SPF BFF SUNSCREEN BROAD SPECTRUM SPF 25- octinoxate and zinc oxide lotion
BERBURY AESTHETICS LLC

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.

SPF BFF Sunscreen Broad Spectrum SPF 25

DRUG FACTS:

ACTIVE INGREDIENTS

Octinoxate 7.0%, Zinc Oxide 6.0%.

PURPOSE

Sunscreen

USES

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.

DIRECTIONS

Apply to all skin exposed to the sun.

- Apply liberally and evenly 15 minutes before sun exposure.
- Reapply at least every 2 hours.
- Use a water-resistant sunscreen if swimming or sweating.
- For children under 6 months of age: Ask a doctor.

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.

INACTIVE INGREDIENTS

Water, Isocetyl Stearate, Cetyl Dimethicone, Styrene/Acrylates Copolymer, Sorbitol, Ethyl Macadamiate, Cetearyl Alcohol, Dimethicone, Acrylates/Dimethicone Copolymer, Phenoxyethanol, Glyceryl Stearate, Glycerin, Hydroxyethyl Acrylate/ Sodium Acryloyldimethyl Taurate Copolymer, PEG-100 Stearate, Ceteareth-20, Ethylhexyl Salicylate, VP/Eicosene Copolymer, Xanthan Gum, Polymethyl Methacrylate, Caprylyl Glycol, Cocos Nucifera Oil, Ethylhexylglycerin, Vaccinium Vitis-Idaea Fruit Extract, Quercus Suber Bark Extract, Triethoxycaprylylsilane, Camellia Sinensis Leaf Extract, Disodium EDTA, Tocopheryl Acetate, Oak Root Extract, Centella Asiatica Extract, Polygonum Aviculare Extract, Citric Acid, Gluconolactone, Isomalt, Calcium Gluconate, Lecithin, Vitis Vinifera Fruit Cell Extract, Sodium Benzoate, Lepidium Sativum Sprout Extract.

OTHER INFORMATION

Protect the product in this container from excessive heat and direct sun.

PRINCIPAL DISPLAY PANEL

SPF BFF Sunscreen Broad Spectrum SP

F 25

SPF BFF SUNSCREEN BROAD SPECTRUM SPF 25

octinoxate and zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:83239-2650
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	6 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ISOCETYL STEARATE (UNII: 3RJ7186O9W)	
SORBITOL (UNII: 506T60A25R)	
ETHYL MACADAMIATE (UNII: ANA2NCS6V1)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%) (UNII: 86FQE96TZ4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
WATER (UNII: 059QF0KO0R)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWJY)	
OCTISALATE (UNII: 4X49Y0596W)	
XANTHAN GUM (UNII: TTV12P4NEE)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
LINGONBERRY (UNII: 0UNK9RZQ7X)	
QUERCUS SUBER BARK (UNII: 8R5219271Q)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CENTELLA ASIATICA WHOLE (UNII: 7M867G6T1U)	
POLYGONUM AVICULARE TOP (UNII: ZCD6009IUF)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
ISOMALT (UNII: S870P55O2W)	
CALCIUM GLUCONATE (UNII: SQE6VB453K)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
GARDEN CRESS SPROUT (UNII: PWQ18YNR62)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83239-2650-2	50 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/01/2023	

Labeler - BERBURY AESTHETICS LLC (101296182)

Establishment

Name	Address	ID/FEI	Business Operations
COSMETIC SOLUTIONS, LLC		807907928	manufacture(83239-2650)

Revised: 2/2023 BERBURY AESTHETICS LLC