

MOISTURIZING LIP BALMSPF30- avobenzone, homosalate, octisalate, octocrylene, oxybenzone stick
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.

MOISTURIZING LIP BALM SPF30

Active ingredients

Avobenzone 2.5%

Homosalate 8.0%

Octisalate 5.0%

Octocrylene 2.20%

Oxybenzone 3.0%

Purpose

Sunscreen

Uses

■Lip moisturizer: 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

Beeswax, Persea Gratissima
(Avocado) Oil, Butyrospermum Parkii (Shea)
Butter, Hydrogenated Vegetable Oil, Acacia
Decurrens/Jojoba/Sunflower Seed Wax Polyglyceryl-3
Esters, Menthyl Lactate, Argania Spinosa Kernel
Oil, Tocopheryl Acetate, Dimethicone, Helianthus
Annuus (Sunflower) Seed Oil Unsaponifiables, Aloe
Barbadensis Flower Extract, Bisabolol, Curcuma
Longa (Turmeric) Root Extract, Lawsonia Inermis
(Henna) Flower/Fruit/Leaf Extract, Melia Azadirachta
Flower Extract, Melia Azadirachta Leaf Extract,
Ocimum Basilicum (Basil) Flower/Leaf Extract,
Ocimum Sanctum Leaf Extract, Coccinia Indica
Fruit Extract, Corallina Officinalis Extract, Amino
Esters-1, Citrus Aurantium Dulcis (Orange) Peel Oil,
Simmondsia Chinensis (Jojoba) Seed Oil, Retinyl
Palmitate, Palmitoyl Oligopeptide, Ethylhexyl
Palmitate, Tribehenin, Sorbitan Isostearate, Menthol,
Caprylyl Glycol, Phenoxyethanol, Chlorphenesin.

Other information

■Protect from excessive heat and direct sun.

Questions or comments visit:

www.arthurglosmandentalbeauty.com

Or call 1.855.333.2544

MOISTURIZING LIP BALM SUNSCREEN BROAD SPECTRUM SPF-30 (62111-0211-3)

advanced dental health - beauty

ARTHUR GLOSMAN DDS

Beverly Hills

MOISTURIZING

LIP BALM

SUNSCREEN

BROAD

SPECTRUM

SPF-30

Net Wt. 0.15 oz. / 4.3 g

Distributed by:

AKG Innovations, LLC

450 N. Roxbury Drive,

Suite 222,

Beverly Hills, CA

90210

Made in USA

#90213

MOISTURIZING

LIP BALM

SPF-30

BROAD SPECTRUM

SUNSCREEN

Ice blue stick glides on smoothly,
leaving a soft sheen on the lips.

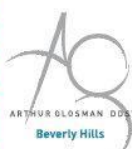
Cools with Menthol; moisturizes
with Avocado Oil, Shea Butter and
Jojoba Seed Oil; calms and soothes

with Dimethicone. UVA/UVB

SPF 30 protection to help prevent
sunburned lips. Can be used as

often as necessary on the lips and
around the lip area.

advanced dental health+beauty

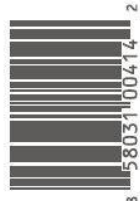


ARTHUR GLOSMAN D.D.S.
Beverly Hills

MOISTURIZING LIP BALM

SUNSCREEN BROAD SPECTRUM SPF-30

Net Wt. 0.15 oz. / 4.3 g



58031100414 2

Drug Facts (continued)

Other information

- Protect from excessive heat and direct sun.

Questions or comments visit:

www.arthurglosman.dentalbeauty.com
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450 N. Roxbury Drive,
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Made in USA
#90214

Drug Facts

Active ingredients	Purpose
Avobenzone 2.5%	Sunscreen
Homosalate 8.0%	
Octisalate 5.0%	
Octocrylene 2.20%	
Oxybenzone 3.0%	

Uses Lip moisturizer; 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.

Stop use and ask a doctor if rash occurs.

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.

