

**SEA AND C GLOW BRONZING BODY OIL SPF 20- avobenzone, octisalate, octocrylene liquid  
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.*

-----  
**Sea and C Glow Bronzing Body Oil SPF 20**

***Active ingredients Purpose***

Avobenzone 2.8% Sunscreen

Octisalate 4.9% Sunscreen

Octocrylene 9.5% Sunscreen

***Uses***

Helps prevent sunburn. If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer & early skin aging caused by the sun.

If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer & early skin aging caused by the sun.

***Warnings***

For external use only. Do not use on damaged or broken skin. Stop use & 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***

Shake well before use Apply liberally 15 minutes before sun exposure. Use water-resistant sunscreen if swimming or sweating. Reapply after swimming or sweating Reapply at least every 2 hours. 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:***

Helianthus Annuus (Sunflower) Seed Oil, Carthamus Tinctorius (Safflower) Seed Oil, Caprylic/Capric Triglyceride, Butyloctyl Salicylate, Silica Silylate, Parfum (Natural),

Simmondsia Chinensis (Jojoba) Seed Oil, Capryloyl Glycerin/Sebacic Acid Copolymer, Caffeine, Tetrahexyldecyl Ascorbate (Vitamin C), Tocopherol (Vitamin E), Laminaria Digitata (Algae) Extract, Laminaria Hyperborea (Kelp) Extract, Hippophae Rhamnoides Oil, Bisabolol, Calcium Sodium Borosilicate, Heptyl Undecylenate, Iron Oxides, Mica, Octyldodecyl Oleate, Tin Oxide, Titanium Dioxide.

**Other information**

Protect this product from excessive heat & direct sun. Can stain clothing, keep away from clothes.

**Questions or comments?**

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

**PACIFICA®**

**SPF 20**

**SEA & C GLOW BRONZING BODY OIL**  
bronze glow  
+  
SPF protection  
broad spectrum UVA/UVB  
+  
vitamin C & sea minerals

**100% VEGAN CRUELTY-FREE**

**4 FL OZ • 118 ML**

**Drug Facts**

Active ingredients	Purpose
Avobenzone 2.8%	Sunscreen
Octisalate 4.9%	Sunscreen
Octocrylene 9.5%	Sunscreen

**Uses**  
•Helps prevent sunburn. •If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer & early skin aging caused by the sun.

**Warnings**  
**For external use only.** •Do not use on damaged or broken skin. •Stop use & 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.

**Directions**  
•Shake well before use •Apply liberally 15 minutes before sun exposure. •Use water-resistant sunscreen if swimming or sweating. •Reapply after swimming or sweating •Reapply at least every 2 hours.  
•**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:**  
Helianthus Annuus (Sunflower) Seed Oil, Carthamus Tinctorius (Safflower) Seed Oil, Caprylic/Capric Triglyceride, Butyloctyl Salicylate, Silica Silylate, Parfum (Natural), Simmondsia Chinensis (Jojoba) Seed Oil, Capryloyl Glycerin/Sebacic Acid Copolymer, Caffeine, Tetrahexyldecyl Ascorbate (Vitamin C), Tocopherol (Vitamin E), Laminaria Digitata (Algae) Extract, Laminaria Hyperborea (Kelp) Extract, Hippophae Rhamnoides Oil, Bisabolol, Calcium Sodium Borosilicate, Heptyl Undecylenate, Iron Oxides, Mica, Octyldodecyl Oleate, Tin Oxide, Titanium Dioxide.

**Other information**  
Protect this product from excessive heat & direct sun.  
**Can stain clothing, keep away from clothes.**

**Questions or comments?**  
Call toll free 1-888-322-2466  
Pacifica Beauty LLC Portland, Oregon

Made in USA with global ingredients.  
Pacifica Beauty LLC Portland, Oregon  
www.pacificabeauty.com

100% VEGAN CRUELTY-FREE

BOTTLE 100% RECYCLED PLASTIC

1912/R001

6 87735 80034 3

**SEA AND C GLOW BRONZING BODY OIL SPF 20**

avobenzone, octisalate, octocrylene liquid

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61197-214
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4.9 g in 100 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	9.5 g in 100 mL
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2.8 g in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>CAFFEINE</b> (UNII: 3G6A5W338E)	
<b>MICA</b> (UNII: V8A1AW0880)	
<b>SAFFLOWER OIL</b> (UNII: 65UEH262IS)	
<b>.ALPHA.-BISABOLOL, (+)-</b> (UNII: 105S6I733Z)	
<b>CALCIUM ALUMINUM BOROSILICATE</b> (UNII: 3JRB8A35M0)	
<b>LAMINARIA HYPERBOREA</b> (UNII: NXA595GQ1K)	
<b>OCTYLDODECYL OLEATE</b> (UNII: MCA43PK7MH)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>LAMINARIA DIGITATA</b> (UNII: 15E7C67EE8)	
<b>HIPPOPHAE RHAMNOIDES FRUIT OIL</b> (UNII: TA4JCF9S1J)	
<b>HEPTYL UNDECYLENATE</b> (UNII: W77QUB6GXO)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>STANNIC OXIDE</b> (UNII: KM7N50LOS6)	
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>JOJOBA OIL</b> (UNII: 724GKU717M)	
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)	
<b>SILICA DIMETHYL SILYLATE</b> (UNII: EU2PSP0G0W)	
<b>CAPRYLOYL GLYCERIN/SEBACIC ACID COPOLYMER (2000 MPA.S)</b> (UNII: N7YC58165T)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61197-214-00	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/02/2023	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	02/02/2023	

**Labeler** - Pacifica Beauty, LLC (868275517)

### Establishment

Name	Address	ID/FEI	Business Operations
Bell International Laboratories, Incorporated		967781555	manufacture(61197-214)

Revised: 2/2023

Pacifica Beauty, LLC