

ENFANTI DERMA SERIES 100% MINERAL SUN SHIELD- titanium dioxide and zinc oxide cream
Orange Lab

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.

Enfanti Derma Series SPF 50 PA++++ 1.8 fl oz.

Active ingredients

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Zinc Oxide 24.5% , Titanium Dioxide 4.8%	Sunscreen

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Uses

Uses ■ Help prevent sunburn ■ If used as directed with other sun protections measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun

Do not use / Warnings

Warning ■ For external use only ■ Do not use on damaged or broken skin. ■ When using the 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. If swallowed, get medical help or contact a poison Control Center right away. Protect this product from excessive heat and direct sun.

Directions :

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- Apply generously 15 minutes before sun exposure
- reapply :
 - After 80 minutes of swimming or sweating
 - Immediately after towel drying
 - At least every 2 hours

Sun Protection Measures

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 :

- Limited time in the sun, especially from 10 a.m-2p.m
- Wear long-sleeved shirt, pants, hats, and sunglasses

****For children under 6months : Ask a doctor***

Keep out of reach of children

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Inactive ingredients

Inactive Ingredients *Aloe Barbadensis Leaf Juice (Aloe Vera Inner Leaf Gel), C12-15 Alkyl Benzoate, Isostearic Acid, Dimethicone, Isononyl Isononanoate, Niacinamide, Glycerin, Butylene Glycol, Pentylene Glycol, Coconut Alkanes, Coco-caprylate/caprates, Pentaerythrityl Tetraisoostearate, *Aloe Barbadensis Leaf Extract (Aloe Vera), *Calendula Officinalis Flower Extract (Marigold), *Camellia Sinensis Leaf Extract (Green Tea), *Chamomilla Recutita Flower Extract (Matricaria), *Equisetum Arvense Extract (Horsetail), *Euterpe Oleracea Fruit Extract (Acai), *Lavandula Angustifolia Flower Extract (Lavender), *Panax Ginseng Root Extract (Ginseng), *Rosmarinus Officinalis Leaf Extract (Rosemary), *Salvia Officinalis Leaf Extract (Sage), *Symphytum Officinale Leaf Extract (Comfrey), *Urtica Dioica Extract (Nettle), *Chenopodium Quinoa Seed Extract (Quinoa), Stearic Acid, Cetyl PEG/PPG-10/1 Dimethicone, Propanediol, Polyhydroxystearic Acid, Sodium PCA, Sodium Hyaluronate, Dimethicone/vinyl Dimethicone Crosspolymer, Polymethylsilsesquioxane, Caprylyl Glycol, Xanthan Gum, Allantoin, Disteardimonium Hectorite, Propylene Carbonate, Cyclopentasiloxane, Fragrance, Alumina, Ethylhexylglycerin, Citric Acid, Iron Oxides (Ci 77491, Ci 77492), Adenosine (* Certified Organics)

Other information - Safety Sotarge, etc.

Other Information ■ Protect this product from excessive heat and direct sun ■ May stain some fabrics

Package front display panel

ENFANTI⁺
Derma Series



LAB **SPF 50**
california **PA++++**
100%MINERAL
SUN Shield

Brightening & Anti-Wrinkle
UVA/UVB BROAD SPECTRUM
Sunblock formulated
Specially for the face




BIOKEN®

1.8 fl.oz (60g)

Outer box artwork



ENFANTI DERMA SERIES 100% MINERAL SUN SHIELD

titanium dioxide and zinc oxide cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:71331-110

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2.88 g in 60 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	14.7 g in 60 g

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
GLYCERIN (UNII: PDC6A3C0OX)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
ALLANTOIN (UNII: 344S277G0Z)	
ROSEMARY (UNII: IJ67X351P9)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
SYMPHYTUM OFFICINALE WHOLE (UNII: H8FJJ6KX5Y)	
CHENOPODIUM QUINOA SEED (UNII: OO4K72NZ2X)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
MATRICARIA CHAMOMILLA LEAF (UNII: 6I9LN466F0)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
EUTERPE OLERACEA WHOLE (UNII: Y57H6218HP)	
PANAX GINSENG ROOT OIL (UNII: P9T4K47OM0)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
EQUISETUM ARVENSE BRANCH (UNII: 1L0VKZ185E)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
SALVIA OFFICINALIS WHOLE (UNII: M9C36LC10E)	
PENTAERYTHRITYL TETRAISOSTEARATE (UNII: 9D7IK5483F)	
URTICA DIOICA LEAF (UNII: X6M0DRN46Q)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
DIMETHICONE 20 (UNII: H8YMB5QY0D)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
PROPANEDIOL (UNII: 5965N8W85T)	
NIACINAMIDE (UNII: 25X51I8RD4)	
COCONUT ALKANES (UNII: 1E5KJY107T)	
LAVANDULA ANGUSTIFOLIA FLOWER (UNII: 19AH1RAF4M)	
CAMELLIA SINENSIS FLOWER (UNII: 9I2BJY2J17)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
ADENOSINE (UNII: K72T3FS567)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
ISOSTEARIC ACID (UNII: X33R8U0062)	

STEARIC ACID (UNII: 4ELV7Z65AP)	
POLYMETHYLSILSESQUIOXANE (11 MICRONS) (UNII: Z570VEV8XK)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71331-110-02	1 in 1 BOX	12/29/2021	
1	NDC:71331-110-01	60 g 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 not final	part352	12/29/2021	

Labeler - Orange Lab (004862271)

Registrant - Orange Lab (004862271)

Establishment

Name	Address	ID/FEI	Business Operations
Orange Lab, Inc.		004862271	manufacture(71331-110)

Revised: 1/2023

Orange Lab