

SUNSCREEN CREME SPF 37 EXEL- octocrylene, octinoxate, octisalate, oxybenzone, titanium dioxide cream

Exelencia Importers Corp

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.

Sun Protection creme SPF 37

Active Sunscreen Ingredients

Octocrylene (sunscreen) 5,0%

Octinoxate (Ethylhexyl Methoxy cinnamate) (sunscreen) 7,5%

Octisalate (Ethylhexyl Salicylate) (sunscreen) 5,0%

Oxybenzone (Benzophenone 3) (sunscreen) 3,0%

Titanium Dioxide (sunscreen) 3,0%

Action:

recommend for use in exfoliating treatments with hydroxy acids during summer and, particularly, when Exel's "Skin Renewal Micro Peel System" is applied.

Helps prevent sunburn

Ultra moisturizing action. Enhanced with Aloe Vera gel, Shea Butter and Vitamin E Acetate.

Dermatologically tested. It does not contain PABA (4-Aminobenzoic Acid).

Keep out of reach of children.

Stop use if and ask a doctor if rash occurs. If swallowed get medical help or contact a poison control center right away.

External use only.

Do not use in on damaged or broken skin.

Contains Oxybenzone.

When using this product, keep out of eyes.

Skin cancer/ Skin aging alert:

Spending time in the sun increases your risk of skin cancer and early skin aging.

This product has been shown only to prevent sunburn and not skin cancer and early skin aging.

Limit time in the sun 10 am to 2 p (North Hemisphere).

Wear long-sleeve shirts, pants, hats and sunglasses.

Children should avoid prolonged exposure to sunlight.

Sunscreens do not prevent heat stroke.

Product only available through a professional.

How to use

No water resistant product: Apply Liberally 15 minutes before sun exposure.

Reapply at least every two hours. Apply generously before exposure to sun as much as needed. Apply again every 2 hours or immediately after having a bath, energetic activity, excessive perspiration or

when using a towel to maintain product effectiveness.

Children under 6 months: ask a doctor.

Protect this product from excessive heat and sunlight.

INCI Inactive Ingredients

Deionized Water (aqua) * Propylene Glycol * Glycerin * Glyceryl Stearate * Cetyl Alcohol * Stearic Acid * Dimethicone * Aloe Barbadensis (Leaf Extract) * Hamamelis Liquid Extract (Hamamelis Virginiana Extract) * Polysorbate 20 * DMDM Hydantoin * Methylparaben * propylparaben * Iron Oxides (CI:77.491, CI:77.492, CI 77.499) * Acrylates/C10-30 Alkyl Acrylate Crosspolymer * Shea butter (Butyrospermum Parkii Butter) * Xanthan Gum * Tocopheryl Acetate (vitamin E acetate) * Triethanolamine * Fragrance (Parfum) * BHT.

IDEADA PARA APLICAR EN "SISTEMA DE RENOVACIÓN CUTÁNEO EFECTO PEELING"

ACCION:

- Recomendada para ser utilizada, en época de tratamientos exfoliantes con hidroxiácidos, y especialmente durante la aplicación del "Sistema de Renovación Cutánea Efecto Peeling" de EXEL. • Ayuda a evitar las quemaduras solares. • Acción ultrahumectante. Adicionada con Aloe vera gel, Manteca de karité y Vitamina E acetato.
- Dermatológicamente Testeado. No contiene PABA (Acido Para- Aminobenzoico).

FORMA DE USO:

- Aplíquese generosamente antes de la exposición al sol, y como sea necesario. • Reiterar la aplicación para mantener la efectividad del producto cada dos horas, o bien inmediatamente después del baño, vigorosa actividad, excesiva sudoración, o al secarse con toalla.
- Uso en niños menores de seis meses: consultar con el médico.

