

**CLEAR DIFFERENCE BB COMPLEXION PERFECTING BB BROAD SPECTRUM SPF 35-
octinoxate, octisalate, oxybenzone, and titanium dioxide 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.

**CLEAR DIFFERENCE BB COMPLEXION PERFECTING BB CREME 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

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\aquea\eau • butylene glycol • dimethicone • phenyl trimethicone • glyceryl stearate • behenyl alcohol • trioctyldodecyl citrate • polymethylsilsesquioxane • octyldodecyl stearyl stearate • peg-40 stearate • polyglyceryl-10 pentastearate • gentiana lutea (gentian) root extract • polygonum cuspidatum root extract • thermus thermophilus ferment • hordeum vulgare (barley) extract\extrait d'orge • fumaria

officinalis flower/leaf/stem extract • citrus medica limonum (lemon) fruit extract • hydrolyzed rice bran extract • laminaria saccharina extract • hydrolyzed rice extract • rosmarinus officinalis (rosemary) leaf extract • artemia extract • vitis vinifera (grape) seed extract • triticum vulgare (wheat) germ extract • cholesterol • caffeine • propylene glycol stearate • octyldodecyl neopentanoate • pentylene glycol • polyglyceryl-6 polyricinoleate • tocopheryl acetate • sucrose • glycerin • sodium stearoyl lactylate • linoleic acid • lecithin • squalane • sodium pca • urea • isopropyl titanium triisostearate • ergothioneine • sodium dehydroacetate • tetrahexyldecyl ascorbate • polysorbate 20 • sorbitan laurate • sodium hyaluronate • citric acid • propylene glycol laurate • glycyrrhetic acid • trehalose • polyquaternium-51 • hydrogenated lecithin • fumaric acid • alumina • palmitoyl hydroxypropyltrimonium • amylopectin/glycerin crosspolymer • ammonium acryloyldimethyltaurate/vp copolymer • cyclodextrin • nordihydroguaiaretic acid • ascorbyl tocopheryl maleate • xanthan gum • stearic acid • silica • ethylbisiminomethylguaiacol manganese chloride • pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate • disodium edta • phenoxyethanol • chlorphenesin • [+/- mica • titanium dioxide (ci 77891) • zinc oxide (ci 77947) • iron oxides (ci 77492) • iron oxides (ci 77499) • iron oxides (ci 77491) • ferric ferrocyanide (ci 77510) • yellow 5 lake (ci 19140) • chromium oxide greens (ci 77288) • chromium hydroxide green (ci 77289) • carmine (ci 75470) • blue 1 lake (ci 42090) • bismuth oxychloride (ci 77163)] <iln40601>

Other information

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

PRINCIPAL DISPLAY PANEL - 30 ml Tube Carton

ESTÉE LAUDER

Clear
Difference

B•B

Complexion Perfecting
BB Creme
Broad Spectrum
SPF 35

1 FL. OZ. LIQ./30 ml e

01 Light



ESTÉE LAUDER



Clear
Difference
D.D.

Complexion Perfecting
BB Creme
Broad Spectrum
SPF 35

Reveal your freshest, healthiest looking skin. This multi-function, oil-free BB Creme instantly neutralizes redness and helps conceal blemish marks, pores and flaws with a specially formulated tint. Sheer shades flatter a wide range of skintones. With one touch, the lightweight formula hydrates, protects, perfects and soothes. Controls oil and leaves skin looking soft, clear and naturally beautiful. Dermatologist-tested. Non-acnegenic, so it won't clog pores. Complexion perfection from the Clear Skin Experts. (Learn more—see enclosure.)

