

FRESH SKIN EFFORTLESS BEAUTY BALM BROAD SPECTRUM SPF 35- octinoxate, octisalate, oxybenzone, titanium dioxide, and zinc oxide cream
AERIN LAUDER BEAUTY DIST.

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.

FRESH SKIN EFFORTLESS BEAUTY BALM BROAD SPECTRUM SPF 35

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
Octinoxate 7.50%	Sunscreen
Octisalate 4.00%	Sunscreen
Oxybenzone 2.50%	Sunscreen
Titanium Dioxide 1.10%	Sunscreen
Zinc Oxide 3.30%	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:
 - 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 • dimethicone • butylene glycol • phenyl trimethicone • pentylene glycol • glyceryl stearate • behenyl alcohol • trioctyldodecyl citrate • polymethylsilsesquioxane • octyldodecyl stearyl stearate • peg-40 stearate • polyglyceryl-10 pentastearate • tocopheryl acetate • sodium hyaluronate •

lecithin • squalane • triticum vulgare (wheat) germ extract • hordeum vulgare (barley) extract\extrait d'orge • cucumis sativus (cucumber) fruit extract • laminaria saccharina extract • pyrus malus (apple) fruit extract • scutellaria baicalensis root extract • glycerin • caffeine • cholesterol • oryzanol • trehalose • octyldodecyl neopentanoate • polyglyceryl-6 polyricinoleate • acetyl hexapeptide-8 • sodium pca • sucrose • urea • polyquaternium-51 • sodium stearyl lactylate • ammonium acryloyldimethyltaurate/vp copolymer • polysorbate 20 • sorbitan laurate • propylene glycol laurate • glycyrrhetic acid • linoleic acid • stearic acid • xanthan gum • silica • isopropyl titanium triisostearate • alumina • propylene glycol stearate • disodium edta • sodium dehydroacetate • chlorphenesin • phenoxyethanol • [+/- mica • iron oxides (ci 77491) • iron oxides (ci 77492) • iron oxides (ci 77499) • titanium dioxide (ci 77891)] <iln41064>

Other information

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

PRINCIPAL DISPLAY PANEL - 50 ml Tube Carton

AERIN

FRESH SKIN

EFFORTLESS BEAUTY BALM

BROAD SPECTRUM SPF 35

1.7 FL. OZ. LIQ/50ml e

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Drug Facts (continued)

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EFFORTLESS BEAUTY BALM
BROAD SPECTRUM SPF 35

1.7 FL. OZ. LIQ./50ml e

INSTRUCTIONS
FOR AN EFFORTLESS APPLICATION,
SMOOTH EVENLY ALL OVER FACE OR TO
THE DESIRED AREA AFTER MOISTURIZER
WITH FINGERTIPS, BRUSH OR SPONGE.

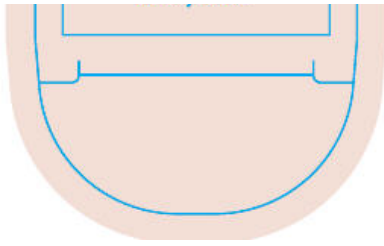
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NEW YORK · LONDON · WIKI · BQ
MADE IN CANADA · TTY
AERIN.COM



