

**GLOW BABY BRIGHTENING SETTING MIST SPF 45- avobenzone, homosalate, octisalate, octocrylene spray**  
**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.*

-----

**Glow Baby Brightening Setting Mist SPF 45**

***Active ingredients Purpose***

Avobenzone 2.9 % Sunscreen

Homosalate 9.8% 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:

Alcohol Denat., Butyloctyl Salicylate, Diheptyl Succinate, Silica Silylate, Coconut Alkanes, Parfum (Natural), Tetrahexyldecyl Ascorbate (Vitamin C), Algae Extract, Ascophyllum Nodosum (Seaweed) Extract, Laminaria Digitata (Algae) Extract, Aqua, Helianthus Annuus (Sunflower) Seed Oil, Hydrolyzed Jojoba Esters, Glycerin, Bisabolol, Capryloyl Glycerin/Sebacic Acid Copolymer, Coco Caprylate/Caprates, Ethyl Ferulate.

## Other information

Protect this product from excessive heat & direct sun.

## Questions or comments?

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

## Glow Baby Brightening Setting Mist SPF 45

**PACIFICA**

**SPF 45**

**SET & PROTECT**  
**MATTE SHEER SETTING MIST**  
vitamin C & sea minerals  
+  
SPF protection broad spectrum UVA/UVB

**100% VEGAN CRUELTY-FREE**

4 FL OZ • 118 ML

Lightweight and sheer, can be used as last step in makeup routine for SPF and blue light protection.

**100% VEGAN CRUELTY-FREE**

Drug Facts	
<b>Active ingredients</b>	<b>Purpose</b>
Avobenzone 2.9%	Sunscreen
Homosalate 9.8%	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:**  
Alcohol Denat., Butyloctyl Salicylate, Diheptyl Succinate, Silica Silylate, Coconut Alkanes, Parfum (Natural), Tetrahexyldecyl Ascorbate (Vitamin C), Algae Extract, Ascophyllum Nodosum (Seaweed) Extract, Laminaria Digitata (Algae) Extract, Aqua, Helianthus Annuus (Sunflower) Seed Oil, Hydrolyzed Jojoba Esters, Glycerin, Bisabolol, Capryloyl Glycerin/Sebacic Acid Copolymer, Coco-Caprylate/Caprates, Ethyl Ferulate.

**Other information**  
Protect this product from excessive heat & direct sun.

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

2005R001 BOTTLE 100% RECYCLED PLASTIC CAP

6 8795 85035 5

## GLOW BABY BRIGHTENING SETTING MIST SPF 45

avobenzone, homosalate, octisalate, octocrylene spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61197-205
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	9.8 mg in 100 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4.9 mg in 100 mL
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2.9 mg in 100 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	9.5 mg in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>SILICA DIMETHYL SILYLATE</b> (UNII: EU2PSP0G0W)	
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)	
<b>FUCUS SERRATUS</b> (UNII: V8K40WNW5B)	
<b>ASCOPHYLLUM NODOSUM</b> (UNII: 168S4EO8YJ)	
<b>ETHYL FERULATE</b> (UNII: 5B8915UELW)	
<b>LAMINARIA DIGITATA</b> (UNII: 15E7C67EE8)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>CAPRYLOYL GLYCERIN/SEBACIC ACID COPOLYMER (2000 MPA.S)</b> (UNII: N7YC58165T)	
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)	
<b>HYDROLYZED JOJOBA ESTERS (ACID FORM)</b> (UNII: UDR641JW8W)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>DIHEPTYL SUCCINATE</b> (UNII: 057N7SS26Y)	
<b>COCONUT ALKANES</b> (UNII: 1E5KJY107T)	
<b>.ALPHA.-BISABOLOL, (+)-</b> (UNII: 105S6I733Z)	
<b>COCO-CAPRYLATE/CAPRATE</b> (UNII: 8D9H4QU99H)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61197-205-00	118 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/23/2023	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	01/23/2023	

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

## Establishment

Name	Address	ID/FEI	Business Operations
Bell International Laboratories, Incorporated		967781555	manufacture(61197-205)

