

**EXEL CLARIFYING LINE SPF 50- octinoxate, octocrylene, oxybenzone, titanium dioxide cream**  
**Biocosmetica Exel Argentina SRL**

*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.*

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**Exel Clarifying Line SPF 50**

Active Ingredient ..... Purpose

Octinoxate 7.5% ..... Sunscreen

Octocrylene 8% ..... Sunscreen

Oxybenzone 3% ..... Sunscreen

Titanium Dioxide 5% ..... Sunscreen

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

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if rash occurs

Warnings

- 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.

Directions

- Apply liberally 15 minutes before sun exposure
- Reapply at least every 2 hours
- Children under 6 month: ask a doctor
- 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-sleeved shirts, pants, hats, and sunglasses Use a water resistant sunscreen if swimming or sweating

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Extract, BHT, Butyrospermum Parkii (shea butter) Extract, Calcium Disodium EDTA, Caprylic/Capric Triglyceride, Cetearyl Alcohol (and) Ceteareth-20, Cyclomethicone, Cyclopentasiloxane, Diethylamino Hydroxybenzoyl Hexyl Benzoate, Dimethicone, DMDM Hydantoin, Ectoin, Fragrance (Parfum), Glyceryl Stearate SE, Hamamelis Virginiana (witch hazel) Extract,

Iron Oxides (C.I. 77497/77492/77499), Phenoxyethanol, Polysorbate 20, Propylene Glycol, Sodium DNA, Tocopheryl Acetate, Water (Aqua), Xanthan Gum, Yeast Extract (saccharomyces cerevisiae extract)

Exel Clarifying Line

SPF 50

Broad Spectrum SPF 50

3.30 fl.oz / 100 ml

**EXEL**  
CLARIFYING LINE

**SPF 50+**

BROAD SPECTRUM SPF 50+

CONTAINS ECTOINE, VITAMIN E ACETATE,  
SHEA BUTTER AND ALOE VERA GEL

DESIGNED TO APPLY  
"EXEL SKIN LIGHTENING PROGRAM"



**SPF 50+**

PROTECCIÓN 50+

CONTIENE ECTOÍNA, VITAMINA E ACETATO,  
MANTECA DE KARITÉ Y ALOE VERA GEL

IDEADA PARA APLICAR EN  
"PROGRAMA EXEL ACLARANTE DE LA PIEL"

Biocosmética Exel Argentina  
3.30 fl. oz / 100 ml e

\*FACTOR DE PROTECCIÓN SOLAR (FPS) SEGÚN NORMAS  
FDA/USA.  
\*\*FACTOR DE PROTECCIÓN UVA SEGÚN NORMAS COLIPA/ECE.

**ACCIÓN:** De textura liviana, forma un film resistente a los rayos UVA y UVB que disminuyen la posibilidad de formación de manchas por hiperpigmentación. Ideal para ser utilizada en tratamientos despigmentantes. Su novedosa formulación con ectoína, activo protector de la agresión ambiental extrema, extractos de células vivas de levaduras, Aloe vera y manteca de Karité ayudan a atenuar los signos del envejecimiento cutáneo prematuro brindando máxima protección y acción ultrahumectante.

• **PROTECCIÓN MUY ALTA.**  
• Ayuda a prevenir las quemaduras solares. **PARA PIELS EXTREMADAMENTE SENSIBLES A LA QUEMADURA SOLAR.**  
• **LOCN: 377,33 ml**  
• No contiene PABA (ácido p-amino benzoico)

**FORMA Y FRECUENCIA DE USO:** Para utilizar especialmente como protección solar en zonas de la piel que reciben tratamiento cosmético por hiperpigmentación. Aplique abundantemente 15 minutos antes de la exposición al sol. Es necesaria la reaplicación del producto cada 2 horas para mantener su efectividad. Reaplicar siempre, luego de sudoración intensa, nadar o bañarse, secarse con toalla y durante la exposición al sol. Si la cantidad aplicada no es adecuada, el nivel de protección será significativamente reducido.

