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.

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

Active Ingredients

Avobenzone 3%

Homosalate 10%

Octisalate 5%

Octocrylene 5%

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 only.

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 40 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

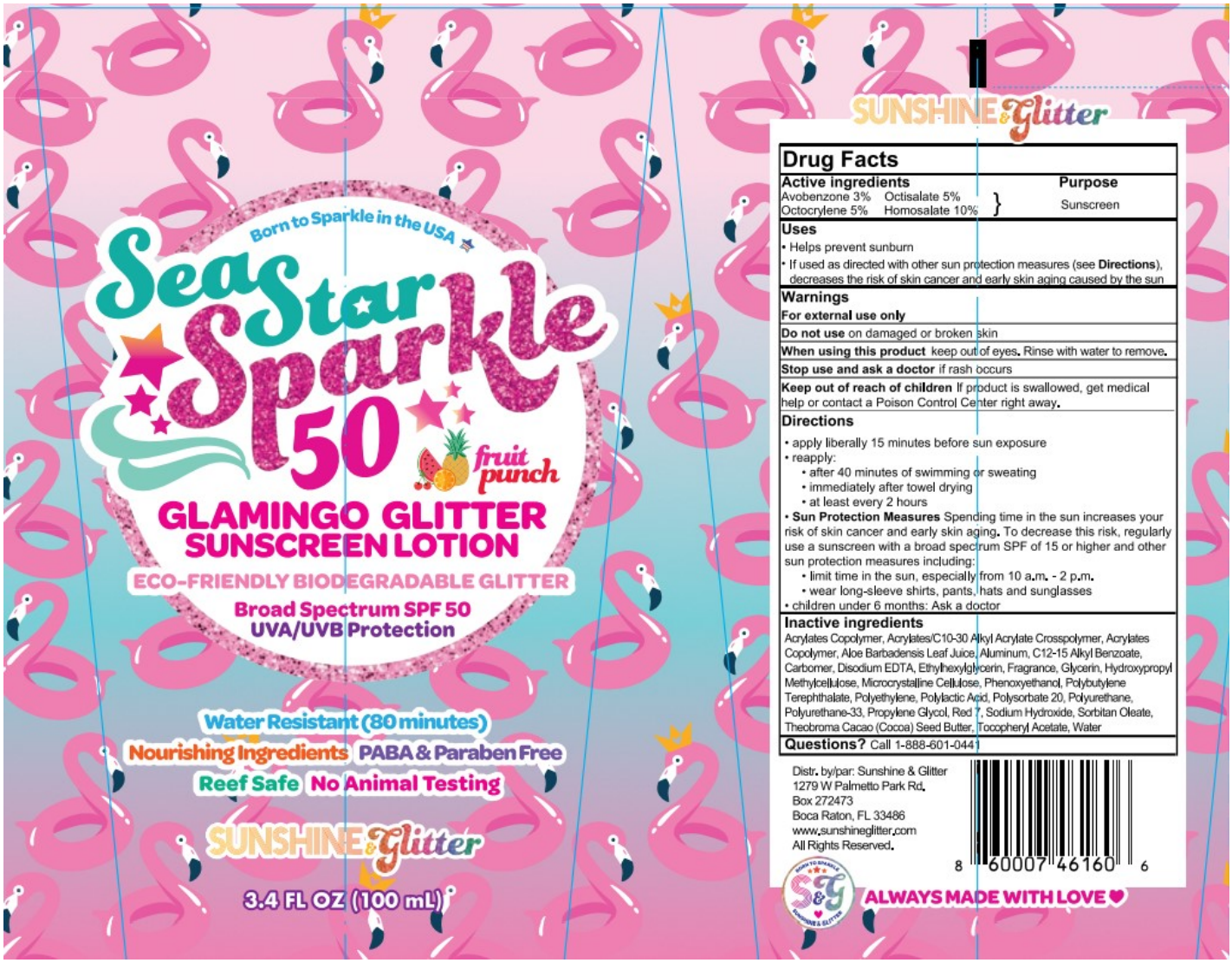
Inactive Ingredients

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 1-888-601-0441

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



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Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58443-0519
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	31 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	51 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	51 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	102 mg in 1 mL

Inactive Ingredients

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

Product Characteristics

Color	white (White with pink speckles)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0519-3	100 mL in 1 TUBE; Type 0: Not a Combination Product	12/13/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/13/2021	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0519) , manufacture(58443-0519) , label(58443-0519) , analysis(58443-0519)

Revised: 1/2022 Prime Enterprises Inc.