

**LIP BALM- octinoxate oxybenzone zinc oxide ointment
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.

CONSUMER LABELING

Active ingredients:

OCTINOXATE 7.5%

OXYBENZONE 5.0%

ZINC OXIDE 4.0%

Purpose: Sunscreen product

Keep out of the reach of children.

A soothing treatment balm that helps heal and protect lips from sun, wind and extreme temperatures. Repairs chapped, sore lips with Bio-Maple™ compound and skin softening oils. Also helps prevent the breakout of lip sores with broad spectrum UVA/UVB sun screening agents. Creates a smoother palette for lipstick application by diminishing the appearance of lip lines and reducing the feathering of lip color. Use anytime for fuller, more luscious lips

Uses

helps prevent sunburn

higher SPF gives more sunburn protection

provides moderate 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.

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.

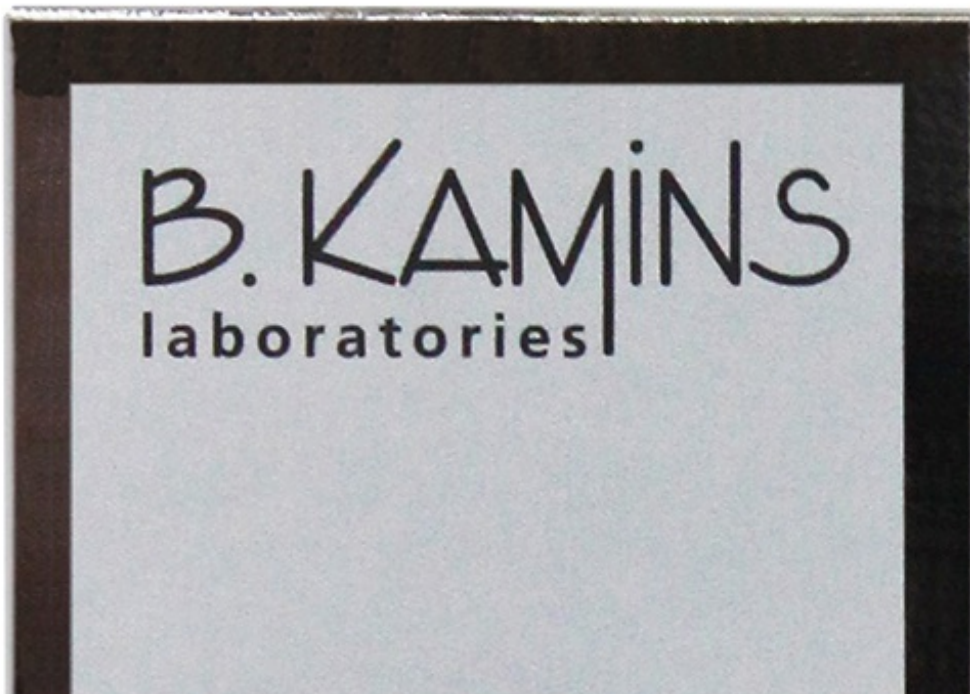
Directions

Using the angled tube applicator, squeeze tube and apply directly to lips 15-30 minutes before sun exposure. Reapply as needed, especially after prolonged sun exposure, drinking or eating.

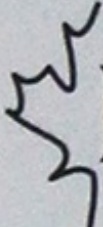
Children under 6 months of age: ask a doctor.

Inactive ingredients: Polybutene, ricinus communis (castor) seed oil, petrolatum, VP/hexadecene copolymer, cera alba (beeswax), cyclopentasiloxane/dimethicone crosspolymer, caprylic/capric triglyceride, squalane, copernicia cerifera (carnauba wax), paraffin, tocopheryl acetate, acer saccharum (maple isolate), flavour/aroma, benzyl benzoate.

B. KAMINS
LIP BALM SPF 20 box



Bio-Maple™

 Lip Balm SPF 20

Repairs chapped, sore lips and helps
heal and protect from sun,
wind and extreme temperatures

ESSENTIALS ● ESSENTIELS

DIN 02248084 | 15 g / 0.5 oz

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LIP BALM SPF 20
15 G / 0.5 oz
DIN 02248084

LIP BALM

octinoxate oxybenzone zinc oxide ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63550-114
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 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	50 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	40 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
POLYBUTENE (1400 MW) (UNII: 1NA5AO9GH7)	
CASTOR OIL (UNII: D5340Y2I9G)	
PETROLATUM (UNII: 4T6H12BN9U)	
1-HEXADECENE (UNII: 97T015M2UX)	
WHITE WAX (UNII: 7G1J5DA97F)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRICAPRIN (UNII: O1PB8EU98M)	
TRICAPRYLIN (UNII: 6P92858988)	
SQUALANE (UNII: GW89575KF9)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
PARAFFIN (UNII: I9O0E3H2ZE)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ACER SACCHARUM SAP (UNII: 75UOH57984)	
BENZYL BENZOATE (UNII: N863NB338G)	

Product Characteristics

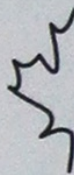
Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63550-114-01	15 g in 1 TUBE; Type 0: Not a Combination Product	02/01/2004	

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laboratories

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 **Lip Balm**

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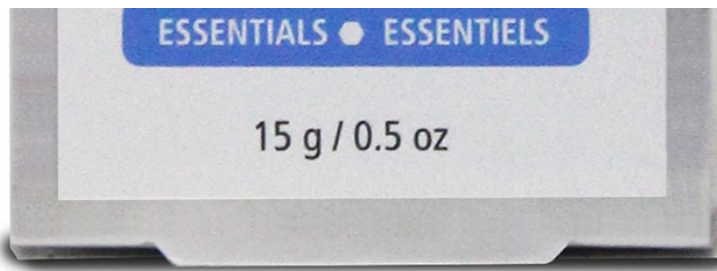
EXP. 12-2019

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Lip Balm

ESSENTIALS • ESSENTIELS

15g/0.5 oz



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/01/2004	

Labeler - Kamins Dermatologics Inc. (254050784)

Registrant - Odan Laboratories Ltd (208585604)

Establishment

Name	Address	ID/FEI	Business Operations
Odan Laboratories Ltd		208585604	manufacture(63550-114)

Revised: 12/2022

Kamins Dermatologics Inc.