**ADVERTENCIAS Y PRECAUCIONES:** Uso externo. Limitar la exposición al sol, el uso de ropa protectora y el uso de productos con protección solar reducen los riesgos del fotoenvejecimiento cutáneo, cáncer de piel y otros efectos adversos del sol. Este producto no ofrece ninguna protección contra la insolación (golpe de calor). Aplíquese con cuidado cerca del área ocular, lavar con abundante agua en caso de contacto con los ojos. Evite la exposición prolongada de los niños al sol. Este producto no fue formulado para su uso en niños. Para niños menores de 6 meses, consultar al médico. Ingestión accidental: consulte al médico. En caso de irritación o picazón o su persistencia: consulte al médico. Contiene Oxibenzona. Mantener el envase protegido del sol. **DERMATOLÓGICAMENTE TESTEADO. LIBRE DE PARABENOS.**

**INCI (INGREDIENTS):** WATER (AQUA), OCTOCRYLENE, DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE, ETHYLHEXYL METHOXYCINNAMATE (OCTINOXATE), TITANIUM DIOXIDE, PROPYLENE GLYCOL, CYCLOMETHICONE, BENZOPHENONE-3 (OXYBENZONE), CAPRYLIC/CAPRIC TRIGLYCERIDE, GLYCERYL STEARATE SE, POLYSORBATE 20, CETEARYL ALCOHOL, CETEARETH-20, HAMAMELIS VIRGINIANA EXTRACT\*, C.I. 77 491/77 492/77 499 (IRON OXIDES), ALOE BARBADENSIS LEAF EXTRACT, SACCHAROMYCES CEREVISIAE EXTRACT\*\*, CYCLOPENTASILOXANE, DIMETHICONE, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, DIMD HYDANTOIN, PHENOXYETHANOL, BUTYROSPERMUM PARKII EXTRACT\*\*\*, CALCIUM DISODIUM EDTA, XANTHAN GUM, FRAGRANCE (PARFUM), TOCOPHERYL ACETATE, BHT, ECTOINE, SODIUM DNA.  
\*Witch hazel. \*\*Yeast extract. \*\*\*Shea butter. Karité butter.

BIOSMÉTICA EXEL ARGENTINA SRL  
E.E. LEG. 2387/ RES. 15/98  
AV. ILLIA 1983 • (1754) SAN JUSTO • PCIA. BS. AS.  
RN: ICAR-039  
exel@exelcosmetics.com.ar • www.exel.com  
Ind. Argentina / Made in Argentina  
Imported into U.S.A by: EXCELLENZA IMPORTERS CORP. DORAL, FL (3122) USA  
NDC: 53863-125  
Imported into EU by: EXCELLENZA IMPORTADORES S.L.  
Gran Via Coria Catalanes, 820 P. planta, 08007 BARCELONA.



**EXEL**  
CLARIFYING LINE

**SPF 50+**

BROAD SPECTRUM SPF 50+

CONTAINS ECTOINE, VITAMIN E ACETATE,  
SHEA BUTTER AND ALOE VERA GEL

DESIGNED TO APPLY  
"EXEL SKIN LIGHTENING PROGRAM"



**SPF 50+**

PROTECCIÓN 50+

CONTIENE ECTOÍNA, VITAMINA E ACETATO,  
MANTECA DE KARITÉ Y ALOE VERA GEL

IDEADA PARA APLICAR EN  
"PROGRAMA EXEL ACLARANTE DE LA PIEL"

Biocosmética Exel Argentina  
3.30 fl. oz / 100 ml e

\*SUN PROTECTION FACTOR (SPF) ACCORDING FDA/USA.  
\*\*UVA PROTECTION FACTOR ACCORDING COLIPA/ECC.

