

EXEL CLARIFYING LINE SPF 50- octinoxate, octocrylene, oxybenzone, titanium dioxide cream
Exelencia importers

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.

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,

EXEL
CLARIFYING LINE

SPF/FPS 50+*
BROAD SPECTRUM SPF 50+
SUNSCREEN
FP UVA (UVA-PP): 27+
CREMA DE PROTECCIÓN SOLAR
PROTECCIÓN MUY ALTA

IDEADA PARA APLICAR EN
"PROGRAMA EXEL ACLARANTE DE LA PIEL"
DESIGNED TO APPLY
"EXEL SKIN LIGHTENING PROGRAM"



FORMA Y FRECUENCIA DE USO: Para utilizar repetidamente como protección solar en áreas de la piel que muestran signos de envejecimiento del fotoprotección. Aplicar abundantemente 15 minutos antes de la exposición al sol. Es necesario la reaplicación del producto cada 2 horas para mantener su efectividad. Reaplicar siempre luego de la exposición intensa, sudar o bañarse, aunque con toallas y después de la exposición al agua. Si la humedad reducida, no es adecuada, el nivel de protección será debilitado. **ADVERTENCIAS Y PRECAUCIONES:** Usar solo en la exposición al sol. El uso de ropa protectora y el uso de productos con protección solar reducen los riesgos del fotoprotección. Evitar el uso de pantalones y otros artículos adheridos al sol. Este producto no debe usarse en combinación con la exposición prolongada de agua. Manténgalo alejado de los ojos. En caso de abundante agua en caso de contacto con los ojos. Este es un producto formulado para uso en niños. Para niños menores de 6 meses, consultar al médico. Evitar la exposición accidental al producto. En caso de irritación o picazón o si persisten consulte al médico. Contiene Colorantes. Manténgalo alejado de niños. **DERMATOLÓGICAMENTE TESTEADO.**

BIOCOSMÉTICA PROFESIONAL
3.30 fl.Oz./100 ml e

■ **STAMPING PLATA**
■ **pantone 1595c**
■ **pantone 425 c**



5mm (mínimo 10mm)

*SUN PROTECTION FACTOR (SPF) ACCORDING FDA/USA
*UVA PROTECTION FACTOR ACCORDING COLIPA/ECC
*FACTO DE PROTECCIÓN SOLAR (FPS) SEGUN NORMAS FDA/USA
*FACTOR DE PROTECCIÓN SOLAR (FPS) SEGUN NORMAS COLIPA/ECC

Drug Facts

Active Ingredient: Purpura Sunscreen, Octinoxate 7.5%, Octocrylene 8%, Oxybenzone 3%, Titanium Dioxide 5%

Uses: Helps prevent sunburn. 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. Do not use and rub in shortly after tanning. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions: Apply liberally 15 minutes before sun exposure. Reapply at least every 2 hours. Use a water resistant sunscreen if swimming or sweating. Sun Protection Message: Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, experts say that sunscreen with a broad spectrum (SPF) value of 15 or higher and other sun protection measures including a hat, sunglasses, and long-sleeved shirts, pants, hats, and sunglasses.

Other Information: Protect this product from excessive heat and direct sun.

BIOCOSMÉTICA EXEL ARGENTINA SRL
Buenos Aires, Argentina
E. Exel, N° Lafage 2387 • Puro, 1° Piso, 1° Local, Av. Bv. 1983 (1754) San José de Flores



3mm (mínimo 3mm)



Pomo diametro 40 mm
largo de pollera 120 mm
2 colores offset + st. plata

EXEL CLARIFYING LINE SPF 50

octinoxate, octocrylene, oxybenzone, titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53863-125
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9DOZ171K)	

SHEANUT OIL (UNII: O88E196QRF)
EDETATE CALCIUM DISODIUM ANHYDROUS (UNII: 8U5D034955)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)
CYCLOMETHICONE (UNII: NMQ347994Z)
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)
DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE (UNII: ANQ870JD20)
DIMETHICONE (UNII: 92RU3N3Y1O)
DMDM HYDANTOIN (UNII: BYR0546TOW)
ECTOINE (UNII: 7GXZ3858RY)
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)
HAMAMELIS VIRGINIANA TOP (UNII: UDA30A2JJY)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROFERRIC OXIDE (UNII: XM0M87F357)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
WATER (UNII: 059QF0KO0R)
XANTHAN GUM (UNII: TTV12P4NEE)
YEAST, UNSPECIFIED (UNII: 3NY3SM6B8U)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53863-125-02	1 in 1 PACKAGE	05/14/2015	
1	NDC:53863-125-01	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 - Exelencia importers (147644335)

Establishment

Name	Address	ID/FEI	Business Operations
Biocosmetica Exel Argentina SRL		971813332	manufacture(53863-125)