SUN SOLAR DEFENSE OIL-FREE GEL SPF 15 - titanium dioxide, ethylhexyl methoxycinnamate, benzophenone-3 cream
Allure Labs, 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.

Drug Facts

Active Ingredients:

Titanium Dioxide 1.6%

Ethylhexyl Methoxycinnamate (Octinoxate) 7.50%

Benzophenone-3: 3.00%

Purpose:

Sunscreen

Uses:

- An oil-free UVA/UVB broad spectrum daily moisturizer. Provides ultimate protection against the aging effects of the sun and other environmental exposure. Enriched with essential vitamins and anti-oxidants that prevent free radical damage and preserving skin hydration for the entire day.
- Water-resistant
- Paraben-free

Directions:

Apply liberally 15-30 minute prior to sun exposure. Reapply after prolonged swimming or vigorous activity.

Indications:

Universal for all skin types.

Warnings:

For external use only.

When using this product

- Keep out of eyes. If contact occurs rinse with water.
- Discontinue use if irritation or redness occurs.

Keep out of reach of children

Inactive Ingredients:

Water (Aqua), Ethylhexyl Methoxycinnamate, Ascorbyl Palmitate, Cyclomethicone, Benzophenone-3, Glycerin, Glyceryl Stearate, Camellia Sinensis Leaf Extract (Green Tea), Tocopheryl Acetate, Phenoxyethanol, Lecithin, C13-14 Isoparaffin Citrus blend, Xanthan Gum, Disodium EDTA.

Distributor:

Image International
Palm Beach, FL 33411 USA

Image of the product:

Sun Solar Defense Oil-free Gel SPF 15

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Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:62742-4039
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	16 mg in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	30 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62742-4039-1	118 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/01/2010	

Labeler - Allure Labs, Inc. (926831603)

Revised: 7/2010 Allure Labs, Inc.