

SUN PLUS SKINCARE SPF 50 MINERAL BRONZING BODY BUTTER COCONUT-zinc oxide cream

Pacifica Beauty, 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.

Sun Plus Skincare SPF 50 Mineral Bronzing Body Butter Coconut Glow

Active ingredients Purpose

Zinc Oxide 22.0% 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.

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Warnings

For external use only. Do not use on damaged or broken skin. Stop use and ask a doctor if rash occurs. When using this product, keep out of eyes. Rinse with water to remove. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Keep out of reach of children.

Directions

Apply liberally 15 minutes before sun exposure. Reapply: After 80 minutes of swimming or sweating. Immediately after towel drying. At least every 2 hours. Children under 6 months: ask a doctor. Sun protection measures. Spending time in the sun increases your risk of skin cancer & early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF value of 15 or higher & other sun protection measures including: - limit time in the sun, especially from 10 a.m. - 2 p.m. - wear long-sleeve shirts, pants, hats & sunglasses.

Inactive ingredients

Arachidyl Alcohol, Arachidyl Glucoside, Behenyl Alcohol, Bisabolol, Butyloctyl Salicylate, Butyrospermum Parkii (Shea Butter), Caffeine, Caprylhydroxamic Acid, Capryloyl Glycerin/Sebacic Acid Copolymer, Caprylyl Glycol, Cellulose Gum, Cetearyl Alcohol, Cetyl Alcohol, Citric Acid, Coco-Glucoside, Cocos Nucifera (Coconut) Oil, Diheptyl Succinate, Glycerin, Iron Oxides, Lactococcus Ferment Lysate, Methyl Dihydroabietate, Mica,

Microcrystalline Cellulose, Octyldodecyl Oleate, Parfum (Natural), Polyhydroxystearic Acid, Sodium Gluconate, Sodium Hyaluronate, Sodium Stearoyl Glutamate, Theobroma Cacao (Cocoa) Seed Butter, Titanium Dioxide, Tocopherol, Water.

Other information

Protect this product from excessive heat and direct sun. Can stain clothing. Keep away from clothes.

Questions or comments?

Call toll free 1-888-322-2466
Pacifca Beauty LLC
Portland, Oregon.

Sun Plus Skincare SPF 50 Mineral Bronzing Body Butter Coconut Label

PACIFICA



100% VEGAN • CRUELTY-FREE
ALL MINERAL SUNSCREEN

- Sun care + skincare
- Shea butter and caffeine
- Free of chemical UV absorbers
- UVA and UVB protection
- Free of nanoparticles
- Water-resistant up to 80 minutes
- Balanced minerals designed to apply evenly

SPF 50

SUN + SKINCARE MINERAL SPF
BRONZING
BODY
BUTTER
COCONUT
BROAD SPECTRUM
UVA/UVB

Surfer
Approved

WATER RESISTANT
80 MINUTES

protect & glow

FREE OF CHEMICAL
UV ABSORBERS

100% VEGAN • CRUELTY-FREE

5 FL OZ • 147 ML

Drug Facts

Active ingredients	Purpose
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Made in the USA with the best globally sourced ingredients.
Pacifica Beauty LLC Portland, Oregon • 888.322.2466 • www.pacificabeauty.com

♻️ TUBE 50% RECYCLED PLASTIC



♻️ LID

SUN PLUS SKINCARE SPF 50 MINERAL BRONZING BODY BUTTER COCONUT

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61197-209
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	22 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
TOCOPHEROL (UNII: R0ZB2556P8)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
OCTYLDODECYL OLEATE (UNII: MCA43PK7MH)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
.ALPHA.-BISABOLOL, (+)- (UNII: 105S6I733Z)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
METHYL DIHYDROABIETATE (UNII: 7666FJ0J9F)	
WATER (UNII: 059QF0KO0R)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
MICA (UNII: V8A1AW0880)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
SODIUM GLUCONATE (UNII: R6Q3791S76)	
SHEA BUTTER (UNII: K49155WL9Y)	
DOCOSANOL (UNII: 9G1OE216XY)	
CAFFEINE (UNII: 3G6A5W338E)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
CAPRYLOYL GLYCERIN/SEBACIC ACID COPOLYMER (2000 MPA.S) (UNII: N7YC58165T)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
COCO GLUCOSIDE (UNII: ICS790225B)	
COCONUT OIL (UNII: Q9L0O73W7L)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
COCOA BUTTER (UNII: 512OYT1CRR)	
GLYCERIN (UNII: PDC6A3C0OX)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
DIHEPTYL SUCCINATE (UNII: 057N7SS26Y)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
ARACHIDYL GLUCOSIDE (UNII: 6JVW35JOOJ)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61197-209-00	147 mL in 1 TUBE; Type 0: Not a Combination Product	01/27/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	01/27/2023	

Labeler - Pacifica Beauty, LLC (868275517)

Establishment

Name	Address	ID/FEI	Business Operations
Bell International Laboratories, Incorporated		967781555	manufacture(61197-209)

Revised: 1/2023

Pacifica Beauty, LLC