

**SUNSHINE AND GLITTER BROAD SPECTRUM SPF 50 GLAMINGO GLITTER  
SUNSCREEN- avobenzone, homosalate, octisalate, octocrylene lotion  
Prime Enterprises Inc.**

*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.*

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**Crayola Sunshine & Glitter Sea Star Sparkle Glamingo Glitter Sunscreen  
Lotion Broad Spectrum SPF 50**

***Active Ingredients***

Avobenzone 3%

Octisalate 5%

Octocrylene 5%

Homosalate 10%

***Purpose***

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.

***Warnings***

**For external use onl**

**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 a 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 liberally 15 minutes before sun exposure
- reapply:
- after 80 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours

- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with broad spectrum SPF of 15 or higher and other sun protection measures including:
  - limit time in the sun, especially from 10 a.m. – 2 p.m.
  - wear long-sleeve shirts, pants, hats, and sunglasses
  - children under 6 months: Ask a doctor

**Inactive Ingredients**

Acrylates Copolymer, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, Aluminum, C12-15 Alkyl Benzoate, Carbomer, Disodium EDTA, Ethylhexylglycerin, Fragrance, Glycerin, Hydroxypropyl Methylcellulose, Microcrystalline Cellulose, Phenoxyethanol, Polybutylene Terephthalate, Polyethylene, Polylactic Acid, Polysorbate 20, Polyurethane, Polyurethane-33, Propylene Glycol, Red 7, Sodium Hydroxide, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Water

**Questions or comments?**

Call Sunshine & Glitter 1-888-601-0441

**Crayola Sunshine & Glitter Broad Spectrum SPF 50 Sunscreen Lotion**

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Octocrylene 5%	
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When using this product keep out of eyes. Rinse with water to remove.	
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<b>Questions or comments?</b> Call Sunshine & Glitter at 1-888-601-0441	
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Official Licensed Product <div style="float: right; text-align: right;"> <p>8 50040 85605 7</p> </div>	

# SUNSHINE AND GLITTER BROAD SPECTRUM SPF 50 GLAMINGO GLITTER SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene lotion

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58443-0590
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	29.1 g in 1 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	48.5 g in 1 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	48.5 g in 1 mL
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	97 g in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>BUTYL ACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID COPOLYMER (18000 MW)</b> (UNII: JZ1374NL9E)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>POLYLACTIDE</b> (UNII: 459TN2L5F5)	
<b>POLYURETHANE-62</b> (UNII: TBK645J3J8)	
<b>POLYURETHANE-34 (55 MPA, TENSILE STRENGTH OF FILM AT BREAK)</b> (UNII: II1242QJ7P)	
<b>D&amp;C RED NO. 7</b> (UNII: ECW0LZ41X8)	
<b>SORBITAN MONOOLEATE</b> (UNII: 06XEA2VD56)	
<b>COCOA BUTTER</b> (UNII: 512OYT1CRR)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>HIGH DENSITY POLYETHYLENE</b> (UNII: UG00KM4WR7)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>ALUMINUM</b> (UNII: CPD4NFA903)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>CARBOMER INTERPOLYMER TYPE A (55000 CPS)</b> (UNII: 59TL3WG5CO)	

## Product Characteristics

<b>Color</b>	white (White with pink speckles)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	

<b>Flavor</b>				<b>Imprint Code</b>			
<b>Contains</b>							
<b>Packaging</b>							
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:58443-0590-3	100 mL in 1 TUBE; Type 0: Not a Combination Product	12/08/2021				
<b>Marketing Information</b>							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC monograph final	M020	12/08/2021					

**Labeler** - Prime Enterprises Inc. (101946028)

**Registrant** - Prime Enterprises Inc. (101946028)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0590) , manufacture(58443-0590) , label(58443-0590) , analysis(58443-0590)

Revised: 11/2022

Prime Enterprises Inc.