**ACTION:** Light texture, forms a film that is resistant to UVA and UV-B rays to reduce the possibility of formation hyperpigmentation spots. It is ideal for use in skin lightening treatments. This novel formulation containing ectoine, an active protector to extreme environmental aggression, extracts of live yeast cells, Aloe Vera and Shea Butter helps lessen signs of premature skin aging providing maximum protection and an ultra-moisturizing action.

• **PROVIDES HIGH PROTECTION AGAINST SUNBURN**  
• **IDEAL FOR USE WITH SKIN LIGHTENING PROGRAMS**

**Drug Facts**

Active Ingredient	Purpose
Octocrylene	8% Sunscreen
Octinoxate	7.5% Sunscreen
Titanium Dioxide	5% Sunscreen
Oxybenzone	3% Sunscreen

**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.

**Warnings**

• 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 swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

• Ideal for hyperpigmented treated zones  
• Apply liberally 15 minutes before sun exposure.  
• Reapply at least every 2 hours.  
• Children under 6 months: ask a doctor.  
• 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-sleeved shirts, pants, hats, and sunglasses.  
• Use a water resistant sunscreen if swimming or sweating.  
• This product was not formulated to be applied to children.

**Other Information**

• Protect this product from excessive heat and direct sun.  
• Dermatologically tested.  
• Para-Amino Benzoic Acid (PABA) free.  
• Paraben free.

**Inactive Ingredients**

ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, ALOE BARBADENSIS LEAF EXTRACT, BHT, BUTYROSPERMUM PARKII (SHEA BUTTER) EXTRACT, CALCIUM DISODIUM EDTA, CAPRYLIC/CAPRIC TRIGLYCERIDE, CETEARYL ALCOHOL, CETEARETH-20, CYCLOMETHICONE, CYCLOPENTASILOXANE, DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE, DIMETHICONE, DIMD HYDANTOIN, ECTOINE, FRAGRANCE (PARFUM), GLYCERYL STEARATE SE, HAMAMELIS VIRGINIANA (WITCH HAZEL) EXTRACT, IRON OXIDES (C.I. 77 491/77 492/77 499), PHENOXYETHANOL, POLYSORBATE 20, PROPYLENE GLYCOL, SODIUM DNA, TOCOPHERYL ACETATE, WATER (AQUA), XANTHAN GUM, YEAST EXTRACT (SACCHAROMYCES CEREVISIAE EXTRACT).



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PA-0867-010-EN/SP-0919

**EXEL CLARIFYING LINE SPF 50**

octinoxate, octocrylene, oxybenzone, titanium dioxide cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:67623-001
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	8 g in 100 mL
<b>OXYBENZONE</b> (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	3 g in 100 mL
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	5 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED)</b> (UNII: 59TL3WG5CO)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>SHEANUT OIL</b> (UNII: O88E196QRF)	
<b>EDETATE CALCIUM DISODIUM ANHYDROUS</b> (UNII: 8U5D034955)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>POLYOXYL 20 CETOSTEARYL ETHER</b> (UNII: YRC528SWUY)	
<b>CYCLOMETHICONE</b> (UNII: NMQ347994Z)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)	
<b>DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE</b> (UNII: ANQ870JD20)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>DMDM HYDANTOIN</b> (UNII: BYR0546TOW)	
<b>ECTOINE</b> (UNII: 7GXZ3858RY)	
<b>GLYCERYL STEARATE SE</b> (UNII: FCZ5MH785I)	
<b>HAMAMELIS VIRGINIANA TOP</b> (UNII: UDA30A2JJY)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>YEAST, UNSPECIFIED</b> (UNII: 3NY3SM6B8U)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67623-001-02	1 in 1 PACKAGE	05/14/2015	
1	NDC:67623-001-01	100 mL in 1 TUBE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	05/14/2015	

**Labeler** - Biocosmetica Exel Argentina SRL (971813332)

**Registrant** - Biocosmetica Exel Argentina SRL (971813332)

Revised: 4/2023

Biocosmetica Exel Argentina SRL