ADVERTENCIAS Y PRECAUCIONES:

- Para uso externo solamente. • Contiene Oxibenzona.
- Aplíquese con cuidado cerca del área ocular. • Lavar con abundante agua en caso de contacto con los ojos. • En caso de aparición de irritación o picazón y su persistencia, consulte al médico. • Ingestión accidental consulte servicio médico. • Mantener el envase protegido del sol. • Limitar la exposición al sol, evitar exponerse entre las 10 y las 16 hs (HEMISFERIO SUR). • Evitar la exposición prolongada de los niños al sol. • Mantener fuera del alcance de los niños. • De venta exclusiva por profesionales.

INFORMACIÓN ADICIONAL:

- SPF: FPS: factor de protección solar según normas FDA (USA).
- Protege de la quemadura solar.
- Los protectores solares no evitan la insolación (golpe de calor).
- Si la cantidad aplicada no es adecuada, el nivel de protección será significativamente reducido.

INGREDIENTES ACTIVOS:

- | | |
|-----------------------|------|
| • OCTOCRYLENO | 5,0% |
| • OCTILMETOXICINAMATO | 7,5% |
| • OCTILSALICILATO | 5,0% |
| • BENZOFENONAS 3 | 3,0% |
| • DIOXIDO DE TITANIO | 3,0% |



Biocosmética Exel Argentina S.R.L.

exel@exelcosmetics.com.ar • www.bioexel.com

E. Elab.: N° Legajo 2397 • Resol.: 155/98

Av. Illia 1983 • (1754) San Justo • FCAR-039

Pcia. Bs. As. • Ind. Argentina • Made In Argentina

Imported into U.S.A. by:

EXELENCIA IMPORTERS CORP

Miami FL (33141) • RN: FL-40351

EXEL

SUN
PROTECTION CRÈME
SPF 37

contains Vitamin E Acetate,
Shea Butter
and Aloe Vera Gel.

PANTALLA
FOTOPROTECTORA
SPF 37

contiene Vitamina E acetato,
Manteca de Karité
y Aloe Vera Gel

Biocosmética Exel Argentina

1.69 fl. oz 50 ml e

IDEAL FOR USING IN
"SKIN RENEWAL PEEL SYSTEM"

ACTION:

- Recommended for use in exfoliating treatments with hydroxy acids during summer and, particularly, when Exel's "Skin Renewal Micro Peel System" is applied.
- Helps prevent sun burns.
- Ultra moisturizing action. • Enhanced with Aloe Vera gel, Shea Butter and Vitamin E Acetate.
- Dermatologically Tested. It does not contain PABA (4-Aminobenzoic Acid).

HOW TO USE:

- No water resistant product: Apply liberally 15 minutes before sun exposure. • Reapply at least every 2 hours.
- Apply generously before exposure to sun and as much as needed. • Apply again every two hours or immediately after having a bath, energetic activity, excessive perspiration or when using a towel to maintain product effectiveness. • Children under 6 months: ask a doctor. • Protect this product from excessive heat and direct sun.

WARNINGS AND CAUTIONS:

- External use only. • Do not use in on damaged or broken skin. • Contains Oxibenzona. • When using this product keep out of eyes. • Rinse with water to remove. • Stop use and ask a doctor if rash occurs. • If swallowed, get medical help or contact a Poison Control Center right away. • Skin cancer/Skin aging ALERT: spending time in the sun increases your risk of skin cancer and early skin aging. • This product has been shown only to help prevent sunburn not skin cancer or early skin aging. • Limit time in the sun 10 am to 2 pm (NORTH HEMISPHERE). • Wear long-sleeve shirts, pants, hats, and sunglasses. • Children should avoid prolonged exposure to sunlight. • Keep out of reach of children. • Sunscreens do not prevent heat stroke. • Product available only through a professional.

