

CLINIQUE REPAIRWEAR UPLIFTING FIRMING BROAD SPECTRUM SPF 15 DRY COMBO OILY- octinoxate, octisalate, and titanium dioxide cream
CLINIQUE LABORATORIES 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.

REPAIRWEAR UPLIFTING FIRMING CREAM BROAD SPECTRUM SPF 15 DRY COMBO OILY

Drug Facts

Active ingredients

Octinoxate 7.5%
Octisalate 3.5%
Titanium dioxide 1.7%

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:
 - 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 • neopentyl glycol diheptanoate • simmondsia chinensis (jojoba) butter • glycerin • petrolatum • octyldodecyl neopentanoate • di-c12-15 alkyl fumarate • dimethicone • hydrogenated lecithin • butylene glycol • hydrogenated polyisobutene • hexyldecyl stearate • sigesbeckia orientalis (st. paul's wort) extract • whey protein\lactis protein\protéine du petit-lait • salvia sclarea (clary) extract • chlorella vulgaris extract • commiphora mukul resin extract • litchi chinensis seed extract • laminaria digitata extract • cladosiphon okamuranus extract • plankton extract • astrocaryum murumuru seed butter • acetyl hexapeptide-8 • lecithin • polyethylene • pentylene glycol • potato starch modified • ergothioneine • glyceryl stearate • caffeine • sorbitol • behenyl alcohol • sodium hyaluronate • methicone • tocopheryl acetate • peg-100 stearate • pentaerythrityl tetraethylhexanoate • caprylyl glycol • c12-16 alcohols • cholesterol • caprylic/capric triglyceride • polysilicone-11 • dextrin • palmitic acid • tetrahexyldecyl ascorbate • hexylene glycol • citric acid • xanthan gum • alumina • ammonium acryloyldimethyltaurate/vp copolymer • sodium hydroxide • disodium edta • potassium sorbate • phenoxyethanol • red 4 (ci 14700) • yellow 5 (ci 19140) • titanium dioxide (ci 77891) • mica [iln39272]

Other information

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

PRINCIPAL DISPLAY PANEL - 50 ml Jar Carton

CLINIQUE

repairwear uplifting

firming cream

broad spectrum SPF 15

DRY COMBINATION TO COMBINATION OILY

POIDS NET WT. 1.7 OZ./50 ml e



CLINIQUE

repairwear uplifting

firming cream
broad spectrum SPF 15

DRY COMBINATION TO COMBINATION OILY

POIDS NET WT. 1.7 OZ./50 ml e

Allergy Tested. 100% Fragrance Free.

Fortifying moisture cream helps protect skin's natural collagen and elastin support network from UVA/UVB damage. Actually uses sunlight to turn on powerful repair ingredients. Daily wear also helps invigorate natural collagen and elastin to help restore skin's bounce and resistance to gravity in as little as 4 weeks. Goes on to help firm up the appearance of jawline and neck. Moisturizes all day. See enclosure.



