EGF FGF DNA UV SHIELD- ethylhexyl methoxycinnamate, titanium dioxide, ethylhexyl salicylate cream Dermaesthetics Inc.

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.

ACTIVE INGREDIENTS

Ethylhexyl Methoxycinnamate 5.40% Titanium Dioxide 5.00% Ethylhexyl Salicylate 3.40%

INACTIVE INGREDIENTS

Aqua, Cyclopentasiloxane, Silica, 4-Methylbenzylidene Camphor, Cyclohexasiloxane, Cetyl Ethylhexanoate, Sorbitan Isostearate, Glycerin,

Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine, Cetyl PEG/PPG-10/1 Dimethicone, Sodium Chloride, Calcium Stearate, Glyceryl Caprylate, Betaine, Beeswax, Allantoin, Ozokerite, Glyceryl Caprylate, Butylene Glycol, Aloe Barbadensis Leaf Juice Powder, Xanthan Gum, Triethoxycaprylylsilane, 1,2-Hexanediol, Sodium DNA, Ginkgo Biloba Leaf Extract, Ethylhexylglycerin, Lecithin, Polysorbate 20, sr-Rainbow Trout Oligopeptide-1 sh-Oligopeptide-1.

PURPOSE

Sunscreen

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.
- Stop use and ask a doctor if rash or irritation develops.
- Keep out of reach of children if swallowed, get medical help or contact a Poison Control Center right away.

DESCRIPTION

Uses:

- Helps prevent sun burn
- 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.

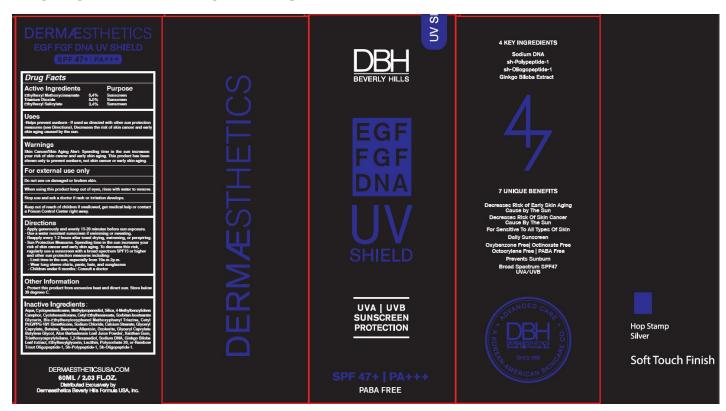
Directions:

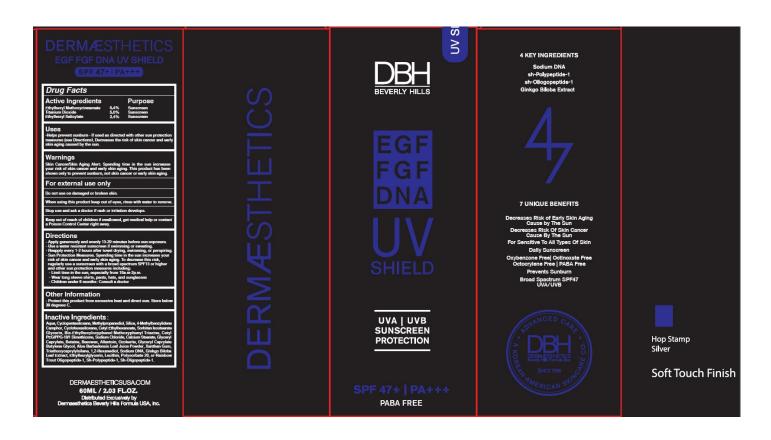
- Apply generously and evenly 15-20 minutes before sun exposure.
- Use a water resistant sunscreen if swimming or sweating.
- Reapply every 1-2 hours after towel drying, swimming, or perspiring.
- Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF 15 or higher and other sun protection measures including:
- Limit time in the sun, especially from 10a.m-2p.m.
- Wear long sleeve shirts, pants, hats, and sunglasses.
- Children under 6 months: Consult a doctor.

Other Information

- Protect this product from excessive heat and direct sun.
- Store below 30 degrees C.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL





EGF FGF DNA UV SHIELD

ethylhexyl methoxycinnamate, titanium dioxide, ethylhexyl salicylate cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58831-1100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3.24 g in 60 mL	
Titanium Dioxide (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	Titanium Dioxide	3.0 g in 60 mL	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	2.04 g in 60 mL	

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58831- 1100-2	1 in 1 CARTON	10/01/2021	
	NDC-E0021	CO ml in 1 TIDE. Time O. Not a Combination		

1 1100-1	Product		
Manufaction of			
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/01/2021	

Labeler - Dermaesthetics Inc. (688384549)

Registrant - Dermaesthetics Inc. (688384549)

Establishment				
Name	Address	ID/FEI	Business Operations	
Aqualex		687515213	manufacture(58831-1100)	

Revised: 6/2023 Dermaesthetics Inc.