

**SOOTHING DAY SPF 15- avobenzone octinoxate oxybenzone cream
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.

Soothing Day Cream SPF 15 CONSUMER LABELING

Active ingredients:

Avobenzone 2%

Octinoxate 7%

Octibenzone 5%

Purpose:

Sunscreen

Keep out of the reach of children.

A gentle cosmetic emollient preparation that helps moisturize dry skin conditions associated with rosacea and related couperose skin complexions. Free of fragrance, this formula contains antioxidants and soothing Bio-Maple compound to help moisturize and relieve inflammation. Also helps protect skin from UVA and UVB sun rays, which are known to be harmful to rosacea type skins. This high-performance, anti-aging daily moisturizer is a perfect primer for makeup.

Uses

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

Warnings

For external use only.

Avoid contact with eyes when using this product. 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.

Inactive ingredients:

water, cetyl alcohol, PEG-100 stearate, glyceryl stearate, soluble collagen, glycerin, squalane, acer saccharum (maple isolate/isolat d'érable), PEG-16 soy sterol, cetareth-

12, diethylhexyl 2,6-naphthalate, cyclotetrasiloxane, cyclopentasiloxane, PEG/PPG-18/18 dimethicone, xanthan gum, tocopheryl acetate, retinyl palmitate, sodium hydroxide, carbomer, phenoxyethanol, chlorphenesin.

Directions

■ Apply liberally and evenly each morning to cleansed face and neck, before sun exposure and as needed

■ Children under 6 months of age: ask a doctor

B. KAMINS

Soothing Day Cream SPF15

50mL / 1.7 fl.oz

DIN 02275791

B. KAMINS
laboratories

 Soothing Day Cream SPF 15
Crème de jour apaisante
FPS 15

Booster Blue

**moisturize
hydratant**



50 ml / 1.7 fl. oz

DIN02135698

SOOTHING DAY SPF 15

avobenzone octinoxate oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63550-192
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	20 mg in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	70 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
XANTHAN GUM (UNII: TTV12P4NEE)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
WATER (UNII: 059QF0KO0R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
POLYOXYL 100 STEARATE (UNII: YD01N1999R)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
GLYCERIN (UNII: PDC6A3C0OX)	
SQUALANE (UNII: GW89575KF9)	
ACER SACCHARUM SAP (UNII: 75UOH57984)	
CETETH-16 (UNII: 94826GMB5B)	
CETEARETH-12 (UNII: 7V4MR24V5P)	
DIETHYLHEXYL 2,6-NAPHTHALATE (UNII: I0DQJ7YGXM)	
QUADROSILAN (UNII: C5KT601WPM)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

Marketing Start Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63550-192-07	50 mL in 1 BOX; Type 0: Not a Combination Product	10/01/2010	

B. KAMINS
laboratories



Bio-Maple™

 Soothing
Day Cream

A lightweight day cream
with water-binding agents
and a blend of natural
moisturizers to hydrate
dry and sensitive skin types



B. KAMINS
laboratories

Soothing Day Cream

RosaCool™

50 ml / 1.7 fl.oz



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	10/01/2010	

Labeler - Kamins Dermatologics Inc. (254050784)

Registrant - Kamins Dermatologics Inc. (254050784)

Establishment

Name	Address	ID/FEI	Business Operations
Odan Laboratories Ltd		208585604	manufacture(63550-192)

Revised: 12/2022

Kamins Dermatologics Inc.