

RESILIENCE MULTI-EFFECT TRI-PEPTIDE FACE AND NECK CREME BROAD SPECTRUM SPF 15- avobenzone, octisalate, and octocrylene 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.

RESILIENCE MULTI-EFFECT TRI-PEPTIDE FACE AND NECK CRÈME BROAD SPECTRUM SPF 15

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
Avobenzone 3.0%	Sunscreen
Octisalate 4.5%	Sunscreen
Octocrylene 2.7%	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/aqua/eau • neopentyl glycol diheptanoate • cetyl alcohol • glycerin • butyloctyl salicylate • pentaerythrityl tetraethylhexanoate • polyethylene • di-c12-15 alkyl fumarate • petrolatum • hydrogenated lecithin • butylene glycol • propanediol • hydrogenated polyisobutene • octyldodecyl

myristate • hexyldecyl stearate • behenyl alcohol • cucumis melo (melon) fruit extract • polygonum aviculare extract • myrtus communis leaf extract • laminaria digitata extract • acetyl hexapeptide-8 • tetradecyl aminobutyrylvalylaminobutyric urea trifluoroacetate • lactoperoxidase • glucose oxidase • cholesterol • propylene glycol dicaprylate • aminopropyl ascorbyl phosphate • sodium hyaluronate • glucose • algae extract • artemia extract • acetyl glucosamine • sigesbeckia orientalis (st. paul's wort) extract • glyceryl stearate • persea gratissima (avocado) oil • dimethicone • c12-16 alcohols • trehalose • ethylhexylglycerin • peg-100 stearate • caffeine • palmitic acid • glycine soja (soybean) sterols • caprylyl glycol • isohehexadecane • polymethyl methacrylate • trifluoroacetyl tripeptide-2 • tocopheryl acetate • zinc pca • polysilicone-11 • polysorbate 80 • yeast extract\faex\extrait de levure • potato starch modified • decarboxy carnosine hcl • xanthan gum • fragrance (parfum) • sodium hydroxide • potassium sulfate • acrylamide/sodium acryloyldimethyltaurate copolymer • dextran • hexylene glycol • disodium edta • bht • potassium sorbate • phenoxyethanol • red 4 (ci 14700) • mica • titanium dioxide (ci 77891) <iln44790>

Other information

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

PRINCIPAL DISPLAY PANEL - 50 ml Jar Carton

ESTÉE LAUDER

Resilience Multi-Effect

Tri-Peptide Face and Neck Creme

Broad Spectrum SPF 15

Normal/Combination Skin

NET WT. 1.7 OZ./50 ml e



ESTÉE LAUDER

Resilience Multi-Effect
Tri-Peptide Face and Neck Creme
Broad Spectrum SPF 15

Normal/Combination Skin

POIDS NET WT. 1.7 OZ./50ml e

Tri-Peptide Face and Neck Creme
Broad Spectrum SPF 15
For Normal/Combination Skin

Look as young as you feel. With this intensely nourishing, multi-effect creme, skin is plumped, supple—more resilient. Lines and wrinkles appear reduced. Radiance is recharged. With our advanced Tri-Peptide Complex, this silky formula targets skin's natural collagen so it looks significantly smoother. Broad Spectrum SPF 15 helps protect against UV damage while anti-oxidants help protect against free radicals to help skin maintain its natural firmness and tone. And, with IR-Defense Technology, it helps defend skin's moisture barrier against damage caused by infrared rays. Pair with Resilience Multi-Effect Night for a 24-hour youth-infusing system.

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W.B. LTD. GL32 3DD, UK • NEW YORK • LONDON • PARIS
MADE IN U.S.A. PIC3 estee.com



COATING
FREE AREA

0 1 0 3 6 1 7 0

SD#G321931202

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Drug Facts (continued)

