

**PRO TRIPLE PROTECTION FACTOR LIP BALM BROAD SPECTRUM SPF 30
SUNSCREEN- octinoxate, octisalate, avobenzone, zinc oxide lotion
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.

Triple Protection Factor Lip Balm provides ultimate lip protection with SPF 30, DNA Enzyme Complex™ + Antioxidants.

Unique lip balm that nourishes and conditions, creating smooth, healthy-looking lips.

Use Directions:

Apply generously and evenly to lips prior to sun exposure.

Reapply frequently to maintain protection.

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.

Store at room temperature.

Clinically and Dermatologist Tested

- Non-Comedogenic
- Fragrance Free
- Paraben Free

INGREDIENTS:

PETROLATUM, BEESWAX/CERA ALBA/CIRE D'ABEILLE, MICROCRYSTALLINE WAX/CERA MICROCRISTALLINA/CIRE MICROCRISTALLINE, BUTYROSPERMUM PARKII (SHEA) BUTTER, ETHYLHEXYL METHOXYCINNAMATE, ETHYLHEXYL SALICYLATE, RICINUS COMMUNIS (CASTOR) SEED OIL, POLYBUTENE, BUTYL METHOXYDIBENZOYLMETHANE, NYLON-12, GLYCERETH-26, BUTYLOCTYL SALICYLATE, DIOCTYLDODECYL DODECANEDIOATE, ZINC OXIDE, C12-15 ALKYL BENZOATE, LANOLIN, SQUALANE, ACETYL FARNESYLCYSTEINE, ARABIDOPSIS THALIANA EXTRACT, ASTROCARYUM MURUMURU SEED BUTTER, BISABOLOL, CARNOSINE, COPERNICIA CERIFERA (CARNAUBA) WAX/CERA CARNAUBA/CIRE DE CARNAUBA, ERGOTHIONEINE, ETHYLHEXYLGLYCERIN, HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL, HONEY EXTRACT, HYDROGENATED CASTOR OIL, LECITHIN, LINOLEIC ACID, LINOLENIC ACID, MICROCOCCUS LYSATE, PLANKTON EXTRACT, RETINYL PALMITATE, RICINOLETH-40, TOCOPHEROL, TOCOPHERYL ACETATE, TRIETHOXYCAPRYLYLSILANE, WATER/AQUA/EAU, BHT, PHENOXYETHANOL.

Elizabeth Arden, London

Made in U.S.A.

Distributed by: Beauty Partner

Enterprise, S.r.l., Rome, 00144, IT

Principal Display Panel - Bottle Label

ElizabethArden

PRO

TRIPLE
PROTECTION
FACTOR
LIP BALM

Broad Spectrum
SPF 30 Sunscreen

HIGH PROTECTION
Cream

UVA

14.g^e

Use Directions: Apply generously and evenly to lips prior to sun exposure. Reapply frequently to maintain protection. **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. **Store at room temperature.** / Baume pour les Lèvres. **Utilisation :** appliquer généreusement et uniformément sur les lèvres avant chaque exposition au soleil. Renouveler l'application fréquemment. **IMPORTANT :** IL EST DECONSEILLE DE S'EXPOSER TROP LONGTEMPS ET CE MEME SOUS LA PROTECTION D'UN ECRAN SOLAIRE. PROTEGER PARTICULIEREMENT LES BEBES ET LES JEUNES ENFANTS DONT LA PEAU EST PLUS VULNERABLE AU SOLEIL. **Conservar à température ambiente.** / Bálsamo para los Labios.

Modo de empleo: Aplicar en una capa generosa y uniforme en labios antes de exponerse al sol. Volver a repetir la aplicación de manera frecuente para conservar la protección. **IMPORTANTE:** NO PERMANEZCA EXPUESTO DURANTE DEMASIADO TIEMPO AL SOL, AUNQUE USE UN PRODUCTO CON PROTECCIÓN SOLAR. MANTENGA A LOS BEBÉS Y A LOS NIÑOS FUERA DE LA LUZ DIRECTA DEL SOL. LA SOBREEXPOSICIÓN AL SOL ES UNA AMENAZA IMPORTANTE PARA LA SALUD. **Mantener a temperatura ambiente.** / Balsamo Labbra. **Istruzioni per l'uso:** Applicare generosamente e uniformemente sulle labbra prima dell'esposizione al sole. Riapplicare spesso per mantenere una protezione ottimale.

