

REPAIRWEAR UPLIFTING FIRMING BROAD SPECTUM SPF 15 - NORMAL COMBO TO COMBINATION OILY- octinoxate, octisalate, and titanium dioxide cream
CLINIQUE LABORATORIES LLC

REPAIRWEAR UPLIFTING FIRMING

BROAD SPECTUM SPF 15 - NORMAL COMBO TO COMBINATION 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,hexyldecyl stearate,hydrogenated polyisobutene,synthetic wax,whey protein\lactis protein\protéine du petit-lait,sigesbeckia orientalis (st. paul's wort) extract,salvia sclarea (clary) extract,chlorella vulgaris extract,litchi chinensis seed extract,laminaria digitata extract,cladosiphon okamuranus extract,plankton extract,astrocaryum murumuru seed butter,acetyl hexapeptide-8,lecithin,pentylene glycol,potato starch modified,ergothioneine,glyceryl stearate,caffeine,sorbitol,behenyl alcohol,sodium hyaluronate,tocopheryl acetate,peg-100 stearate,pentaerythrityl tetraethylhexanoate,caprylyl glycol,c12-16 alcohols,cholesterol,polysilicone-11,dextrin,palmitic acid,tetrahexyldecyl ascorbate,hexylene glycol,aluminum hydroxide,methicone,citric acid,xanthan gum,ammonium acryloyldimethyltaurate/vp copolymer,sodium hydroxide,disodium edta,potassium sorbate,phenoxyethanol,sodium lactate,chlorphenesin,bht,mica,titanium dioxide (ci 77891),red 4 (ci 14700),yellow 5 (ci 19140) <iln51403>

Other information

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

DIST. N.Y., N.Y. 10022

PRINCIPAL DISPLAY PANEL - 50 mL Jar Carton

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CLINIQUE

repairwear uplifting

firming cream

broad spectrum SPF 15

DRY COMBINATION TO COMBINATION OILY

POIDS NET WT. 1.7. OZ./50 ml e



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octinoxate, octisalate, and titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49527-022
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	35 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	17 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM LACTATE (UNII: TU7HW0W0QT)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
WHEY (UNII: 8617Z5FMF6)	
METHICONE (20 CST) (UNII: 6777U11MKT)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
WATER (UNII: 059QF0KO0R)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
JOJOBA BUTTER (UNII: XIA46H803R)	
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)	
CLARY SAGE (UNII: U3H5K5JC0Q)	
CHLORELLA VULGARIS (UNII: RYQ4R60M02)	
LITCHI CHINENSIS SEED (UNII: 9294024N9Q)	
LAMINARIA DIGITATA (UNII: 15E7C67EE8)	
CLADOSIPHON OKAMURANUS (UNII: 2IJE0CH09J)	
ASTROCARYUM MURUMURU SEED BUTTER (UNII: 12V64UPU6R)	
ACETYL HEXAPEPTIDE-8 (UNII: L4EL31FWL)	
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: S4827SZ E3L)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
ICODEXTRIN (UNII: 2NX48Z0A9G)	
PALMITIC ACID (UNII: 2V16EO95H1)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
XANTHAN GUM (UNII: TTV12P4NEE)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
MICA (UNII: V8A1AW0880)	

HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	
STARCH, POTATO (UNII: 8I089SAH3T)	
SIGESBECKIA ORIENTALIS FLOWERING TOP (UNII: 6UL878YAR7)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
SYNTHETIC WAX (1200 MW) (UNII: Q3Z4BCH099)	
BHT (UNII: 1P9D0Z171K)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
CHLORPHENESIN (UNII: I670DAL4SZ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49527-022-01	1 in 1 CARTON	10/01/2012	
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 Drug	M020	10/01/2012	

Labeler - CLINIQUE LABORATORIES LLC (044475127)

Registrant - Estee Lauder Companies Inc. (790802086)

Establishment

Name	Address	ID/FEI	Business Operations
The Estee Lauder Inc		802599436	manufacture(49527-022) , pack(49527-022) , label(49527-022)