

**EIGHT HOUR CREAM NOURISHING LIP BALM SPF 20- octinoxate and avobenzone salve
Elizabeth Arden, 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.

197107

DESCRIPTION

This daily moisturizing treatment replenishes lips with eight essential vitamins, nutrients and minerals while providing advanced broad spectrum SPF 20 sun protection against damaging UVA/UVB rays.

INDICATIONS AND USAGE

To use: Squeeze tube and apply liberally with self-applicator tip.

WARNINGS

WARNING

:

FOR EXTERNAL USE ONLY. DO NOT USE ON DAMAGED OR BROKEN SKIN. WHEN USING THIS PRODUCT KEEP OUT OF EYES. RINSE WITH WATER TO REMOVE. STOP USE AND ASK A DOCTOR IF RASH OCCURS. KEEP OUT OF REACH OF CHILDREN. IF PRODUCT IS SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

OTC - ACTIVE INGREDIENT

ACTIVE INGREDIENTS: OCTINOXATE, 4.0 % W/W
AVOBENZONE, 3.0 % W/W

INACTIVE INGREDIENT

Inactive Ingredients

POLYBUTENE, MICROCRYSTALLINE WAX/CERA
MICROCRISTALLINA/CIRE MICROCRISTALLINE,
PETROLATUM, RICINUS COMMUNIS (CASTOR)
SEED OIL, BUTYROSPERMUM PARKII (SHEA) BUTTER,
NYLON-12, DIOCTYLDODECYL DODECANEDIOATE, C12-15

ALKYL BENZOATE, GLYCERETH-26, BUTYLOCTYL SALICYLATE, LANOLIN, ASTROCARYUM MURUMURU SEED BUTTER, BEESWAX/CERA ALBA/CIRE D'ABEILLE, COPERNICIA CERIFERA (CARNAUBA) WAX/CERA CARNAUBA/CIRE DE CARNAUBA, HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL, HONEY EXTRACT, HYDROGENATED CASTOR OIL, LINOLEIC ACID, LINOLENIC ACID, NASTURTIUM OFFICINALE FLOWER/LEAF EXTRACT, RETINYL PALMITATE, TOCOPHEROL, TOCOPHERYL ACETATE, BHT, IRON OXIDES (CI 77491, CI 77492).

DOSAGE & ADMINISTRATION

apply liberally

**OTC - KEEP OUT OF REACH OF CHILDREN
KEEP OUT OF REACH OF CHILDREN.**

OTC - PURPOSE

Provides SPF 20 sun protection.

OTC - WHEN USING

KEEP OUT OF EYES.



Elizabeth Arden

**Eight Hour® Cream
Nourishing Lip Balm
Broad Spectrum Sunscreen SPF 20**

This daily moisturizing treatment replenishes lips with eight essential vitamins, nutrients and minerals while providing advanced broad spectrum SPF 20 sun protection against damaging UVA/UVB rays. Lips feel softer and smoother with a healthy-looking, radiant shine.

To use: Squeeze tube and apply liberally with self-applicator tip.

This carton is recyclable.



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The Eight Hour® Cream Skincare Collection

THE ALL-DAY, ALL-NIGHT, ALL-IN-ONE BEAUTY SECRET.

The Original Skin Protectant

The skincare classic that soothes, restores, calms and renews.

- Helps alleviate symptoms of chapping, peeling and windburn due to dryness, and cracked dry skin on hands, elbows, knees, and feet.
- Shapes brows, revitalizes shine, smooths hands, cuticles and nails.
- Contains super emollients and vitamin E (Tocopherol).

To use: Apply liberally as often as necessary.

Fragrance Free Skin Protectant

All the same benefits as our original skincare classic, in a fragrance free formula.

Eight great ways to use Eight Hour® Cream Skin Protectant

1. Alleviate dry and chapped skin.
2. Shape eyebrows into a perfect arch.
3. Soften rough, dry cuticles and hands.
4. Smooth chapped, cracked heels and soles.
5. Relieve sun-exposed skin.
6. Refresh jet-lagged skin.
7. Smooth legs after shaving or waxing.
8. Add shine to eyelids, cheeks and lips.

Lip Protectant Stick Sunscreen SPF 15

(Not available in all markets.)

A super-protective, portable stick for lips.

- Enriched with super emollients to relieve symptoms of chapping and cracked lips due to dryness.
- SPF 15 sunscreen to help prevent sunburn.
- Contains moisturizing vitamin E (Tocopherol).

To use: Apply liberally as often as necessary.

Lip Protectant Stick Sheer Tint Sunscreen SPF 15

(Not available in all markets.)

All the benefits of the original Lip Protectant Stick SPF 15. Choose from a range of beautifully sheer shades.

To use: Apply liberally as often as necessary.

Intensive Lip Repair Balm

This deeply moisturizing balm helps heal dry, chapped lips.

- Scientifically shown to strengthen lip's delicate moisture barrier.
- Leaves lips looking healthier and more beautiful with continued use.

