [] GLYCERIN [] SORBITOL [] SILICA [] CAPRYLIC/CAPRIC  
TRIGLYCERIDE [] FRAGRANCE (PARFUM) [] DISODIUM EDTA [] CITRIC ACID []  
PHENOXYETHANOL [] SODIUM DEHYDROACETATE [] MICA [] TITANIUM DIOXIDE (CI  
77891) [] RED 33 (CI 17200) [] BLUE 1 (CI 42090)

## **OTHER INFORMATION**

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

PRINCIPAL DISPLAY PANEL:

ESTEE LAUDER

RE-NUTRIV

RADIANT UV BASE

BROAD SPECTRUM

SPF 50

1FL OZ LIQ / 30 ML

ESTEE LAUDER DIST  
NY, NY 10022

**Drug Facts**

Active Ingredients	Purpose
Avobenzone 3.00%	Sunscreen
Homosalate 5.00%	Sunscreen
Octocrylene 2.70%	Sunscreen
Octyl Salicylate 5.00%	Sunscreen
Oxybenzone 3.00%	Sunscreen

**Use**  
helps prevent sunburn

**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 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 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 • butyloctyl salicylate • methyl trimethicone • neopentyl glycol diheptanoate •

**Drug Facts (continued)**

aleurites moluccana (kukui) seed oil • lauryl peg-9 polydimethylsilyloxyethyl dimethicone-peg-100 stearate • butylene glycol • dipentaerythrityl tri-polyhydroxystearate • glyceryl stearate • algae extract • laminaria ochroleuca extract • laminaria digitata extract • cetyl alcohol • caffeine • hydrolyzed wheat protein • vp/decosene copolymer • pearl powder • gold • sodium hyaluronate • ergothioneine • stearic acid • dehydroxanthan gum • potassium cetyl phosphate • ethylhexylglycerin • ammonium acryloyldimethylsulfonate copolymer • saccharide isomerate • caprylyl glycol • glycerin • sorbitol • silica • caprylyl capric triglyceride • fragrance (parfum) • disodium edta • citric acid • phenoxethanol • sodium dehydroacetate • mica • titanium dioxide (ci 77891) • red 33 (ci 17200) • blue 1 (ci 42090) <ln37271>

**Other information**

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



ESTÉE LAUDER  
Re-Nutriv

Radiant UV Base  
Broad Spectrum  
SPF 50

1 FL. OZ. LIQ./30 ml e

**Radiant UV Base**

Radiant UV Base with exclusive soft-focus optics instantly creates an even, luminous look and brings out the radiant best in skin tones. Skin is immediately hydrated, enhancing makeup application. Radiant UV Base glides on and absorbs quickly, minimizing imperfections and leaving a radiant veil of protection as powerful as it is invisible. SPF 50 helps protect against UVA and UVB rays to reduce the aging effects of everyday exposure. Every drop is fortified with Life-Renewing Molecules™, the secret strength behind Re-Nutriv, helping repair, recharge and restore skin's energized, radiant appearance.

To use: Apply as last step of AM skincare.

*Estée Lauder*

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NEW YORK, N.Y. 10022  
LONDON W1K 3BQ  
MADE IN BELGIUM W/LQ  
esteeauder.com

**RE NUTRIV RADIANT UV BASE BROAD SPECTRUM SPF 50**

homosalate, octyl salicylate, avobenzone, oxybenzone, octocrylene lotion

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11559-017
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	5.0 mL in 100 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5.0 mL in 100 mL

<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3.0 mL in 100 mL
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	3.0 nmol in 100 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2.7 mL in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0K00R)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>METHYL TRIMETHICONE</b> (UNII: S73ZQ10GXM)	
<b>NEOPENTYL GLYCOL DIHEPTANOATE</b> (UNII: 5LKW3C543X)	
<b>KUKUI NUT</b> (UNII: J87WJ3E7VW)	
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>NORI</b> (UNII: 477TV3P5UX)	
<b>LAMINARIA DIGITATA</b> (UNII: 15E7C67EE8)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>CAFFEINE</b> (UNII: 3G6A5W338E)	
<b>HYDROLYZED WHEAT PROTEIN (ENZYMATIC, 3000 MW)</b> (UNII: J2S07SB0YL)	
<b>CALCIUM CARBONATE</b> (UNII: H0G9379FGK)	
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)	
<b>ERGOTHIONEINE</b> (UNII: BDZ3DQM98W)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>POTASSIUM CETYL PHOSPHATE</b> (UNII: 03KCY6P7UT)	
<b>SACCHARIDE ISOMERATE</b> (UNII: W8K377W98I)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>SODIUM DEHYDROACETATE</b> (UNII: 8W46YN971G)	
<b>MICA</b> (UNII: V8A1AW0880)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11559-017-01	1 in 1 CARTON		
1	NDC:11559-017-02	30 mL in 1 TUBE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	04/01/2012	

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

### Establishment

Name	Address	ID/FEI	Business Operations
Len-Ron Manufacturing Division of Aramis Inc.		809771152	manufacture

### Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Inc		042918826	manufacture

### Establishment

Name	Address	ID/FEI	Business Operations
Northtec Keystone		949264774	manufacture, relabel, repack

### Establishment

Name	Address	ID/FEI	Business Operations
Northtec Bristol		959338336	manufacture, relabel, repack

### Establishment

Name	Address	ID/FEI	Business Operations
Northtec Keystone		943871157	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.		205952385	manufacture

### Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Cosmetics, Ltd.		244669714	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 Centre		208579636	repack, relabel

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
ELGC K.K.		712808195	relabel, repack

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Estee Lauder N.V.		370 151326	manufacture

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Whitman Laboratories Ltd.		216866277	manufacture

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Aveda Corporation		071352058	manufacture

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Pennsylvania Logistics Center (PALC)		078364654	repack, relabel

Revised: 4/2012

ESTEE LAUDER INC