CERAMIDE PREMIERE BROAD SPECTRUM SPF 30- octinoxate, octisalate, oxybenzone, octocrylene, avobenzone emulsion
REVLON

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.

CERAMIDE PREMIERE INTENSE MOISTURE AND RENEWAL ACTIVATION CREAM BROAD SPECTRUM SUNSCREEN SPF 30

Active Ingredients Purpose

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OCTINOXATE 7.5% ..... Sunscreen
OCTISALATE 5.0%..... Sunscreen
OXYBENZONE 4.0%..... Sunscreen
OCTOCRYLENE 3.0%. ..... Sunscreen
AVOBENZONE 2.0%..... Sunscreen

Inactive Ingredients

WATER/AQUA/EAU, DIMETHICONE, GLYCERIN, HYDROGENATED POLYISOBUTENE, PETROLATUM, GLYCERYL STEARATE, BUTYLENE GLYCOL, BUTYLOCTYL SALICYLATE, CAPRYLIC/CAPRIC TRIGLYCERIDE, CETEARYL ALCOHOL, PEG-100 STEARATE, BUTYROSPERMUM PARKII (SHEA BUTTER), HYDROGENATED LECITHIN, DIMETHYL CAPRAMIDE, CERAMIDE 1, CERAMIDE 3, CERAMIDE 6 II, FUCUS SERRATUS EXTRACT, YEAST EXTRACT/FAEX/EXTRAIT DE LEVURE, RETINYL LINOLEATE, TOCOPHERYL ACETATE, CETEARYL DIMETHICONE CROSSPOLYMER, PEG-40 HYDROGENATED CASTOR OIL, SOY AMINO ACIDS, 3-AMINOPROPANE SULFONIC ACID, CALCIUM HYDROXYMETHIONINE, HYDROLYZED SOY PROTEIN, METHYL METHACRYLATE CROSSPOLYMER, PHYTOSPHINGOSINE, AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER, CHOLESTEROL, SODIUM LAUROYL LACTYLATE, PEG-8 LAURATE, POLYSORBATE 20, SODIUM DODECYLBENZENESULFONATE, STYRENE/ACRYLATES COPOLYMER, BEHENYL ALCOHOL, PENTYLENE GLYCOL, CARBOMER, HYDROXYETHYLCELLULOSE, POLYETHYLENE, XANTHAN GUM, EDTA, SODIUM HYDROXIDE, BHT, DISODIUM EDTA, MICA, TIN OXIDE, AMINOPROPYL DIMETHICONE, FRAGRANCE/PARFUM, ALPHA-ISOMETHYL IONONE, BUTYLPHENYL METHYLPROPIONAL, CITRONELLOL, HYDROXYCITRONELLAL, ETHYLPARABEN, METHYLPARABEN, PHENOXYETHANOL, POTASSIUM SORBATE, PROPYLPARABEN, SODIUM BENZOATE, TITANIUM DIOXIDE (CI 77891).