IMPORTANTE: NON RIMANERE TROPPO A LUNGO AL SOLE, ANCHE SE SI UTILIZZA UNA PROTEZIONE SOLARE. TENERE NEONATI E BAMBINI PICCOLI AL RIPARO DALLA LUCE DIRETTA. L'ECESSIVA ESPOSIZIONE AL SOLE È UNA GRAVE MINACCIA PER LA SALUTE. **Conservare a temperatura ambiente.** / Leppbalsam/læbebalsam. **Brukerveiledning:** Påfør generøst og jevnt på lepper/læber før solesponering. Påfør regelmessig og ofte for å/at opprettholde beskyttelsen. **VIKTIG:** IKKE OPPHOLD DEG FOR LENGE/LÆNGE I SOLEN OM/AD GANGEN, SELV OM DU BRUKER ET SOLPRODUKT. IKKE EKSPONER BABYER OG SMÅ BARN FOR DIREKTE SOLLYS/BABYER OG SMÅ BØRN BØR IKKE OPHOLDE SIG I DIREKTE SOLLYS. OVERDREVET SOLING UTGJØR EN ALVORLIG HELSERISIKO/SUNDHEDSRISIKO.

Oppbevares i romtemperatur/stuetemperatur. / Läppbalsam. **Användning:** Applicera jämnt och generöst över läppar på morgonen. Upprepa ofta för att bibehålla solskyddet. **FÖRSIKTIGHETSÅTGÄRDER VID SOLNING:** STANNA INTE FÖR LÅNGE I SOLEN, ÄVEN OM DU ANVÄNDER EN SOLSKYDDSPRODUKT. SPÅDBARN OCH SMÅBARN BÖR SKYDDAS FRÅN DIREKT SOLLJUS. ÖVERDRIVET SOLANDE UTGÖR EN ALLVARLIG HÅLSORISK. **Förvaras i rumtemperatur.**

Elizabeth Arden, London Distributed by: Beauty Partner

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7352-142-01 P10-15

Elizabeth Arden



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TRIPLE
PROTECTION
FACTOR
LIP BALM
Broad Spectrum
SPF 30 Sunscreen
HIGH PROTECTION
Cream**



14.2g e

Principal Display Panel - Carton Label

Elizabeth Arden

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Broad Spectrum
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Triple Protection Factor Lip Balm provides ultimate lip protection with SPF 30, DNA Enzyme Complex™ + Antioxidants. Unique lip balm that nourishes and conditions, creating smooth, healthy-looking lips. **Use Directions:** Apply generously and evenly to lips prior to sun exposure. Reapply frequently to maintain protection. **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. **Store at room temperature.** Clinically and Dermatologist Tested • Non-Comedogenic • Fragrance Free • Paraben Free

Baume pour les Lèvres. Ecran Triple Protection Baume pour les Lèvres apporte une protection optimale aux lèvres grâce à un facteur de protection solaire IPS 30, au DNA Enzyme Complex™ et à des antioxydants. Ce baume lèvres unique nourrit et adoucit ; les lèvres sont lisses et visiblement rayonnantes de santé. **Utilisation :** appliquer généreusement et uniformément sur les lèvres avant chaque exposition au soleil. Renouveler l'application fréquemment. **IMPORTANT :** IL EST DÉCONSEILLÉ DE S'EXPOSER TROP LONGTEMPS ET CE MEME SOUS LA PROTECTION D'UN ECRAN SOLAIRE. PROTÉGER PARTICULIÈREMENT LES BÉBÉS ET LES JEUNES ENFANTS DONT LA PEAU EST PLUS VULNÉRABLE AU SOLEIL. **Conservé à température ambiante.** Soumis à des tests cliniques et dermatologiques • Non comédogène • Sans parfum • Sans parabène