ACTIVE SUNSCREEN INGREDIENTS:

- | | |
|---|------|
| • OCTOCRYLENE (sunscreen) | 5,0% |
| • OCTINOATE (ETHYLHEXYL METHOXYCINNAMATE) (sunscreen) | 7,5% |
| • OCTISALATE (ETHYLHEXYL SALICYLATE) (sunscreen) | 5,0% |
| • OXYBENZONE (Benzophenone 3) (sunscreen) | 3,0% |
| • TITANIUM DIOXIDE (sunscreen) | 3,0% |

INCI INACTIVE INGREDIENTS:

- DEIONIZED WATER (AQUA) * PROPYLENE GLYCOL * GLYCERIN * GLYCERYL STEARATE * CETYL ALCOHOL * STEARIC ACID * DIMETHICONE * ALOE BARBADENSIS (LEAF EXTRACT) * HAMAMELIS LIQUID EXTRACT (HAMAMELIS VIRGINIANA EXTRACT) * POLYSORBATE 20 * DMDM HYDANTOIN * METHYL PARABEN * PROPYL PARABEN * IRON OXIDES (CI: 77.491, CI: 77.492, CI: 77.499) * ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER * SHEA BUTTER (BUTYROSPERMUM PARKII BUTTER) * XANTHAN GUM * TOCOPHERYL ACETATE (VITAMIN E ACETATE) * TRIETHANOLAMINE * FRAGRANCE (PARFUM) * BHT.

FRAGRANCE CONTAINS:

- 2-(4-TERT-BUTYL)BENZYL PROPIONALDEHYDE (LILIAL) * CITRONELLOL * LINALOOL * LIMONENE * CITRAL

EXEL

PROTEZIONE
SOLARE
SPF 37

contiene Vitamina E acetato,
Burro di Karité
ed Aloe Vera Gel

ÉCRAN PHOTO
PROTECTRICE
SPF 37

contenant Vitamine E acétate,
Beurre de Karité
et Aloès Vera Gel

Biocosmética Exel Argentina

1.69 fl. oz 50 ml e

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- OCTOCRYLENE (sunscreen) 5,0%
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WARNING: • External use only. • Do not use in on damaged or broken skin. • Contains Oxybenzone. • When using this product keep out of eyes. • Rinse with water to remove. • Stop use and ask a doctor if rash occurs. • If swallowed, get medical help or contact a Poison Control Center right away from sun. • Skin cancer/Skin aging ALERT: spending time in the sun increases your risk of skin cancer and early skin aging. • This product has been shown only to help prevent sunburn not skin cancer or early skin aging. • Limit time in the sun 10 am to 2 pm (NORTH HEMISPHERE). • Wear long-sleeve shirts, pants, hats, and sunglasses. • Children should avoid prolonged exposure to sunlight. • Keep out of reach of children. • Sunscreens do not prevent heat stroke. • Product available only through a professional.

FORMA Y FRECUENCIA DE USO: • Aplíquese generosamente antes de la exposición al sol, y como sea necesario. • Reiterar la aplicación para mantener la efectividad del producto cada dos horas, o bien inmediatamente después del baño, vigorosa actividad, excesiva sudoración, o al secarse con toalla. • Uso en niños menores de seis meses: consultar con el médico.

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EXEL

SUN PROTECTION CRÈME SPF 37

contains Vitamin E Acetate, Shea Butter and Aloe Vera Gel.

PANTALLA FOTOPROTECTORA SPF 37

contiene Vitamina E acetato, Manteca de Karité y Aloe Vera Gel

Biocosmética Exel Argentina

1.69 fl. oz

50 ml e

Exel

Sun Protection Creme SPF

contains Vitamin E Acetate, Shea Butter, and Aloe Vera Gel.

1.69 fl. oz 50

SUNSCREEN CREME SPF 37 EXEL

octocrylene, octinoxate, octisalate, oxybenzone, titanium dioxide cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:53863-120

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	5 g in 100 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	3 g in 100 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	3 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
HAMAMELIS VIRGINIANA TOP (UNII: UDA30A2JJY)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
SHEA BUTTER (UNII: K49155WL9Y)	
XANTHAN GUM (UNII: TTV12P4NEE)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53863-120-02	1 in 1 CARTON		
1	NDC:53863-120-01	50 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/15/2012	

Labeler - Exelencia Importers Corp (147644335)

Registrant - Exelencia Importers Corp (147644335)

Establishment

Name	Address	ID/FEI	Business Operations
BIOCOSMETICA EXEL ARGENTINA S.R.L.		971813332	manufacture(53863-120)

Revised: 11/2012

Exelencia Importers Corp