

EXEL CLARIFYING LINE DAILY FLUID SUN SHIELD WHITE COLOR BROAD SPECTRUM SPF 60 PLUS- octocrylene, octinoxate, octisalate, titanium dioxide, ensulizole cream
Biocosmetica Exel Argentina SRL

Active ingredients , purpose

Octocrylene 10%, sunscreen
Octinoxate 5%, sunscreen
Octisalate 5%, sunscreen
Titanium dioxide 5%, sunscreen
Ensulizole 4 %, 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 swallow.
If swallowed, get medical help or contact a Poison Control Center right away.
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 .
This product is not formulated for use in children.

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 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.
Children under 6 months of age: ask a doctor.

Inactive Ingredients

BISABOLOL, BUTYROSPERMUM PARKII BUTTER, CALCIUM DISODIUM EDTA, CAMELLIA SINENSIS LEAF EXTRACT, CAPRYLIC/CAPRIC TRIGLYCERIDE, CAPRYLYL GLYCOL, CARBOMER, CETEARETH-20, CETEARYL ALCOHOL, DIETHYLAMINO HYDROXYBENZOYL

EXTERIOR	
MATERIAL	CARTULINA 300 g.
COLORES	 PANTONE 1595 C  COOL GRAY 11  PANTONE 279C
STAMPING	 STAMPING PLATA
TROQUEL	155 X 53 X 53 mm.  TROQUEL
LAMINADO	BARNIZ BRILLANTE

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67623-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ENSULIZOLE (UNII: 9YQ9DI1W42) (ENSULIZOLE - UNII:9YQ9DI1W42)	ENSULIZOLE	4 g in 100 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	5 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6VM) (OCTOCRYLENE - UNII:5A68WGF6VM)	OCTOCRYLENE	10 g in 100 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	5 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
LINOLEIC ACID (UNII: 9KJL21T0QJ)	
WATER (UNII: 059QF0KO0R)	
BISABOLOL (UNII: 24WE03BX2T)	
DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE (UNII: ANQ870JD20)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
PHLEBODIUM AUREUM LEAF (UNII: BG58BW230G)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PALMITOYL PENTAPEPTIDE-4 (UNII: KK181SM5JG)	
CAMELLIA SINENSIS LEAF (UNII: W2ZU1RY8B0)	
PROPANEDIOL (UNII: 5965N8W85T)	
SODIUM HYALURONATE (UNII: YSE9PPT4TH)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
BUTYROSPERMUM PARKII (SHEA) BUTTER (UNII: K49155WL9Y)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	

CALCIUM DISODIUM EDTA (UNII: 8U5D034955)	
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)	
CETEARETH-20 (UNII: YRC528SWJY)	
CETEARYL ALCOHOL (UNII: 2DMT128M1S)	
HYDROGENATED SOYBEAN PHOSPHATIDYLCHOLINE (UNII: QHQ97HF0PY)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
XANTHAN GUM (UNII: TTV12P4NEE)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67623-004-01	1 in 1 CARTON	01/01/2025	
1		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 Drug	M020	01/01/2025	

Labeler - Biocosmetica Exel Argentina SRL (971813332)

Establishment

Name	Address	ID/FEI	Business Operations
Biocosmetica Exel Argentina SRL		971813332	manufacture(67623-004)

Revised: 1/2025

Biocosmetica Exel Argentina SRL