Balsamo para los Labios. Triple Protección Bálsamo para los Labios aporta una protección perfecta a los labios gracias a su SPF 50, al DNA Enzyme Complex™ y a sus antioxidantes. Este bálsamo único nutre y suaviza, para unos labios lisos y con un aspecto saludable. **Modo de empleo:** Aplicar en una capa generosa y uniforme en labios antes de exponerse al sol. Volver a repetir la aplicación de manera frecuente para conservar la protección. **IMPORTANTE:** NO PERMANEZA EXPUESTO DURANTE DEMASIADO TIEMPO AL SOL, AUNQUE USE UN PRODUCTO CON PROTECCIÓN SOLAR. MANTÉNGA A LOS BEBÉS Y A LOS NIÑOS FUERA DE LA LUZ DIRECTA DEL SOL. LA SOBREEXPOSICIÓN AL SOL ES UNA AMENAZA IMPORTANTE PARA LA SALUD.

Mantenere a temperatura ambiente. Dermatologicamente provato • No comedogénico • Sin fragancia • Sin parabenos

Balsamo Labbra. Triple Protection Factor Balsamo Labbra fornisce la massima protezione per le labbra con SPF 50, DNA Enzyme Complex™ e antiossidanti. Questo balsamo unico per le labbra nutre e lenisce, per un effetto di morbidezza e benessere. **Istruzioni per l'uso:** Applicare generosamente e uniformemente sulle labbra prima dell'esposizione al sole. Riapplicare spesso per mantenere una protezione ottimale.

IMPORTANTE: NON RIMANERE TROPPO A LUNGO AL SOLE, ANCHE SE SI UTILIZZA UNA PROTEZIONE SOLARE. TENERE NEONATI E BAMBINI PICCOLI AL RIPARO DALLA LUCE DIRETTA. L'ECESSIVA ESPOSIZIONE AL SOLE È UNA GRAVE MINACCIA PER LA SALUTE. **Conservare a temperatura ambiente.** Clinicamente e dermatologicamente testato • Non comedogeno • Senza profumo • Senza parabeni

INGREDIENTS: PETROLATUM, BEESWAX/CERA ALBA/CIRE D'ABEILLE, MICROCRYSTALLINE WAX/CERA MICROCRISTALLINA/CIRE MICROCRISTALLINE, BUTYROSPERMUM PARKII (SHEA) BUTTER, ETHYLHEXYL METHOXYCINNAMATE, ETHYLHEXYL SALICYLATE, RICINUS COMMUNIS (CASTOR) SEED OIL, POLYBUTENE, BUTYL METHOXYDIBENZOYL METHANE, NYLON-12, GLYCERETH-26, BUTYLOCTYL SALICYLATE, DIOCTYLDODECYL DODECANEDIODATE, ZINC OXIDE, C12-15 ALKYL BENZOATE, LANOLIN, SQUALANE, ACETYL FARNESYL CYSTEINE, ARABIDOPSIS THALIANA EXTRACT, ASTROCARYUM MURUMURU SEED BUTTER, BISABOLOL, CARNOSINE, COPERNICIA CERIFERA (CARNAUBA) WAX/CERA CARNAUBA/CIRE DE CARNAUBA, ERGOTHIONEINE, ETHYLHEXYLGLYCERIN, HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL, HONEY EXTRACT, HYDROGENATED CASTOR OIL, LECITHIN, LINOLEIC ACID, LINOLENIC ACID, MICROCOCCUS LYSATE, PLANKTON EXTRACT, RETINYL PALMITATE, RICINOLETH-40, TOCOPHEROL, TOCOPHERYL ACETATE, TRIETHOXYCAPRYLYLSILANE, WATER/AQUA/EAU, BHT, PHENOXYETHANOL.