D·D

Complexion Perfecting
BB Creme
Broad Spectrum
SPF 35

1 FL. OZ. LIQ./30ml e

© ESTÉE LAUDER, DIST.
NEW YORK, N.Y. 10022
NEW YORK • LONDON W1K 3BQ
PARIS • MILANO
MADE IN BELGIUM YT2Y
esteeauder.com



0950

TP 707

1

Drug Facts

Active ingredients	Purpose
Octinoxate 7.50%	Sunscreen
Octisalate 4.00%	Sunscreen
Oxybenzone 2.50%	Sunscreen
Titanium dioxide 1.10%	Sunscreen

Use

helps prevent sunburn

Drug Facts (continued)

extract/extract d'orge • fumaria
officinalis flower/leaf/stem extract •
citrus medica limonum (lemon) fruit
extract • hydrolyzed rice bran extract •
laminaria saccharina extract •
hydrolyzed rice extract • rosmarinus
officinalis (rosemary) leaf extract •
artemisia extract • vite vinifera (grape)

© 2015 Johnson & Johnson

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 • butylene glycol • dimethicone • phenyl trimethicone • glyceryl stearate • behenyl alcohol • triethyldecyl citrate • polymethylsiloxane • octyldodecyl stearoyl stearate • peg-40 stearate • polyglyceryl-10 pentastearate • gentiana lutea (gentian) root extract • polygonum cuspidatum root extract • thermus thermophilus ferment • hordeum vulgare (barley) ▶

seed extract • tridax vulgare (wild radish) extract • cholesterol • caffeine • propylene glycol stearate • octyldodecyl neopentanoate • pentylene glycol • polyglyceryl-6 polyricinoleate • tocopheryl acetate • sucrose • glycerin • sodium stearoyl lactylate • linoleic acid • lecithin • aqualane • sodium pca • urea • isopropyl titanium trisecosterate • ergothioneine • sodium denyrosuccinate • tetrahexyldecyl ascorbate • polysorbate 20 • sorbitan laurate • sodium hyaluronate • citric acid • propylene glycol laurate • glycyrrhetic acid • trehalose • polyquaternium-61 • hydrogenated lecithin • humic acid • alumina • palmitoyl hydroxypropyltrimonium amylopectin/glycerin crosspolymer • ammonium acryloyldimethyltaurate/vp copolymer • cyclodextrin • nordihydroguaiaric acid • ascorbyl tocopheryl maleate • xanthan gum • stearic acid • silica • ethylbisiminomethylguaiacol manganese chloride • pentaerythrityl tetra-di-*t*-butyl hydroxyhydrocinnamate • disodium octa-*p*-phenoxyethanol • chlorphenesin • [+/- mica • titanium dioxide (ci 77891) • zinc oxide (ci 77947) • iron oxides (ci 77492) • iron oxides (ci 77499) • iron oxides (ci 77491) • ferric ferrocyanide (ci 77510) • yellow 5 lake (ci 19140) • chromium oxide greens (ci 77288) • chromium hydroxide green (ci 77289) • carmine (ci 75473) • blue 1 lake (ci 42090) • bismuth oxychloride (ci 77163)] <[n43801]>

Other information

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

2095 0163



YT2Y-01-111



CLEAR DIFFERENCE BB COMPLEXION PERFECTING BB BROAD SPECTRUM SPF 35

octinoxate, octisalate, oxybenzone, and titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11559-039
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

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
1,3-butylene glycol (UNII: 3XUS85K0RA)	
dimethicone (UNII: 92RU3N3Y1O)	
phenyl trimethicone (UNII: DR0K5NOJ4R)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
DOCOSANOL (UNII: 9G1OE216XY)	
trioctyldodecyl citrate (UNII: 35X8CT063R)	
octyldodecyl stearyl stearate (UNII: 3D47Q6D93C)	
peg-40 stearate (UNII: ECU18C66Q7)	
GENTIANA LUTEA ROOT (UNII: S72O3284MS)	
POLYGONUM CUSPIDATUM ROOT (UNII: 7TRV45YZF7)	
THERMUS THERMOPHILUS LYSATE (UNII: 775R692494)	
BARLEY (UNII: 5PWM7YLI7R)	
FUMARIA OFFICINALIS FLOWERING TOP (UNII: VH659J61ZL)	
LEMON (UNII: 24RS0A988O)	
SACCHARINA LATISSIMA (UNII: 68CMP2MB55)	
ROSEMARY (UNII: IJ67X351P9)	
VITIS VINIFERA SEED (UNII: C34U15ICXA)	
WHEAT GERM (UNII: YR3G369F5A)	
cholesterol (UNII: 97C5T2UQ7J)	
caffeine (UNII: 3G6A5W338E)	
propylene glycol stearate (UNII: MZM1I680W0)	
octyldodecyl neopentanoate (UNII: X8725R883T)	
pentylene glycol (UNII: 50C1307PZG)	

