

ESSENTIAL SHOCKEYE AND LIP - avobenzene, homosalate, octinocate, octocrylene, oxybenzone cream

Natura Bisse International, S.A.

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.

Essential Shock Eye and Lip

Active Ingredients: Avobenzene (Butyl Methoxydibenzoylmethane) 3 percent. Homosalate 10 percent. Octinoxate (Ethylhexyl Methoxycinnamate) 4 percent. Octocrylene 2.5 percent. Oxybenzone (Benzophenone-3) 1 percent.

Other Ingredients: Water. Glycerin. Polyglyceryl-2 Dipolyhydroxystearate. Dimethicone. Beeswax (cera Alba). Polyglyceryl-4 Isostearate. Cetearyl Ethylhexanoate. Butylene Glycol. C12-15 Alkyl Benzoate. Rosa Canina Fruit Oil. Benxotriazolil Dodecil. Hydrolyzed Collagen. Silybum Marianum Extract. Iris Florentina Root Extract. Ananas Saticus (Pineapple) Fruit Extract. Glycine Soja (Soybean) Germ Extract. Triticum Vulgare (Wheat) Germ Extract. Propylene Glycol. PEG-60 Hydrogenated Castor Oil. Alcohol Denat. Epsom Salt (Magnesium Sufate. Retinol. Tocopheryl Acetate. Ascorbyl Palmitate. Disodium Edta. BHT. Phynoxyethanol. Methylparaben. Ethylparaben. Butylparaben. Propylparaben. Isobutylparaben. Fragrance (Parfum). Yellow 5 (CI 19140).

Uses: Helps prevent sunburn. Higher SPF gives more sunburn protection.

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. Moderate sun protection product.

Natura Bisse

Barcelona

Essential Shock Eye and Lip Treatment

Nourishing eye and lip firming cream with sunscreen

Net wt. 0.5 oz. 15 ml.

This product can be sold only by authorized Natura Bisse retailers

Made in Spain by

Natura Bisse Int. S.A.

Cerdanyola - 08290 Barcelona

C.P. 11590 Mexico, D.F. RFC NBI0402132P0

Not tested on animals

RB

Natura Bissé
Barcelona

ESSENTIAL
SHOCK
EYE AND LIP
TREATMENT

Crema reafirmante contorno de ojos
y labios con protección solar
Nourishing eye and lip firming cream
with sunscreen

Soin raffermissant nourrissant
pour les yeux et les lèvres avec
protection solaire

Питательный крем для повышения
упругости кожи вокруг глаз и губ с
защитой от солнца

معالج فوري للحرق من الشمس إلى الرقبة مع رطب من الفم الحساس

Reichhaltige, stabilisierende Pflege
für Augen und Lippen mit Lichtschutz
Tratamiento nutritivo firmador con
protector solar para os olhos e lábios
Trattamento rassodante nutriente
contorno occhi e labbra
con protezione solare

Made in Spain by
NATURA BISSÉ INT. S. A.
Cerdanyola - 08290 BARCELONA
Producto hecho en España y exportado por
NATURA BISSÉ INT. S.A. Barcelona, España.
Importado y distribuido en México por
NATURA BISSÉ INTERNATIONAL S.A. DE C.V.
Herschel No 50 Colonia Anzures.
Delegación Miguel Hidalgo
C.P. 11590 México, D.F. RFC NBO400132PO

Usos: Ayuda a prevenir la quemadura solar. Un factor de protección más alto ofrece mayor protección frente a la quemadura solar.
Alerta solar: Limitar la exposición al sol, usar ropa de protección. El uso de protectores solares puede reducir el riesgo de envejecimiento de la piel, cáncer de piel y otros efectos nocivos del sol. Producto de protección solar media.

Uses: Helps prevent sunburn. Higher SPF gives more sunburn protection.

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. Moderate sun protection product.

ESTE PRODUCTO SÓLO PUEDE VENDERSE
EN ESTABLECIMIENTOS AUTORIZADOS
POR NATURA BISSÉ

THIS PRODUCT CAN BE SOLD ONLY BY
AUTHORIZED NATURA BISSÉ RETAILERS

Natura Bissé
Barcelona

ESSENTIAL
SHOCK
EYE AND LIP
TREATMENT

Crema reafirmante contorno de
ojos y labios con protección solar

Nourishing eye and lip
firming cream with sunscreen

NET WT. 0.5 OZ e15 ml.