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Leppebalsam/læbebalsam. Leppebalsam/læbebalsam med trippel beskyttelsesfaktor som gir/giver ultimativ/ultimativ leppebeskyttelse/læbebeskyttelse med SPF 30, DNA Enzyme Complex™ og antioksidanter. En unik leppebalsam/læbebalsam som gir næring og pleie til leppene/læberne, og gjør så de blir myke/bløt og ser sunne/sunde ut. **Brukerveiledning:** Påfør generøst og jevnt på læber for soleksponering. Påfør regelmessig og ofte for å/ta opprettholde beskyttelsen. **VIKTIG:** IKKE OPPHOLD DEG FOR LENGE/LÆNGE I SOLEN OM/AD GANGEN. SELV OM DU BRUKER ET SOLPRODUKT, IKKE EKSPONER BABYER OG SMÅ BARN FOR DIREKTE SOLLYS/BABYER OG SMÅ BØRN BØR IKKE OPPLØSE SIG I DIREKTE SOLLYS. OVERDREVET SOLING UTGØR EN ALVORLIG HELSERISIKO/SUNDHEDSRISIKO. **Oppbevares i romtemperatur/stuetemperatur.** Dermatologisk testet • Ikke-komedogen • Uten parfyme • Uten parabener

Læppebalsam. Trippel skyddsfaktor læppebalsam ger læpparna optimalt skydd med SPF 30, DNA Enzyme Complex™ + antioksidanter. Unik læppebalsam med närande och vårdande egenskaper som ger mjuka läppar med ett friskt utseende. **Användning:** Applicera jämnt och generöst över läppar på morgonen. Upprepa ofta för att bibehålla solskyddet. **FÖRSIKTIGHETSÅTGÄRDER VID SOLNING:** STANNA INTE FÖR LÅNGE I SOLEN, ÄVEN OM DU ANVÄNDER EN SOLSKYDDSPRODUKT. SPÅDBARN OCH SMÅBARN BÖR SKYDDAS FRÅN DIREKT SOLLJUS. ÖVERDRIVET SOLANDE UTGÖR EN ALLVARLIG HÄLSORISIK. **Förvaras i rumtemperatur.** Dermatologiskt testad • Icke-komedogen (täpper inte till porerna) • Fri från parfym • Parabenfri

FPO – UPC
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PRO TRIPLE PROTECTION FACTOR LIP BALM BROAD SPECTRUM SPF 30 SUNSCREEN

octinoxate, octisalate, avobenzone, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67938-2082
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1.065 g in 14.2 g
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	.71 g in 14.2 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	.426 g in 14.2 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	.142 g in 14.2 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
SHEA BUTTER (UNII: K49155WL9Y)	
CASTOR OIL (UNII: D5340Y2I9G)	
GLYCERETH-26 (UNII: NNE56F2N14)	
NYLON-12 (UNII: 446U8J075B)	
DIOCTYLDODECYL DODECANEDIOATE (UNII: 7QDB5EE79Y)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
SQUALANE (UNII: GW89575KF9)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
LANOLIN (UNII: 7EV65EAW6H)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ASTROCARYUM MURUMURU SEED BUTTER (UNII: 12V64UPU6R)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
RICINOLETH-40 (UNII: 6S0J4W9IQY)	
LEVOMENOL (UNII: 24WE03BX2T)	
LINOLEIC ACID (UNII: 9KJL21T0QJ)	
ACETYL FARNESYL CYSTEINE (UNII: KK6984C8O3)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	

CARNAUBA WAX (UNII: R12CBM0EIZ)
LINOLENIC ACID (UNII: 0RBV727H71)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
TRIETHOXYCAPRYL YLSILANE (UNII: LDC331P08E)
CARNOSINE (UNII: 8HO6PVN24W)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
TOCOPHEROL (UNII: R0ZB2556P8)
ARABIDOPSIS THALIANA (UNII: AIBL60HQ81)
HONEY (UNII: Y9H1V576FH)
ERGOTHIONEINE (UNII: BDZ3DQM98W)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67938-2082-1	1 in 1 BOX	02/01/2017	
1	NDC:67938-2082-2	14.2 g in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/01/2017	

Labeler - ELIZABETH ARDEN, INC (849222187)

Revised: 2/2017

ELIZABETH ARDEN, INC