

SET AND PROTECT MATTE SHEER 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.

Set and Protect Matte Sheer 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.

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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/Caprinate, 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

Set and Protect Matte Sheer Setting Mist SPF 45 Label

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	
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1912R001 BOTTLE 100% RECYCLED PLASTIC CAP

SET AND PROTECT MATTE SHEER SETTING MIST SPF 45

avobenzone, homosalate, octisalate, octocrylene spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61197-215
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
SUNFLOWER OIL (UNII: 3W1JG795YI)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
FUCUS SERRATUS (UNII: V8K40WNV5B)	
ASCOPHYLLUM NODOSUM (UNII: 168S4EO8YJ)	
LAMINARIA DIGITATA (UNII: 15E7C67EE8)	
GLYCERIN (UNII: PDC6A3C0OX)	
.ALPHA.-BISABOLOL, (+)- (UNII: 105S6I733Z)	
DIHEPTYL SUCCINATE (UNII: 057N7SS26Y)	
ALCOHOL (UNII: 3K9958V90M)	
COCONUT ALKANES (UNII: 1E5KJY107T)	
CAPRYLOYL GLYCERIN/SEBACIC ACID COPOLYMER (2000 MPA.S) (UNII: N7YC58165T)	
ETHYL FERULATE (UNII: 5B8915UELW)	
COCO-CAPRYLATE (UNII: 4828G836N6)	
HYDROLYZED JOJOBA ESTERS (ACID FORM) (UNII: UDR641JW8W)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61197-215-00	118 mL in 1 BOTTLE, SPRAY; 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(61197-215)

