PLANET SUN SPF 30 - octinoxate, zinc oxide lotion Shine & Pretty (USA), Corp.

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.

Planet Sun SPF 30

Active Ingredients

Octinoxate, 7.5% (UVB sunscreen), Zinc oxide, 10.0% (UVA/UVB sunscreen)

Warnings

For external use only, not to be swallowed. Avoid contact with eye. Discontinue if signs of irritation or rash appear.

Purpose

For Sun protection for surfaces of skin, face, arm and hand. SPF-15 provides the face and body skin with effective protection against harmful UVA and UVB rays. Use daily over moisture cream to help prevent premature aging and wrinkling due to prolonged exposure to the sun, reapply after swimming or excessive exercise.

Paraben and PABA free. Fairly water resistant. Not tested on animals.

Made in the USA specifically for professional dermatology and esthetic practices.

Directions for Use

Home Care: Apply SPF 30 liberally to face and body at least ten minutes before sun exposure or two minutes before applying makeup. Reapply after swimming or excessive perspiration. As part of effective age-fighting program, apply every morning throughout the year. Because SPF 30 is a blend of UV absorbing and reflecting sunscreens, it may be applied over or under moisturizer.

Facial Procedure: SPF 30 is recommended as the finishing product at the end of the facial procedure for any skin type. It may be applied over finishing cream or moisturizer. It should not be rubbed in completely, but left on the skin until it becomes transparent.

Inactive Ingredients

Water, ethylhexyl palmitate, cyclomethicone, laurylmethicone, butylene glycol, tocopheryl acetate, sodium chloride, kukui (aleurites moluccana) seed oil (lipid-rich plant oil), green tea (camellia oleifera) seed extract, aloe vera (aloe barbadensis) leaf extract, tetrahexyldecyl ascorbate (time-released agefighting vitamin C), allantoin, sodium PCA (hydrating), disodium EDTA, ethylhexylglycerin, methylisothiazolinone, fragrance (synthetic citrus).

Questions?

(805) 388-8581

Keep out of the reach of children

Keep Out of the reach of children. Use on children under six months of age only with the advice of a physician.

Principal Panel Display

MM1



PLANET SUN SPF 30

octinoxate, zinc oxide lotion

| Product Information | Product Information | | | | |
|----------------------------|---------------------|--------------------|---------------|--|--|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:59663-120 | | |
| 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 |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE | 100 mg in 1 mL |
| | | |

| Ingredient Name | Strength |
|--|----------|
| VITAMIN A PALMITATE (UNII: 1D1K0N0VVC) | |
| CHAMO MILE (UNII: FGL3685T2X) | |
| CUCUMBER (UNII: YY7C30VXJT) | |
| ETHYLHEXYL PALMITATE (UNII: 2865993309) | |
| CYCLOMETHICONE (UNII: NMQ347994Z) | |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | |
| ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| KUKUI NUT (UNII: J87WJ3E7VW) | |
| CAMELLIA OLEIFERA SEED (UNII: 59ED29FM2J) | |
| ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X) | |
| TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ) | |
| ALLANTO IN (UNII: 344S277G0 Z) | |
| SO DIUM PYRRO LIDO NE CARBO XYLATE (UNII: 469 OTG57A2) | |
| EDETATE DISO DIUM (UNII: 7FLD9 1C8 6 K) | |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) | |

| Packaging | | | | |
|-----------|------------------|---------------------|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:59663-120-04 | 120 mL in 1 TUBE | | |

| Marketing Information | | | | |
|-------------------------|--|----------------------|--------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph not final | part352 | 03/01/2013 | | |
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Labeler - Shine & Pretty (USA), Corp. (603528605)

Revised: 7/2013 Shine & Pretty (USA), Corp.