Drug Facts (continued)

with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:

- Limit time in the sun, especially from 10AM - 2 PM
- wear long sleeve shirts, pants, hats, and sunglasses

Inactive ingredients Beeswax, Persea Gratissima (Avocado) Oil, Butyrospermum Parkii (Shea) Butter, Hydrogenated Vegetable Oil, Acacia Decurrens/Jojoba/Sunflower Seed Wax Polyglyceryl-3 Esters, Menthyl Lactate, Argania Spinosa Kernel Oil, Tocopheryl Acetate, Dimethicone, Helianthus Annuus (Sunflower) Seed Oil Unsaponifiables, Aloe Barbadensis Flower Extract, Bisabolol, Curcuma Longa (Turmeric) Root Extract, Lawsonia Inermis (Henna) Flower/Fruit/Leaf Extract, Melia Azadirachta Flower Extract, Melia Azadirachta Leaf Extract, Ocimum Basilicum (Basil) Flower/Leaf Extract, Ocimum Sanctum Leaf Extract, Coccinia Indica Fruit Extract, Corallina Officinalis Extract, Amino Esters-1, Citrus Aurantium Dulcis (Orange) Peel Oil, Simmondsia Chinensis (Jojoba) Seed Oil, Retinyl Palmitate, Palmitoyl Oligopeptide, Ethylhexyl Palmitate, Tribehenin, Sorbitan Isosearate, Menthol, Caprylyl Glycol, Phenylethanol, Chlorphenesin.

MOISTURIZING LIP BALM

SPF-30 BROAD SPECTRUM SUNSCREEN

Ice blue stick glides on smoothly,
leaving a soft sheen on the lips.
Cools with Menthol; moisturizes
with Avocado Oil, Shea Butter and
Jojoba Seed Oil; calms and soothes
with Dimethicone. UVA/UVB
SPF 30 protection to help prevent
sunburned lips. Can be used as
often as necessary on the lips and
around the lip area.

MOISTURIZING LIP BALM SPF30
avobenzone, homosalate, octisalate, octocrylene, oxybenzone stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62111-0211
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 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	80 mg in 1 g
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	50 mg in 1 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	22.0 mg in 1 g
OXYBENZONE (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y)	OXYBENZONE	30 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
YELLOW WAX (UNII: 2ZA36H0S2V)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
SHEA BUTTER (UNII: K49155WL9 Y)	
MENTHYL LACTATE, (-)- (UNII: 2BF9E65L7I)	
ARGAN OIL (UNII: 4V59G5UW9 X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
DIMETHICONE (UNII: 92RU3N3Y10)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
ALOE VERA FLOWER (UNII: 575DY8C1ER)	
LEVOMENOL (UNII: 24WE03BX2T)	
CURCUMA LONGA LEAF (UNII: H2HC4RY52C)	
LAWSONIA INERMIS FLOWERING TOP (UNII: UF2093XE64)	
AZADIRACHTA INDICA FLOWER (UNII: 3TE8A92UPM)	
AZADIRACHTA INDICA LEAF (UNII: HKY915780 T)	
O CIMUM BASILICUM FLOWERING TOP (UNII: 7SAB275FP2)	
O CIMUM TENUIFLORUM TOP (UNII: 34T63W8ULS)	
COCCINIA GRANDIS FRUIT (UNII: VLJ6WOT3K5)	
CORALLINA OFFICINALIS (UNII: 4004498D06)	
CITRUS SINENSIS FLOWER OIL (UNII: AJ56JP5TFP)	
JOJOBA OIL (UNII: 724GKU717M)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
PALMITOYL OLIGOPEPTIDE (UNII: HO4ZT5S86C)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
TRIBEHENIN (UNII: 8OC9U7TQZ0)	
Sorbitan Isostearate (UNII: 01S2G2C1E4)	
MENTHOL (UNII: L7T10EIP3A)	
CAPRYLYL GLYCOL (UNII: 00YIU5438 U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CHLORPHENESIN (UNII: I670DAL4SZ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62111-0211-3	1 in 1 BOX		
1		4.3 g 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
Englewood Labs LLC		172198223	manufacture(62111-0211)

Revised: 2/2014

AKG Innovations LLC