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

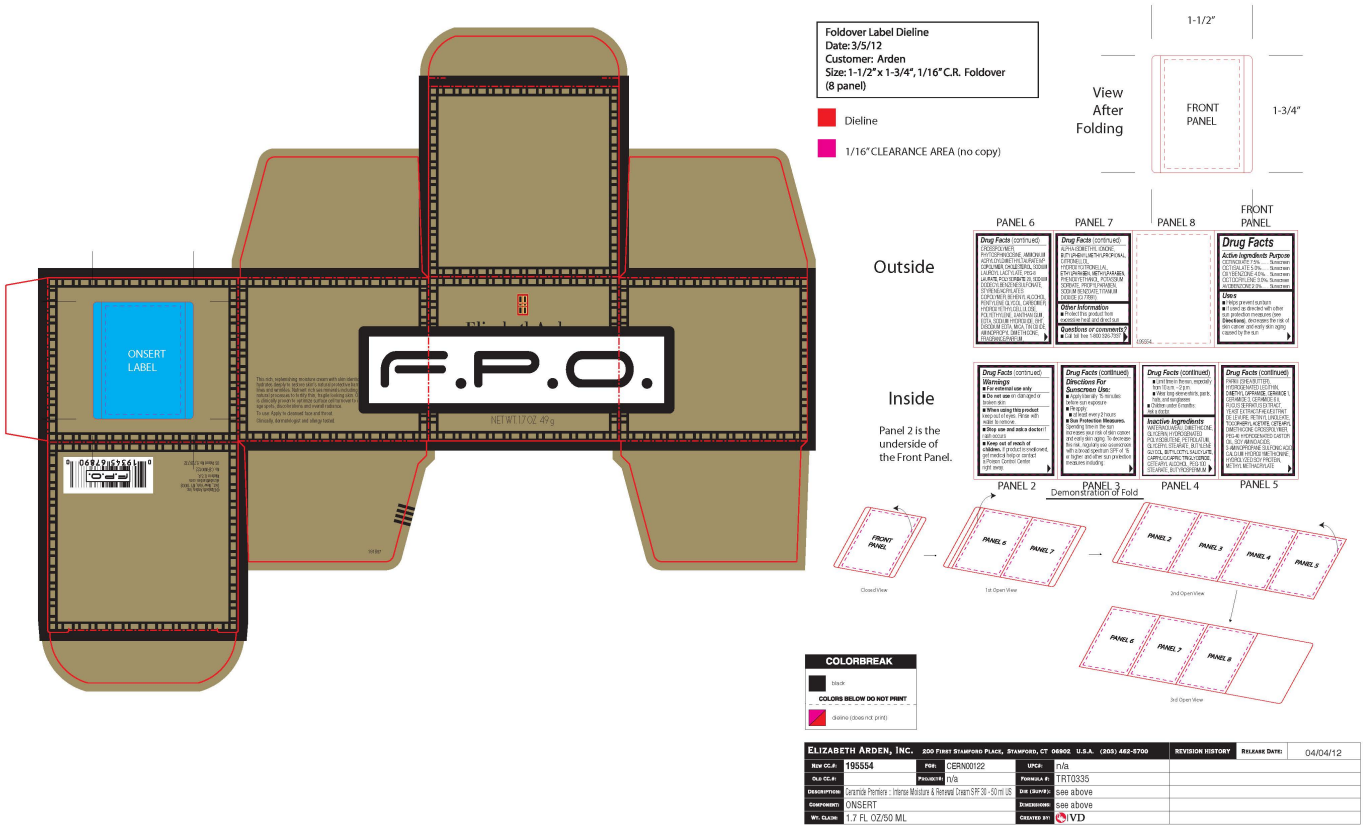
- Apply liberally 15 minutes before sun exposure
- Reapply:
- at least every 2 hours

- 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 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-sleeve shirts, pants, hats, and sunglasses

- Children under 6 months: Ask a doctor.

Artwork



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octinoxate, octisalate, oxybenzone, octocrylene, avobenzone emulsion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:10967-669
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	4 mg in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 mg in 1 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	3 mg in 1 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
HYDROLYZED SOY PROTEIN (ENZYMATIC; 2000 MW) (UNII: 1394NXB9L6)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHYTOSPHINGOSINE (UNII: GIN46U9Q2Q)	
ETHYLPARABEN (UNII: 14255EXE39)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
STANNIC OXIDE (UNII: KM7N50LOS6)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CERAMIDE 1 (UNII: 5THT33P7X7)	
FUCUS SERRATUS (UNII: V8K40WNW5B)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
AMINO ACIDS, SOY (UNII: NWB9514AZM)	
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
EDETIC ACID (UNII: 9G34HU7RV0)	
MICA (UNII: V8A1AW0880)	
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DIMETHYL CAPRAMIDE (UNII: O29Y6X2JEZ)	
CERAMIDE 6 II (UNII: F1X8L2B00J)	
PEG-100 STEARATE (UNII: YD01N1999R)	
SODIUM DODECYLBENZENESULFONATE (UNII: 554127163Y)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PEG-8 LAURATE (UNII: 762O8IWA10)	
TRAMIPROSATE (UNII: 5K8EAX0G53)	
METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: EG97988M5Q)	

AMINOPROPYL DIMETHICONE (1000 MPA.S) (UNII: P4P48I53XH)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
DOCOSANOL (UNII: 9G1OE216XY)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
DESMENINOL CALCIUM (UNII: 1VK0YS654L)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	
PETROLATUM (UNII: 4T6H12BN9U)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
CERAMIDE 3 (UNII: 4370DF050B)	
YEAST (UNII: 3NY3SM6B8U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10967-669-17	49 g in 1 JAR; Type 0: Not a Combination Product	02/06/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/06/2017	

Labeler - REVLON (788820165)

Registrant - REVLON (788820165)

Establishment

Name	Address	ID/FEI	Business Operations
Englewood Lab. INC.		080987545	manufacture(10967-669)

Revised: 2/2022 REVLON