

**SUN PROTECTION CREME SPF 30 PLUS EXEL CLARIFYING LINE- 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.*

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**Exel Clarifying SPF 30 Plus**

Active ingredients	Purpose
Octocrylene 5%	Sunscreen
Octinoxate 7.5%	Sunscreen
Octisalate 5%	Sunscreen
Oxybenzone 3%	Sunscreen
Titanium Dioxide 3%	Sunscreen

**Uses**

- Helps Prevent Sunburn

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

Stop use and ask a doctor if rash occurs

**Warnings**

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, not skin cancer or early skin aging.

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 months ask doctor

WATER, PROPYLENE GLYCOL, GLYCERIN, GLYCERYL STEARATE, CETYL ALCOHOL, STEARIC ACID, DIMETHICONE, ALOE VERA LEAF, HAMAMELIS VIRGINIANA (WITCH HAZEL) EXTRACT, POLYSORBATE-20, DMDM HYDANTOIN, METHYLPARABEN, PROPYLPARABEN, IRON OXIDE CI 77491, CI 77492, CI 77499, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, SHEA BUTTER, XANTHAN GUM, TOCOPHERYL ACETATE, TRIETHANOLAMINE, FRAGRANCE, BHT

Exel Clarifying Line

High Sun Protection Creme  
SPF 30 PLUS

for use in "Exel Clarifying program"

3.30 fl. oz



EXEL  
CLARIFYING LINE

EXEL  
CLARIFYING LINE

HIGH SUN PROTECTION CREME  
SPF 30 PLUS

FOR USE IN "EXEL  
CLARIFYING PROGRAM"

**Drug Facts**

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WATER, PROPYLENE GLYCOL, GLYCERIN, GLYCERYL STEARATE, CETYL ALCOHOL, STEARIC ACID, DIMETHICONE, ALOE VERA LEAF, HAMAMELIS VIRGINIANA(WITCH HAZEL) EXTRACT, POLYSORBATE 20, DMDM HYDANTOIN, METHYLPARABEN, PROPYLPARABEN, IRON OXIDE



## SUN PROTECTION CREME SPF 30 PLUS EXEL CLARIFYING LINE

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### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53863-122
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	5 g in 100 mL
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 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>WATER</b> (UNII: 059QF0KO0R)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	

<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)
<b>HAMAMELIS VIRGINIANA LEAF</b> (UNII: T07U1161SV)
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)
<b>DMDM HYDANTOIN</b> (UNII: BYR0546TOW)
<b>METHYL PARABEN</b> (UNII: A2I8C7HI9T)
<b>PROPYL PARABEN</b> (UNII: Z8IX2SC1OH)
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)
<b>FERROSO FERRIC OXIDE</b> (UNII: XM0M87F357)
<b>CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 71DD5V995L)
<b>SHEA BUTTER</b> (UNII: K49155WL9Y)
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53863-122-02	1 in 1 CARTON		
1	NDC:53863-122-01	97.5 mL in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/09/2014	

**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(53863-122)