

SUN DEFENSE SPF 30 - avobenzone octinoxate oxybenzone titanium dioxide lotion
Kamins Dermatologics 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.

SUN DEFENSE SPF30 CONSUMER LABELING

Active ingredients:

Avobenzone 2.5%

Octinoxate 7.5%

Oxybenzone 6%

Titanium dioxide 2%

Purpose: Sunscreen

Keep out of reach of children.

This oil and fragrance-free broad spectrum UVA/UVB sunscreen provides important protection against the sun's harmful rays. Recommended for use on face and body, for everyday wear and outdoor activities. This cosmetically elegant formula is non-greasy, leaves a matte finish, and can be reapplied over makeup.

- fragrance-free • oil-free
- for face and body

Uses

- Helps prevent sunburn.
- Higher SPF gives more sunburn protection.
- Provides high protection against sunburn.

Warnings

For external use only.

When using this product, keep out of eyes. If contact occurs, rinse abundantly with water to remove.

Stop use and ask a doctor if rash or irritation develops and lasts.

If swallowed, seek medical assistance or contact a Poison Control Center immediately.

Other information

Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.

Store at room temperature 15-30°C (59-86°F).

Directions

- Apply liberally and evenly to face and exposed areas 15-30 minutes before sun exposure.
- Reapply every two hours or as needed.

- Reapply after swimming, towel drying, washing or perspiring heavily.
- Children under 6 months of age: ask a doctor.

Inactive ingredients: water, octyldodecyl neopentanoate, propylene glycol, acer saccharum, tocopheryl acetate, cetyl alcohol, stearic acid, DEA-cetyl phosphate, panthenol, dimethicone, xanthan gum, carbomer, sodium hydroxide, phenoxyethanol, chlorphenesin, BHT, iron oxides (CI 77491).


SUN DEFENSE SPF 30

120 mL / 4 fl. oz

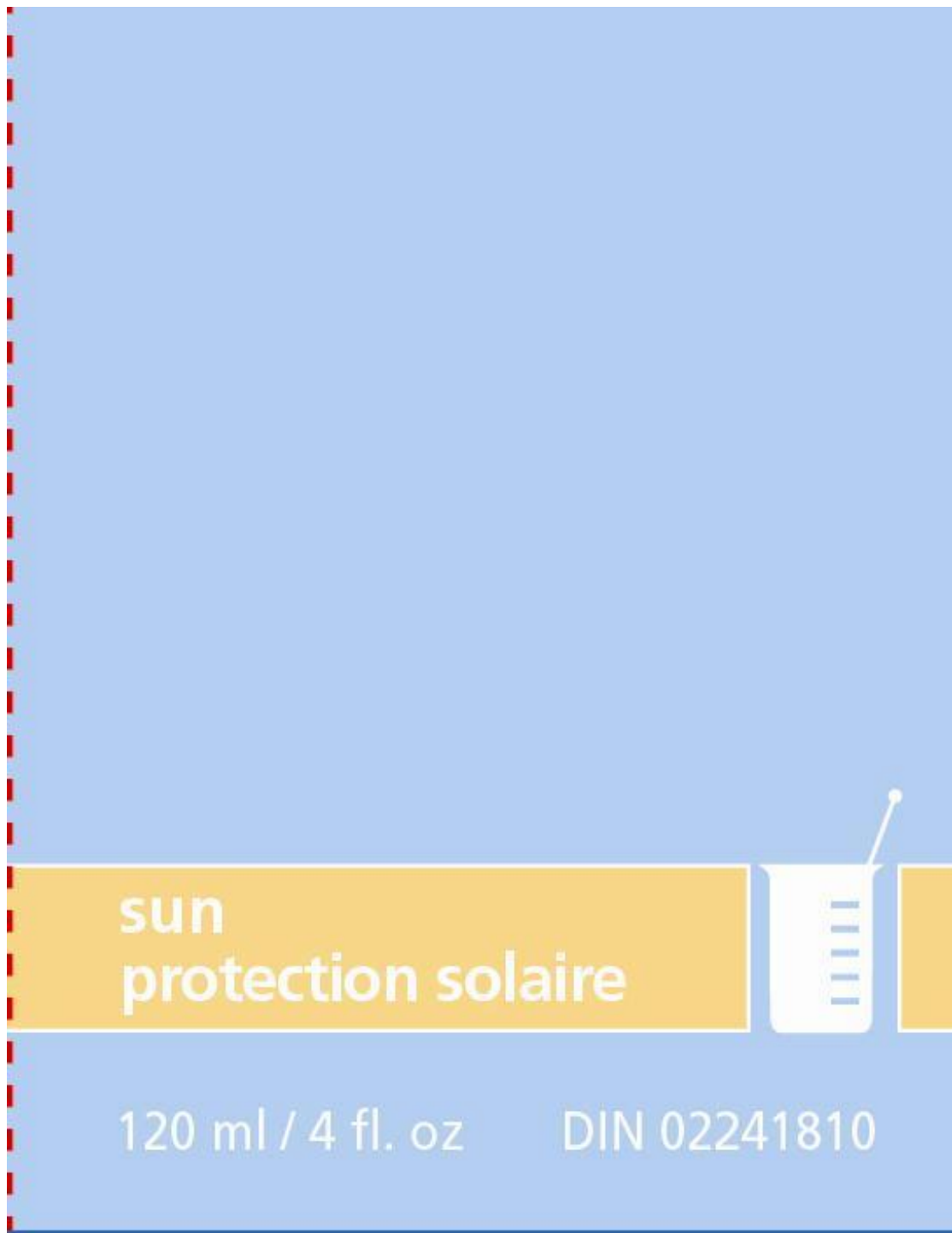
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B. KAMINS
laboratories



Sun Defense
SPF 30
Écran solaire
FPS 30



SUN DEFENSE SPF 30

avobenzone octinoxate oxybenzone titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63550-851
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	25 mg in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	6 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	20 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ACER SACCHARUM SAP (UNII: 75UOH57984)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
DIETHANOLAMINE CETYL PHOSPHATE (UNII: 4UG0316V9S)	
PANTHENOL (UNII: WV9CM0O67Z)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63550-851-10	120 mL in 1 BOX		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	09/02/2011	

Labeler - Kamins Dermatologics Inc. (254050784)**Registrant** - Kamins Dermatologics Inc. (254050784)**Establishment**

Name	Address	ID/FEI	Business Operations
Kamins Dermatologics Inc.		254050784	manufacture, pack, label