To use: Apply liberally at bedtime or as needed.

Nourishing Lip Balm SPF 20 (Not available in all markets.)

This daily lip treatment nourishes with moisture and contains eight essential vitamins, nutrients and minerals.

- Leaves lips softer and smoother with a healthy-looking, radiant shine.
- SPF 20 sunscreen provides sunburn protection and broad spectrum UVA/UVB protection.

To use: Apply liberally and frequently before sun exposure.

Intensive Moisturizing Hand Treatment

A fast-absorbing moisturizing gel cream for the hands.

- Soothes and softens with micro-encapsulated emollients and moisturizing vitamin E (Tocopherol).
- Reverses signs of dryness and cracking.

To use: Apply liberally as often as necessary.

Intensive Moisturizing Body Treatment

A fast-absorbing moisturizing treatment for the body.

- Moisturizes intensely to reverse skin dryness and flaking.
- Leaves skin soft, smooth and hydrated for eight hours.

To use: Apply generously on body.

Intensive Daily Moisturizer for Face SPF 15

(Not available in all markets.)

This daily moisturizer leaves skin feeling soft, smooth and hydrated for up to eight hours.

- Protects skin from the effects of extreme weather and climate changes while SPF 15 shields skin from the harmful effects of the sun.
- Suitable for all skin types.

To use: Smooth onto cleansed face and throat daily.

Sun Defense for Face SPF 50 (Not available in all markets.)

Provides powerful SPF 50 protection to help shield skin against harmful UVA/UVB rays that can cause sunburn, surface skin cell damage and premature signs of aging. Lightweight, oil-free lotion helps protect your skin from sun exposure while hydrating for up to 8 hours. PABA free.

To use: Apply liberally to face before sun exposure. Reapply frequently to maintain protection, especially after perspiring, swimming or toweling. IMPORTANT: Do not stay too long in the sun, even while using a sunscreen product. Keep babies and young children out of direct sunlight. Overexposure to the sun is a serious, health threat.

Targeted Sun Defense Stick SPF 50

Target over-exposed areas such as lips, nose, earlobes, even scars to shield from the burning and aging effects of UVA and UVB rays.

Eight Hour® Cream hydrating benefits soothe and smooth for up to 8 hours. Oil-free. Water-resistant. PABA-free. Non-acnegenic. Perspiration-resistant. Suitable for all skin types. Ophthalmologist.

Clinically and dermatologist tested.

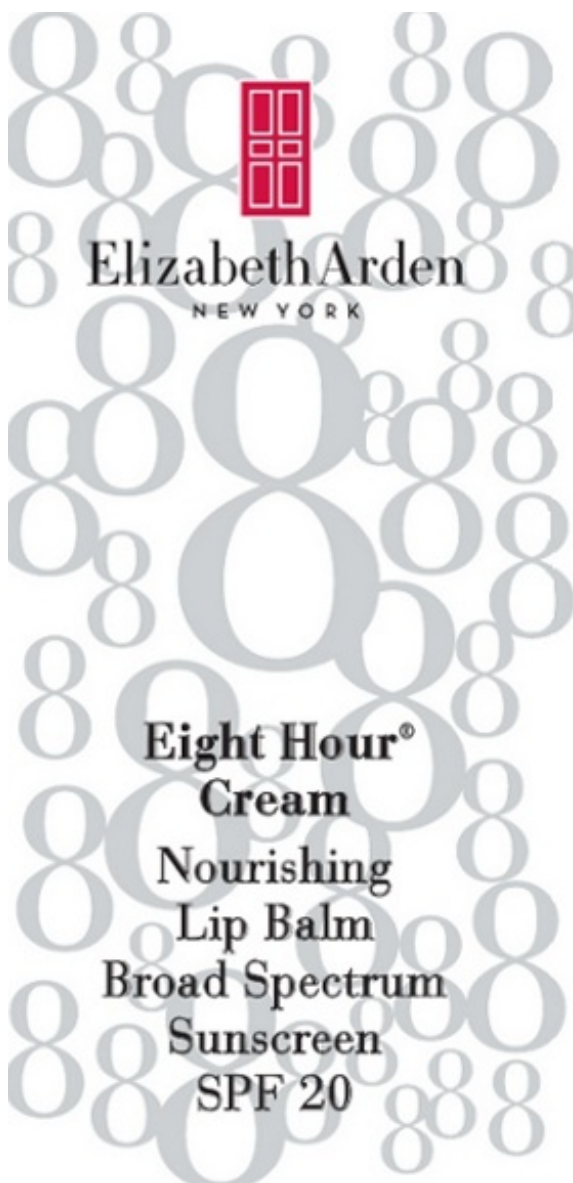
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Clinically and dermatologist tested.

