

LIP ENHANCER GLOSS SUNSCREEN BROAD SPECTRUM SPF15- avobenzone, octinoxate, octisalate gel

AKG Innovations LLC

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.

LIP ENHANCER GLOSS SUNSCREEN BROAD SPECTRUM SPF15

Active ingredients

AVOBENZONE 3.0%

OCTINOXATE 7.5%

OCTISALATE 3.0%

Purpose

Sunscreen

Uses

Helps prevent sunburn.

Warnings

For external use only

When using this product keep out of eyes.

Rinse with water to remove - do not use on broken skin.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally and evenly 15 minutes before sun exposure.
- Reapply at least every two hours.
- Sun Protection Measures: Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
 - limit time in the sun, especially from 10 AM – 2 PM
 - wear long sleeve shirts, pants, hats, and sunglasses

Inactive ingredients

MINERAL OIL, ETHYLENE/PROPYLENE/STYRENE COPOLYMER,

BUTYLENE/ETHYLENE/STYRENE COPOLYMER, POLYETHYLENE, BEESWAX, MICA, MENTHA

PIPERITA (PEPPERMINT) OIL, TITANIUM DIOXIDE, CAPRYLYL GLYCOL, HEXYLENE GLYCOL,

RICINUS COMMUNIS (CASTOR) OIL, PHENOXYETHANOL, BHT

Other information

■Protect from excessive heat and direct sun.

Questions or comments visit:

www.arthurglosmandentalbeauty.com

Or call 1.855.333.2544

LIP ENHANCER GLOSS SUNSCREEN BROAD SPECTRUM SPF-15 (62111-0210-1)

advanced dental health - beauty

ARTHUR GLOSMAN DDS

Beverly Hills

LIP ENHANCER

GLOSS

SUNSCREEN

BROAD

SPECTRUM

SPF-15

0.26 fl. oz. / 7.4 mL

Distributed by:

AKG Innovations, LLC

450 N. Roxbury Drive,

Suite 222,

Beverly Hills, CA

90210

Made in USA

#90213

LIP ENHANCER

GLOSS

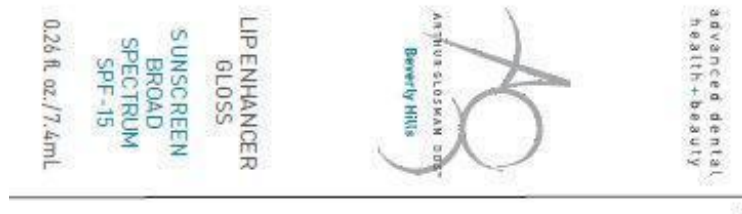
SPF-15

BROAD SPECTRUM

SUNSCREEN

Apply the pearlized, soft blue glaze

to the lips and either use alone for a superb shine, over lip color for extra shine, or under a favorite lipstick to help enhance the wear. The soft blue hue, along with the pearl helps make teeth appear whiter and brighter. And, although the gloss is very moisturizing, it is not the least bit tacky or sticky. The Peppermint Oil provides a cooling sensation and as a result, helps lips appear fuller and more voluptuous. It tastes good too! UVA/UVB SPF-15 protection helps prevent dry, sunburned lips. Can be used as often as necessary.

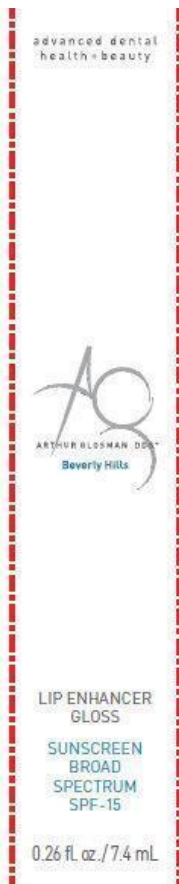


Active ingredients: Avobenzone 3.0%, Octinoxate 7.5%, Octisalate 3.0%

Warnings For external use only.

■ Do not use on damaged or broken skin ■ Avoid eyes, rinse with water to remove ■ Stop use and ask doctor if rash occurs. ■ **Keep out of reach of children.** If swallowed get medical help or contact a poison control center immediately.

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Drug Facts

Active ingredients	Purpose
AVOBENZONE 3.0% OCTINOXATE 7.5% OCTISALATE 3.0%	Sunscreen

Uses ■ Helps prevent sunburn.

Warnings For external use only.
When using this product keep out of eyes. Rinse with water to remove - do not use on broken skin.
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions
 ■ Apply liberally and evenly 15 minutes before sun exposure.
 ■ Reapply at least every two hours.
 ■ **Sun Protection Measures:** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
 • limit time in the sun, especially from 10 AM – 2 PM
 • wear long sleeve shirts, pants, hats, and sunglasses

Inactive ingredients MINERAL OIL, ETHYLENE/PROPYLENE/STYRENE COPOLYMER, BUTYLENE/ETHYLENE/STYRENE COPOLYMER, POLYETHYLENE, BEESWAX, MICA, MENTHA PIPERITA (PEPPERMINT) OIL, TITANIUM DIOXIDE, CAPRYLYL GLYCOL, HEXYLENE GLYCOL, RICINUS COMMUNIS (CASTOR) OIL, PHENOXYETHANOL, BHT.

Other information
 ■ Protect from excessive heat and direct sun.

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LIP ENHANCER GLOSS
 SPF-15 BROAD SPECTRUM SUNSCREEN

Apply the pearlescent, soft blue glaze to the lips and either use alone for a superb shine, over lip color for extra shine, or under a favorite lipstick to help enhance the wear. The soft blue hue, along with the pearl helps make teeth appear whiter and brighter. And, although the gloss is very moisturizing, it is not the least bit tacky or sticky. The Peppermint Oil provides a cooling sensation and as a result, helps lips appear fuller and more voluptuous. It tastes good too! UVA/UVB SPF-15 protection helps prevent dry, sunburned lips. Can be used as often as necessary.

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avobenzone, octinoxate, octisalate gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62111-0210
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
	OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL
	OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	30 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
MINERAL OIL (UNII: T5L8T28FGP)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
MICA (UNII: V8A1AW0880)	
MENTHA PIPERITA (UNII: 79M2M2UDA9)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CAPRYLYL GLYCOL (UNII: 00YIU5438 U)	

HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
CASTOR OIL (UNII: D5340Y2I9G)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62111-0210-1	1 in 1 BOX		
1		7.4 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/06/2014	

Labeler - AKG Innovations LLC (056576137)

Establishment

Name	Address	ID/FEI	Business Operations
Dermaceutical Laboratories LLC		078457159	manufacture(62111-0210)

Revised: 2/2014

AKG Innovations LLC