FPO/UPC

YFPY-01-1112



FRESH SKIN EFFORTLESS BEAUTY BALM BROAD SPECTRUM SPF 35

octinoxate, octisalate, oxybenzone, titanium dioxide, and zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43072-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.08175 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	0.0436 g in 100 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.02725 g in 100 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	0.01199 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.03597 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0K00R)	
dimethicone (UNII: 92RU3N3Y1O)	
butylene glycol (UNII: 3XUS85K0RA)	
phenyl trimethicone (UNII: DR0K5NOJ4R)	
pentylene glycol (UNII: 50C1307PZG)	
glyceryl monostearate (UNII: 230OU9XXE4)	
docosanol (UNII: 9G1OE216XY)	
trioctylododecyl citrate (UNII: 35X8CT063R)	
octyldodecyl stearyl stearate (UNII: 3D47Q6D93C)	
peg-40 stearate (UNII: ECU18C66Q7)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	
hyaluronate sodium (UNII: YSE9PPT4TH)	
squalane (UNII: GW89575KF9)	
wheat germ (UNII: YR3G369F5A)	
barley (UNII: 5PWM7YLI7R)	
cucumber (UNII: YY7C30VXJT)	
saccharina latissima (UNII: 68CMP2MB55)	
apple (UNII: B423VGH5S9)	
scutellaria baicalensis root (UNII: 7J95K7ID2S)	
glycerin (UNII: PDC6A3C0OX)	
caffeine (UNII: 3G6A5W338E)	
cholesterol (UNII: 97C5T2UQ7J)	

gamma oryzanol (UNII: SST9XCL51M)
trehalose (UNII: B8WCK70T7I)
octyldodecyl neopentanoate (UNII: X8725R883T)
acetyl hexapeptide-8 (UNII: L4EL31FWIL)
sodium pyrrolidone carboxylate (UNII: 469OTG57A2)
sucrose (UNII: C151H8M554)
urea (UNII: 8W8T17847W)
sodium stearoyl lactylate (UNII: IN99IT31LN)
ammonium acryloyldimethyltaurate/vp copolymer (UNII: W59H9296ZG)
polysorbate 20 (UNII: 7T1F30V5YH)
sorbitan monolaurate (UNII: 6W9PS8B71J)
propylene glycol monolaurate (UNII: 668Z5835Z3)
enoxolone (UNII: P540XA09DR)
linoleic acid (UNII: 9KJL21T0QJ)
stearic acid (UNII: 4ELV7Z65AP)
xanthan gum (UNII: TTV12P4NEE)
silicon dioxide (UNII: ETJ7Z6XBU4)
isopropyl titanium triisostearate (UNII: 949E3KBJ1I)
aluminum oxide (UNII: LMI26O6933)
propylene glycol stearate (UNII: MZM1I680W0)
edetate disodium (UNII: 7FLD91C86K)
sodium dehydroacetate (UNII: 8W46YN971G)
chlorphenesin (UNII: I670DAL4SZ)
phenoxyethanol (UNII: HIE492ZZ3T)
mica (UNII: V8A1AW0880)
ferric oxide red (UNII: 1K09F3G675)
ferric oxide yellow (UNII: EX438O2MRT)
ferrosoferric oxide (UNII: XM0M87F357)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43072-001-01	1 in 1 CARTON		
1		50 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 NOT FINAL	part352	12/01/2014	

Labeler - AERIN LAUDER BEAUTY DIST. (078518500)

Establishment			
Name	Address	ID/FEI	Business Operations
ELGC K.K.		712808195	RELABEL(43072-001) , REPACK(43072-001)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COMPANY, THE		828534516	RELABEL(43072-001) , REPACK(43072-001)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(43072-001)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		202952982	MANUFACTURE(43072-001)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(43072-001)

Establishment

Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(43072-001)

Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC INC		943871157	RELABEL(43072-001) , REPACK(43072-001)

Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC LLC		959338336	MANUFACTURE(43072-001)

Establishment

Name	Address	ID/FEI	Business Operations
PADC 1		949264774	RELABEL(43072-001) , REPACK(43072-001)

Establishment

Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(43072-001)

Establishment

Name	Address	ID/FEI	Business Operations
Aveda Corporation		071352058	MANUFACTURE(43072-001)

Establishment

Name	Address	ID/FEI	Business Operations
Pennsylvania Logistics Center (PALC)		078364654	REPACK(43072-001) , RELABEL(43072-001)

Establishment

Name	Address	ID/FEI	Business Operations
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ESTEE LAUDER COSMETICS, LTD

255175580

MANUFACTURE(43072-001)

Revised: 12/2014

AERIN LAUDER BEAUTY DIST.