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
sucrose (UNII: C151H8M554)
glycerin (UNII: PDC6A3C0OX)
sodium stearoyl lactylate (UNII: IN99IT31LN)
linoleic acid (UNII: 9KJL21T0QJ)
squalane (UNII: GW89575KF9)
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)
urea (UNII: 8W8T17847W)
isopropyl titanium triisostearate (UNII: 949E3KBJ1I)
ergothioneine (UNII: BDZ3DQM98W)
sodium dehydroacetate (UNII: 8W46YN971G)
tetrahexyldecyl ascorbate (UNII: 9LBV3F07AZ)
polysorbate 20 (UNII: 7T1F30V5YH)
SORBITAN MONOLAURATE (UNII: 6W9PS8B71J)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
PROPYLENE GLYCOL MONOLAURATE (UNII: 668Z5835Z3)
ENOXOLONE (UNII: P540XA09DR)
trehalose (UNII: B8WCK70T7I)
fumaric acid (UNII: 88XHZ13131)
ALUMINUM OXIDE (UNII: LM26O6933)
ammonium acryloyldimethyltaurate/vp copolymer (UNII: W59H9296ZG)
MASOPROCOL (UNII: 7B08G1BYQU)
ascorbyl tocopheryl maleate (UNII: D2G6259XR5)
xanthan gum (UNII: TTV12P4NEE)
stearic acid (UNII: 4ELV7Z65AP)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
manganese chloride (UNII: QQE170PANO)
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)
EDETATE DISODIUM (UNII: 7FLD91C86K)
phenoxyethanol (UNII: HIE492ZZ3T)
chlorphenesin (UNII: I670DAL4SZ)
mica (UNII: V8A1AW0880)
ZINC OXIDE (UNII: SOI2LOH54Z)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC FERROCYANIDE (UNII: TLE294X33A)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
CHROMIC OXIDE (UNII: X5Z09SU859)
CHROMIUM HYDROXIDE GREEN (UNII: RV8FT8XF5R)
CARMINIC ACID (UNII: CID8Z8N95N)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11559-039-01	1 in 1 CARTON		

1	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	12/01/2013	

Labeler - ESTEE LAUDER INC (005914387)

Establishment			
Name	Address	ID/FEI	Business Operations
ELGC K.K.		712808195	RELABEL(11559-039) , REPACK(11559-039)

Establishment			
Name	Address	ID/FEI	Business Operations
Estee Lauder Pennsylvania Distribution Center 2 (PADC 2)		828534516	MANUFACTURE(11559-039) , RELABEL(11559-039) , REPACK(11559-039)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(11559-039)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		205952385	MANUFACTURE(11559-039)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(11559-039)

Establishment			
Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(11559-039)

Establishment			
Name	Address	ID/FEI	Business Operations
NORTEC KEYSTONE		943871157	MANUFACTURE(11559-039) , RELABEL(11559-039) , REPACK(11559-039)

Establishment			
Name	Address	ID/FEI	Business Operations
NORTHTEC BRISTOL		959338336	MANUFACTURE(11559-039) , RELABEL(11559-039) , REPACK(11559-039)

Establishment			
Name	Address	ID/FEI	Business Operations
NORTHTEC KEYSTONE		949264774	MANUFACTURE(11559-039) , RELABEL(11559-039) , REPACK(11559-039)

Establishment

Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(11559-039)

Establishment

Name	Address	ID/FEI	Business Operations
Aveda Corporation		071352058	MANUFACTURE(11559-039)

Establishment

Name	Address	ID/FEI	Business Operations
Pennsylvania Logistics Center		078364654	REPACK(11559-039) , RELABEL(11559-039)

Revised: 1/2014

ESTEE LAUDER INC