SPF 15

Active Ingredients (Ingredientes Activos)
AVOBENZONE (BUTYL
METHOXYDIBENZOYL METHANE) (BUTYL
METHOXYDIBENZOLIMETHANE) (5%) HOMOSALATE
(HOMOSALATE) (10%) OCTINOXATE
(ETHYLHEXYL METHOXYCINNAMATE)
(METHOXYCINAMATE DE OCTILO) (8%)
OCTOXYLENE (OCTOXYLENE) (2.5%)
OXYBENZONE (BENZOPHENONE-3)
(BENZOPHENONE-3) (1%)

Other Ingredients (Otros Ingredientes)
WATER (AQUA) (EAU) GLYCERIN (GLYCERIN)
POLYGLYCERYL-2 DPOLYHYDROXYSTEARATE
(POLYGLYCERYL-2 POLYHYDROXYSTEARATE)
DE POLYGLYCEROL-2 (DIMETHICONE (DIMETHICONE)
BESNAVA (CERA ALBA) (CERA DE ABEEJA)
POLYGLYCERYL-4 ISOSTEARATE
(ISOSTEARATE DE POLYGLYCEROL-4)
CETEARYL ETHYLHEXANOATE (OCTANOATE
DE CETEARIL) BUTYLENE GLYCOL
(BUTYLENGLICOL) C12-15 ALKYL BENZOATE
(C12-15 ALKYL BENZOATE) ROSA CANINA
FRUIT OIL (ACEITE DE ESCARAMUJO DE
AGARANDI) BENZOTRIAZOLYL DOCEBYL
P-CRESOL (BENZOTRIAZOLYL DOCEBYL
P-CRESOL) HYDROLYZED GLUTIN ELASTINA
HYDROLIZADA) HYDROLYZED COLLAGEN
(COLÁGENO HIDROLIZADO) SILYBUM
MARIANUM EXTRACT (EXTRACTO DE FRUTO
CARDU LEBEHR) IRIS FLORIBUNDA ROOT
EXTRACT (EXTRACTO DE RIS FLORIBUNDA)
ANANAS SATIVUS (PINEAPPLE) FRUIT
EXTRACT (EXTRACTO DE PIÑA) GLYCINE
SOJA (SOYBEAN GERM EXTRACT) EXTRACTO
DE GERME DE SOJA) TRITICUM VULGARE
(WHEAT) GERM EXTRACT (EXTRACTO DE
GERME DE TRIGO) PROPYLENE GLYCOL
(PROPILENGLICOL) PEG-60 HYDROGENATED
CASTOR OIL (PEG-60 ACEITE DE RICINO
HIDROGENADO) ALCOHOL DENAT (ALCOHOL
DESNATURALIZADO) EPSOM SALT
(MAGNESIUM SULFATE) (SULFATO DE
MAGNESIO) RETINOL TOCOPHERYL
ACETATE (ACETATO DE TOCOFERILO)
ASCORBYL PALMITATE (PALMITATO DE
ASCORBILO) DISODIUM EDTA (EDA
DISÓDICO) BHT PHENOXYETHANOL
(FENOXIETANOL) METHYLPARABEN
(METILPARABENO) ETHYLPARABEN
(ETILPARABENO) BUTYLPARABEN
(BUTILPARABENO) PROPYLPARABEN
(PROPILPARABENO) ISOBUTYLPARABEN
(ISOBUTILPARABENO) FRAGRANCE (PARFUM)
(PERFUME) YELLOW 5 (CI 19140) (F040
AMARILLO NO. 5).

NO TESTADO EN ANIMALES
NOT TESTED ON ANIMALS

Lote nº

v5.1

Cód. 63-CA
001503
F0



31A204



35 mm

35 mm

ESSENTIAL SHOCKEYE AND LIP

avobenzone, homosalate, octinoxate, octocrylene, oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63730-204
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Avobenzone (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)	Avobenzone	454 mg in 15 mL
Homosalate (UNII: V06SV4M95S) (Homosalate - UNII:V06SV4M95S)	Homosalate	1.44 mL in 15 mL
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.60 mL in 15 mL
Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	0.36 mL in 15 mL
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	151 mg in 15 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
MILK THISTLE (UNII: 822I9LEJ7S)	
PINEAPPLE (UNII: 2A88ZO081O)	
SOYBEAN (UNII: L7HT8F1ZOD)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYOXYL 60 HYDROGENATED CASTOR OIL (UNII: 02NG325BQG)	
RETINOL (UNII: G2SH0XKK91)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
PHENOXYETHANOL (UNII: HE492ZZ3T)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
ETHYLPARABEN (UNII: 14255EXE39)	
BUTYLPARABEN (UNII: 3QPIIU3FV8)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Product Characteristics

Color	yellow (FD&C YELLOW NO. 5)	Score	
Shape		Size	

Flavor		Imprint Code	
Contains			
Packaging			
#	Item Code	Package Description	Marketing Start Date
1	NDC:63730-204-01	15 mL in 1 TUBE	
2	NDC:63730-204-02	1.5 mL in 1 TUBE	
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/04/2010	

Labeler - Natura Bisse International, S.A. (464431576)

Registrant - Natura Bisse International, S.A. (464431576)

Establishment

Name	Address	ID/FEI	Business Operations
464431576		464431576	manufacture

Revised: 6/2010

Natura Bisse International, S.A.