

SILK LINE SILK DAY CREAM SPF 15- octinoxate, octocrylene, octisalate 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.

Silk Line Silk Day Cream SPF 15

Active Ingredient Purpose

Octinoxate(Ethylhexyl methoxycinnamate) 7.5% Sunscreen

Octocrylene 7.0% Sunscreen

Octisalate (Ethylhexyl salicylate) 2.0 Sunscreen

Uses

Helps prevent sunburn

Higher SPF gives more sunburn protection

If used as directed with other sun-protection measures (see Directions) decreases the risk of skin cancer and early skin aging caused by de sun

Do not use in children. Keep out of reach of children.

Stop use and ask a doctor if rash occurs

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.

If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

Apply and massage with a gentle circular motion in face and neck until completely absorbed 15 minutes before sun exposure.

Reapply at least every 2 hours after towel drying, swimming or perspiring.

Sun protection measures: spending time in the sun increases your risk of skin cancer and early skin ageing. To decrease this risk, regularly use a sunscreen with Broad Spectrum SPF value of 15 or higher or other sun protection measures including:

Limit time in the sun, especially between 10am-2pm

Wear long sleeved shirts, pants, hats and sunglasses

Use a water resistant sunscreen if swimming or sweating.

Inactive ingredients

Purified Water (aqua), Cyclopentasiloxane, Glycerin1, Glyceryl Stearate SE, Caprylic/Capric Triglyceride, Cyclomethicone, Dimethiconol, Hydrolyzed Silk, Ceteraryl Alcohol, Cetareth-20, Yeast Extract, Sodium DNA, Aloe Barbadosis Leaf Extract, Panthenol, Xanthan Gum, Acrylates/C10-30 Alkyl Acrylates Crosspolymer, Imidazoliny Urea, Butyrospermum Parkii Butter, Phenoxyethanol, Bisabolol, Tocopheryl Acetate,

Calcium Disodium EDTA, DM DM Hydantoin, Polysorbate 20, Methylparaben, Fragrance (parfum), BHT, Propylparaben, Sodium Hyaluronate, Betacarotene

Exel

Silk Line

Silk Day Cream SPF 15

with hydrolyzed silk proteins

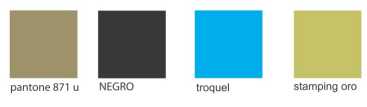
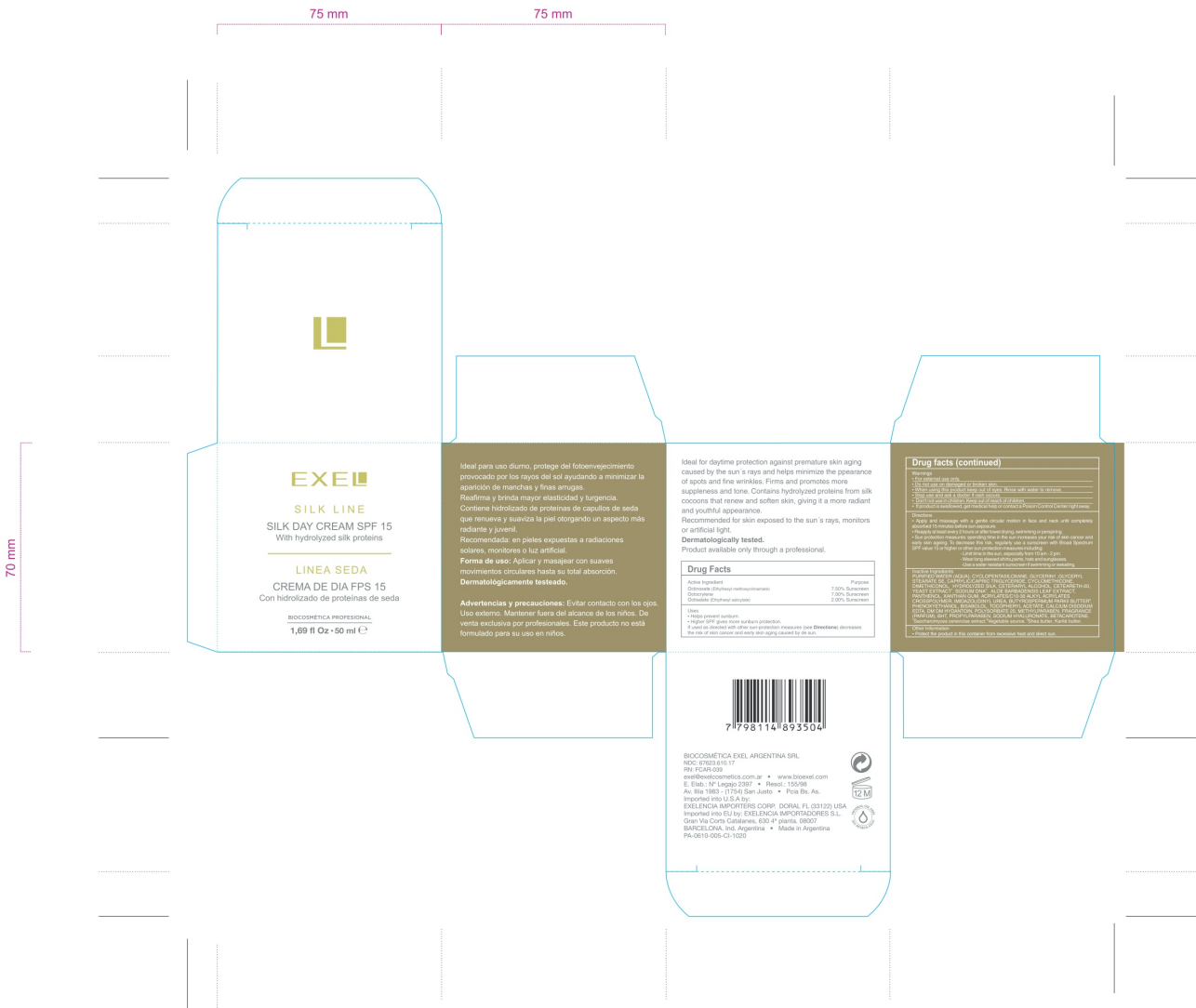
Linea Seda

Crema De Dia FPS 15

Con hidrolizado de proteinas de seda

Biocosmetica Proffesional

1,69 fl Oz 50 ml



SILK LINE SILK DAY CREAM SPF 15

octinoxate, octocrylene, octisalate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53863-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	7 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	2 g in 100 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
WATER (UNII: 059QF0KO0R)	
LEVOMENOL (UNII: 24WE03BX2T)	
PROPYLPARABEN (UNII: Z8IX2SC10H)	
BETA CAROTENE (UNII: 01YAE03M7J)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PANTHENOL (UNII: WW9CM0067Z)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
XANTHAN GUM (UNII: TTV12P4NEE)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DIMETHICONOL (40 CST) (UNII: 343C7U75XW)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
IMIDUREA (UNII: M629807ATL)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
YEAST, UNSPECIFIED (UNII: 3NY3SM6B8U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
EDETATE CALCIUM DISODIUM ANHYDROUS (UNII: 8U5D034955)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53863-003-01	50 mL in 1 BOX; Type 0: Not a Combination Product	10/26/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	10/26/2020	

Labeler - Exelencia Importers, Corp. (147644335)

Establishment

Name	Address	ID/FEI	Business Operations
Biocosmetica Exel Argentina SRL		971813332	manufacture(53863-003)

Revised: 4/2023

Exelencia Importers, Corp.