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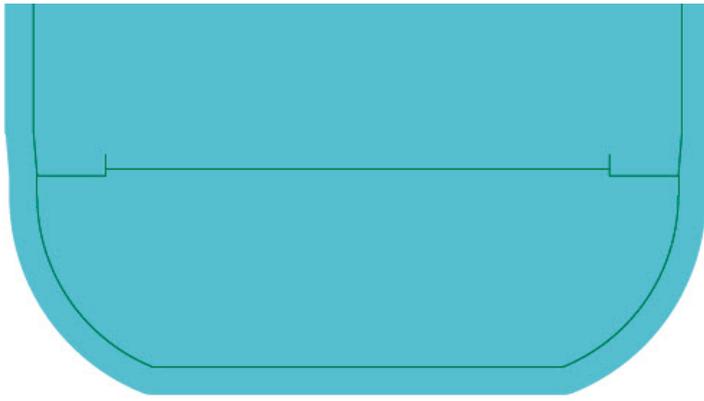
water/aqua/eau • neopentyl glycol diheptanoate • cetyl alcohol • glycerin • butylcetyl salicylate • pentaerythrityl tetraethylhexanoate • polyethylene di-c12-15 alkyl fumarate • petrolatum • hydrogenated lecithin • butylene glycol • propanediol • hydrogenated polyisobutene • octyldodecyl myristate • hexyldecyl stearate • behenyl alcohol • cucumis melo (melon) fruit extract • polygonum aviculare extract • myrtus communis leaf extract • laminaria digitata extract • acetyl hexapeptide-8 • tetradecyl aminobutyrylvalylaminobutyric urea trifluoroacetate • lactoperoxidase • glucose oxidase • cholesterol • propylene glycol dicaprylate • aminopropyl ascorbyl phosphate • sodium hyaluronate • glucose • algae extract • artemia extract • acetyl glucosamine • sigesbeckia orientalis (st. paul's wort) extract • glyceryl stearate • persea gratissima (avocado) oil • dimethicone • c12-16 alcohols • trehalose • ethylhexylglycerin • peg-100 stearate • caffeine • palmitic acid • glycine soja (soybean) sterols • capryl glycol • isohexadecane • polymethyl methacrylate • trifluoroacetyl tripeptide-2 • tocopheryl acetate • zinc pca • polysilicone-11 • polysorbate 80 • yeast extract/leax/extract de levure • potato starch modified • decarboxy carnosine hcl • xanthan gum • fragrance (parfum) • sodium hydroxide • potassium sulfate • acrylamide/sodium acryloyldimethyltaurate copolymer • dextran • hexylene glycol • disodium edta • bht • potassium sorbate • phenoxyethanol • red 4 (ci 14700) • mica • titanium dioxide (ci 77891) <ln44790>

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PIG3-01-1116



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avobenzone, octisalate, and octocrylene cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11559-052
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.03 g in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	0.045 g in 1 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	0.027 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
PENTAERYTHRITYL TETRAETHYLHEXANOATE (UNII: XJ7052W897)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
DI-C12-15 ALKYL FUMARATE (UNII: A1CB3Z898P)	
PETROLATUM (UNII: 4T6H12BN9U)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
PROPANEDIOL (UNII: 5965N8W85T)	
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	
OCTYLDODECYL MYRISTATE (UNII: S013N99GR8)	
HEXYLDECYL STEARATE (UNII: OJX2P28Y14)	
DOCOSANOL (UNII: 9G10E216XY)	
MELON (UNII: 5CIT1X6U5V)	
ACETYL HEXAPEPTIDE-8 (UNII: L4EL31FWIL)	

MYELOPEROXIDASE (UNII: JQZ6YM58U5)	
GLUCOSE OXIDASE (UNII: 0T8392U5N1)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
PROPYLENE GLYCOL DICAPRYLATE (UNII: 581437HWX2)	
AMINOPROPYL ASCORBYL PHOSPHATE (UNII: 290O2PQ83R)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
ANHYDROUS DEXTROSE (UNII: 5SLOG7R0OK)	
N-ACETYLGALUCOSAMINE (UNII: V956696549)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
AVOCADO (UNII: SDS87L369F)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
C12-16 ALCOHOLS (UNII: S4827SZE3L)	
TREHALOSE (UNII: B8WCK70T7I)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PEG-100 STEARATE (UNII: YD01N1999R)	
CAFFEINE (UNII: 3G6A5W338E)	
PALMITIC ACID (UNII: 2V16EO95HI)	
SOY STEROL (UNII: PL360EPO9J)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ISOHEXADECANE (UNII: 918X10UF1E)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
ZINC PIDOLATE (UNII: C32PQ86DH4)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
STARCH, POTATO (UNII: 8I089SAHBT)	
DECARBOXY CARNOSINE HYDROCHLORIDE (UNII: 6X7K9I5QR7)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
POTASSIUM SULFATE (UNII: 1K573LC5TV)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11559-052-01	1 in 1 CARTON	11/01/2018	
1		50 mL in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	11/01/2018	

Labeler - ESTEE LAUDER INC (005914387)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COMPANY, THE		828534516	RELABEL(11559-052) , REPACK(11559-052)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(11559-052)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		202952982	MANUFACTURE(11559-052)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(11559-052)

Establishment

Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(11559-052)

Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC INC		943871157	RELABEL(11559-052) , REPACK(11559-052)

Establishment

Name	Address	ID/FEI	Business Operations
PADC 1		949264774	RELABEL(11559-052) , REPACK(11559-052)

Establishment

Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(11559-052)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		255175580	MANUFACTURE(11559-052)