

PELLE WELLNESS SPF 50 FACE AND BODY BROAD SPECTRUM MINERAL SUNSCREEN- titanium dioxide, zinc oxide cream
Pelle Wellness LLC

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.

Pelle Wellness (as PLD) - Face & Body Sunscreen SPF-50 (83625-101)

ACTIVE INGREDIENTS

ZINC OXIDE 7.0%

TITANIUM DIOXIDE 3.0%

PURPOSE

SUNSCREEN

USES

- Helps prevent sunburn
- If used as directed
- Decreases the risk of skin cancer and early signs of aging caused by the sun

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 doctor if rash occurs.

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

DIRECTIONS

- Apply generously and evenly 15 minutes before sun exposure
- Reapply after 40 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours
- Use a water-resistant sunscreen if swimming.

Children after 6 months: Ask a doctor

- Protect this product from excessive heat and direct sun.


INACTIVE INGREDIENTS

Water, Glycerin, Ethylhexyl Palmitate, Cyclopentasiloxane, C12-15 Alkyl Benzoate, Propanediol, Sodium PCA, Glyceryl Stearate, PEG-100 Stearate, Polysorbate 60, Cetyl Alcohol, Dimethicone, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Citric Acid, Sodium Citrate, Glyceryl Caprylate, Caprylyl Methicone, Alumina, Xanthan Gum, Triethoxysilylethyl Polydimethylsiloxyethyl Hexyl Dimethicone, Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone, Chlorphenesin, Cyclotetrasiloxane, Allantoin, Polyhydroxystearic Acid, Triethoxycaprylylsilane, Glyceryl Undecylenate, 1,2-Hexanediol, Caprylyl Glycol, Disodium EDTA, Panthenol, Camellia Oleifera Leaf Extract, Chamomilla Recutita (Matricaria) Flower Extract, Cucumis Sativus (Cucumber) Fruit Extract, Euterpe Oleracea Fruit Extract, Sodium Hyaluronate, Phenoxyethanol


Questions or Comments?

call 626-877-8505


<p>Drug Facts</p> <p>Active Ingredients.....Purpose Zinc Oxide 7.0%, Titanium Dioxide 3.0%.....Sunscreen</p> <p>Uses: • Helps prevent sunburn • If used as directed • Decreases the risk of skin cancer and early signs of aging caused by the sun</p> <p>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 doctor if rash occurs. • Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions: • Apply generously and evenly 15 minutes before sun exposure • Reapply after 40 minutes of swimming or sweating • immediately after towel drying • at least every 2 hours • Use a water-resistant sunscreen if swimming. Children after 6 months: Ask a doctor</p> <p>Other information: • Protect this product from excessive heat and direct sun.</p> <p>Inactive Ingredients: Water, Glycerin, Ethylhexyl Palmitate, Cyclopentasiloxane, C12-15 Alkyl Benzoate, Propanediol, Sodium PCA, Glyceryl Stearate, PEG-100 Stearate, Polysorbate 60, Cetyl Alcohol, Dimethicone, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Citric Acid, Sodium Citrate, Glyceryl Caprylate, Caprylyl Methicone, Alumina, Xanthan Gum, Triethoxysilylethyl Polydimethylsiloxyethyl Hexyl Dimethicone, Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone, Chlorphenesin, Cyclotetrasiloxane, Allantoin, Polyhydroxystearic Acid, Triethoxycaprylylsilane, Glyceryl Undecylenate, 1,2-Hexanediol, Caprylyl Glycol, Disodium EDTA, Panthenol, Camellia Oleifera Leaf Extract, Chamomilla Recutita (Matricaria) Flower Extract, Cucumis Sativus (Cucumber) Fruit Extract, Euterpe Oleracea Fruit Extract, Sodium Hyaluronate, Phenoxyethanol</p> <p>Questions or Comments? call 626-877-8505</p>	<p style="text-align: center;">PELLE WELLNESS</p> <p style="text-align: center;">SPF 50</p> <p style="text-align: center;">FACE & BODY</p> <p style="text-align: center;">BROAD SPECTRUM MINERAL SUNSCREEN</p> <p style="text-align: center;">• Paraben Free •</p> <p style="text-align: center;">Celebrity X Cruises®</p> <p style="text-align: center;">32 FL OZ</p>
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Distributed by PELLE WELLNESS LLC
Pasadena CA 91101
pellewellness.com
Made in USA



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PELLE WELLNESS SPF 50 FACE AND BODY BROAD SPECTRUM MINERAL SUNSCREEN

titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83625-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	3 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	7 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
CYCLOMETHICONE 4 (UNII: CZ227117JE)	
MATRICARIA CHAMOMILLA FLOWERING TOP (UNII: 3VNC7T6Z02)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
PROPANEDIOL (UNII: 5965N8W85T)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPA.S AT 1%) (UNII: 86FQE96TZ4)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
XANTHAN GUM (UNII: TTV12P4NEE)	
TRIETHOXSILYLETHYL POLYDIMETHYLSILOXYETHYL HEXYL DIMETHICONE (UNII: X75PL53TZJ)	
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
ALLANTOIN (UNII: 344S277G0Z)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
GLYCERYL 1-UNDECYLENATE (UNII: B68LJT9544)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
PANTHENOL (UNII: WW9CM0067Z)	
CAMELLIA OLEIFERA LEAF (UNII: 5077ELOC60)	
CUCUMIS SATIVUS WHOLE (UNII: 50560UL2YV)	

EUTERPE OLERACEA WHOLE (UNII: Y57H6218HP)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83625-101-32	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/26/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	08/26/2023	

Labeler - Pelle Wellness LLC (063980271)

Revised: 8/2023

Pelle Wellness LLC