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MADE IN U.S.A. 7337



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 octinoxate, octisalate, and titanium dioxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49527-014
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 mL in 100 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	3.5 mL in 100 mL
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	1.7 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
neopentyl glycol diheptanoate (UNII: 5LKW3C543X)	
glycerin (UNII: PDC6A3C0OX)	
petrolatum (UNII: 4T6H12BN9U)	
octyldodecyl neopentanoate (UNII: X8725R883T)	
di-c12-15 alkyl fumarate (UNII: A1CB3Z898P)	
dimethicone (UNII: 92RU3N3Y1O)	
butylene glycol (UNII: 3XUS85K0RA)	
hexyldecyl stearate (UNII: OJX2P28Y14)	
chlorella vulgaris (UNII: RYQ4R60M02)	
guggul (UNII: 34969JX79R)	
litchi chinensis seed (UNII: 9294024N9Q)	
laminaria digitata (UNII: 15E7C67EE8)	
cladosiphon okamuranus (UNII: 2IJE0CH09J)	
astrocaryum murumuru seed butter (UNII: 12V64UPU6R)	
acetyl hexapeptide-8 (UNII: L4EL31FWIL)	
high density polyethylene (UNII: UG00KM4WR7)	
pentylene glycol (UNII: 50C1307PZG)	
ergothioneine (UNII: BDZ3DQM98W)	
glyceryl monostearate (UNII: 230OU9XXE4)	
caffeine (UNII: 3G6A5W338E)	
sorbitol (UNII: 506T60A25R)	
docosanol (UNII: 9G1OE216XY)	
hyaluronate sodium (UNII: YSE9PPT4TH)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	
peg-100 stearate (UNII: YD01N1999R)	
pentaerythrityl tetraethylhexanoate (UNII: XJ7052W897)	
caprylyl glycol (UNII: 00YIU5438U)	
c12-16 alcohols (UNII: S4827SZE3L)	
cholesterol (UNII: 97C5T2UQ7J)	
medium-chain triglycerides (UNII: C9H2L21V7U)	
icodextrin (UNII: 2NX48Z0A9G)	
palmitic acid (UNII: 2V16EO95H1)	
tetrahexyldecyl ascorbate (UNII: 9LBV3F07AZ)	
hexylene glycol (UNII: KEH0A3F75J)	
citric acid monohydrate (UNII: 2968PHW8QP)	
xanthan gum (UNII: TTV12P4NEE)	
aluminum oxide (UNII: LM26O6933)	
ammonium acryloyldimethyltaurate/vp copolymer (UNII: W59H9296ZG)	

sodium hydroxide (UNII: 55X04QC32I)	
edetate disodium (UNII: 7FLD91C86K)	
potassium sorbate (UNII: 1VPU26JZZ4)	
phenoxyethanol (UNII: HIE492ZZ3T)	
FD&C red no. 4 (UNII: X3W0AM1JLX)	
FD&C yellow no. 5 (UNII: I753WB2F1M)	
mica (UNII: V8A1AW0880)	

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Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49527-014-01	1 in 1 CARTON		
1		50 mL in 1 JAR		

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Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	05/02/2012	

Labeler - CLINIQUE LABORATORIES INC (173047747)

Establishment			
Name	Address	ID/FEI	Business Operations
ELGC K.K.		712808195	RELABEL(49527-014) , REPACK(49527-014)

Establishment			
Name	Address	ID/FEI	Business Operations
Estee Lauder Pennsylvania Distribution Center 2 (PADC 2)		828534516	MANUFACTURE(49527-014) , RELABEL(49527-014) , REPACK(49527-014)

Establishment			
Name	Address	ID/FEI	Business Operations
Estee Lauder Inc.		042918826	MANUFACTURE(49527-014)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS DISTRIBUTION CENTER		208579636	REPACK(49527-014) , RELABEL(49527-014)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		253616536	MANUFACTURE(49527-014)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(49527-014)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		205952385	MANUFACTURE(49527-014)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(49527-014)

Establishment			
Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(49527-014)

Establishment			
Name	Address	ID/FEI	Business Operations
NORTEC KEYSTONE		943871157	MANUFACTURE(49527-014) , RELABEL(49527-014) , REPACK(49527-014)

Establishment			
Name	Address	ID/FEI	Business Operations
NORTHTEC BRISTOL		959338336	MANUFACTURE(49527-014) , RELABEL(49527-014) , REPACK(49527-014)

Establishment			
Name	Address	ID/FEI	Business Operations
NORTHTEC KEYSTONE		949264774	MANUFACTURE(49527-014) , RELABEL(49527-014) , REPACK(49527-014)

Establishment			
Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(49527-014)

Establishment			
Name	Address	ID/FEI	Business Operations
Aveda Corporation		071352058	MANUFACTURE(49527-014)

Establishment			
Name	Address	ID/FEI	Business Operations
Pennsylvania Logistics Center		078364654	REPACK(49527-014) , RELABEL(49527-014)

Revised: 8/2012

CLINIQUE LABORATORIES INC