

**CLARIFYING LINE BROAD SPECTRUM SPF 50 EXEL- 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**

**Broad Spectrum SPF 50**

<b>Active Ingredients</b>	<b>Purpose</b>
Octinoxate 7.5% .....	Sunscreen
Octocrylene 8% .....	Sunscreen
Oxybenzone 3% .....	Sunscreen
Titanium Dioxide 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.
- Keep out 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

**ⓧInactive Ingredients**

ⓧAcrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Extract, BHT, Butyrospermum Parkii (Shea Butter) Extract, Calcium Disodium EDTA, Caprylic/Capric Triglyceride, Cetaryl Alcohol (and) Cetareth-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.

77.491/77.492/77.499), Phenoxyethanol, Polysorbate 20, Propylene Glycol, Sodium DNA, Tocopheryl Acetate, Water (Aqua), Xanthan Gum, Yeast Extract (Saccharomyces Cerevisiae Extract)

☐ **SPF 50+**

☐ **Broad Spectrum SPF 50+**

Designed to Apply "Exel Skin Lightening Program"

Contains Ectoin, Vitamin E Acetate

3.30 fl.oz . 100 ml

CLARIFYING LINE BROAD SPECTRUM SPF 50 EXEL			
octinoxate, octocrylene, oxybenzone, titanium dioxide cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53863-124
Route of Administration	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: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	3 g in 100 mL
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	3 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: 2DMT128MIS)	
<b>POLYOXYL 20 CETOSTEARYL ETHER</b> (UNII: YRC528SWUY)	
<b>CYCLOMETHICONE</b> (UNII: NMQ347994Z)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PC10R)	
<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:53863-124-02	1 in 1 CARTON		
1	NDC:53863-124-01	100 mL in 1 TUBE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/23/2015	

**Labeler** - Exelencia importers (147644335)

**Registrant** - Exelencia importers (147644335)

**Establishment**

Name	Address	ID/FEI	Business Operations
Biosmetica Exel Argentina SRL		971813332	manufacture(53863-124)

Revised: 2/2015

Exelencia importers