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Drug Facts (continued) <ul style="list-style-type: none">Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away. Directions For Sunscreen Use: <ul style="list-style-type: none">Apply liberally 15 minutes before sun exposureReapply at least every 2 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 of 15 or higher and other sun protection measures including: <ul style="list-style-type: none">Limit time in the sun, especially from 10 a.m. – 2 p.m.Wear long-sleeve shirts, pants, hats, and sunglassesChildren under 6 months: Ask a doctor.	Drug Facts (continued) <p>NYLON-12, DIOCTYLDODECYL DODECANEDIOATE, C12-15 ALKYL BENZOATE, GLYCERETH-26, BUTYLOCTYL SALICYLATE, LANOLIN, ASTROCARYUM MURUMURU SEED BUTTER, BEESWAX/CERA ALBA/CIRE D'ABEILLE, COPERNICIA CERIFERA (CARNAUBA) WAX/CERA CARNAUBA/CIRE DE CARNAUBA, HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL, HONEY EXTRACT, HYDROGENATED CASTOR OIL, LINOLEIC ACID, LINOLENIC ACID, NASTURTIIUM OFFICINALE FLOWER/LEAF EXTRACT, RETINYL PALMITATE, TOCOPHEROL, TOCOPHERYL ACETATE, BHT, IRON OXIDES (CI 77491, CI 77492).</p> Other Information <ul style="list-style-type: none">Protect this product from excessive heat and direct sun Questions or comments? <ul style="list-style-type: none">Call toll free 1-800-326-7337	Drug Facts (continued) <ul style="list-style-type: none">Stop use and ask a doctor if rash occurs to remove.When using this product keep out of eyes. Rinse with water to remove. Warnings <ul style="list-style-type: none">For external use onlyDo not use on damaged or broken skin	Drug Facts (continued) Uses <ul style="list-style-type: none">Helps prevent sunburnIf used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun						
Inactive Ingredients <p>POLYBUTENE, MICROCRYSTALLINE WAX/CERA MICROCRYSTALLINA/CIRE MICROCRISTALLINE, PETROLATUM, RICINUS COMMUNIS (CASTOR) SEED OIL, BUTYROSPERMUM PARKII (SHEA) BUTTER.</p>	Drug Facts <table border="1"><thead><tr><th>Active Ingredients</th><th>Purpose</th></tr></thead><tbody><tr><td>OCTINOXATE 4.0%</td><td>Sunscreen</td></tr><tr><td>AVOBENZONE 3.0%</td><td>Sunscreen</td></tr></tbody></table>	Active Ingredients	Purpose	OCTINOXATE 4.0%	Sunscreen	AVOBENZONE 3.0%	Sunscreen		
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Elizabeth Arden
NEW YORK

Eight Hour[®]
Cream
Nourishing
Lip Balm
Broad Spectrum
Sunscreen
SPF 20

USES: Helps prevent sunburn. If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun.

WARNING: FOR EXTERNAL USE ONLY. DO NOT USE ON DAMAGED OR BROKEN SKIN. WHEN USING THIS PRODUCT KEEP OUT OF EYES. RINSE WITH WATER TO REMOVE. STOP USE AND ASK A DOCTOR IF RASH OCCURS. KEEP OUT OF REACH OF CHILDREN. IF PRODUCT IS SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

Directions for Sunscreen use: apply liberally 15 minutes before sun exposure. Reapply at least every 2 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 of 15 or higher and other sun protection measures including: limit time in the sun, especially from 10 a.m. – 2 p.m., wear long-sleeve shirts, pants, hats, and sunglasses. Children under 6 months: Ask a doctor.

Other information: protect this product from excessive heat and direct sun.

Questions or comments? Call toll free 1-800-326-7337

Clinically and dermatologist tested. Hypoallergenic.

ACTIVE INGREDIENTS: OCTINOXATE, 4.0 % W/W
AVOBENZONE, 3.0 % W/W

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elizabetharden.com

EIGHT HOUR CREAM NOURISHING LIP BALM SPF 20

octinoxate and avobenzone salve

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67938-1111
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.568 g in 14.2 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.426 g in 14.2 g

Inactive Ingredients

Ingredient Name	Strength
POLYBUTENE (1400 MW) (UNII: 1NA5AO9GH7)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PETROLATUM (UNII: 4T6H12BN9U)	
NYLON-12 (UNII: 446U8J075B)	
DIOCTYLDODECYL DODECANEDIOATE (UNII: 7QDB5EE79Y)	
GLYCERETH-26 (UNII: NNE56F2N14)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
LANOLIN (UNII: 7EV65EAW6H)	
ASTROCARYUM MURUMURU SEED BUTTER (UNII: 12V64UPU6R)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
LINOLEIC ACID (UNII: 9KJL21T0QJ)	
LINOLENIC ACID (UNII: 0RBV727H71)	
TOCOPHEROL (UNII: R0ZB2556P8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67938-1111-1	1 in 1 BOX		
1	NDC:67938-1111-2	14.2 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	07/24/2012	

Labeler - Elizabeth Arden, Inc (849222187)