SUN DEFENSE SPF 15 - avobenzone homosalate octisalate oxybenzone spray
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 SPF15 - CONSUMER LABELING

Active ingredients:

Avobenzone 3%

Homosalate 10%

Octisalate 5%

Oxybenzone 6%

Purpose: Sunscreen

Keep out of reach of children.

A broad spectrum UVA/UVB sunscreen to help protect the skin from sunburn. Sun Defense Spray SPF 15 is enriched with moisturizing açai oil, pomegranate extract and Bio-Maple^{TM} compound to help skin remain hydrated.

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.

Flammable: Keep away from open flame or source of heat. Do not use while smoking. Avoid long term storage above 40 °C (104°F)

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.

Directions

■ Apply 15-30 minutes before sun exposure.

■ Hold bottle 8-10 inches from the skin and press pump to spray a fine even mist.

■ Spray liberally and evenly over all exposed areas to ensure complete coverage.

■ Do not spray directly onto face; spray into hands, then immediately apply to face.

■ Rub into skin on all exposed areas.

■ Reapply every two hours or as needed, after swimming, washing, towel drying, or perspiring heavily.

Inactive ingredients: alcohol denat., ethyl macadamiate, tocopherol, malic acid, diethylhexyl 2,6-naphthalate, PPG-5-ceteth-20, acrylates/octylacrylamide copolymer, ethylene brassylate, lauryl PCA, tocopheryl acetate, acer saccharum (maple isolate), punica granatum (pomegranate) extract, propylene glycol, water, euterpe oleracea (acai) oil, retinyl palmitate, magnesium ascorbyl phosphate.

B. KAMINS

SUN DEFENSE SPRAY SPF15

150mL / 5 fl.oz

DIN 02312484

image/jpg

Sun Defense SPF 15 Spray
Écran solaire FPS 15

SUN DEFENSE SPF 15

avobenzone homosalate octisalate oxybenzone spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63550-850
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	60 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
MALIC ACID (UNII: 817L1N4CKP)	
DIETHYLHEXYL 2,6-NAPHTHALATE (UNII: I0DQJ7YGXM)	
PPG-5-CETETH-20 (UNII: 4AAN25P8P4)	
ETHYLENE BRASSYLATE (UNII: 9A87HC7ROD)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
ACER SACCHARUM SAP (UNII: 75UOH57984)	
POMEGRANATE (UNII: 56687D1Z4D)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
ACAI (UNII: 46AM2VJ0AW)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
MAGNESIUM ASCORBYL PHOSPHATE (UNII: 0R822556M5)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63550-850-12	150 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

Revised: 9/2011 Kamins Dermatologics Inc.