CONCEPT II SOLSCENTS BROAD SPECTRUM SPF 50 RASPBERRY DREAMS-
avobenzone, homosalate, octisalate, octocrylene and oxybenzone 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.

Concept II SolScents Broad Spectrum SPF 50 Raspberry Dreams

Active Ingredients

Avobenzone 3% Homosalate 12.5%

Octisalate 5% Octocrylene 2.75% Oxybenzone 2%

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.

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 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 a 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.

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Allantoin, Aloe Barbadensis Leaf Juice, Butylphthalimide, C12-15 Alkyl Benzoate, Carbomer, Disodium EDTA, Fragrance (Parfum), Hydroxypropyl Methylcellulose, Isopropylphthalimide, Methylisothiazolinone, Methylparaben, Polyethylene, Polysorbate 20, Propylene Glycol, Propylparaben, Sorbitan Oleate, Sorbitol, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Triethanolamine, Water (Aqua)

Other Information

- protect this product from excesive heat and direct sun

Questions or comments?

SolScents, LLC. 2200 N.W. 92nd Avenue. Miami, Florida 33172

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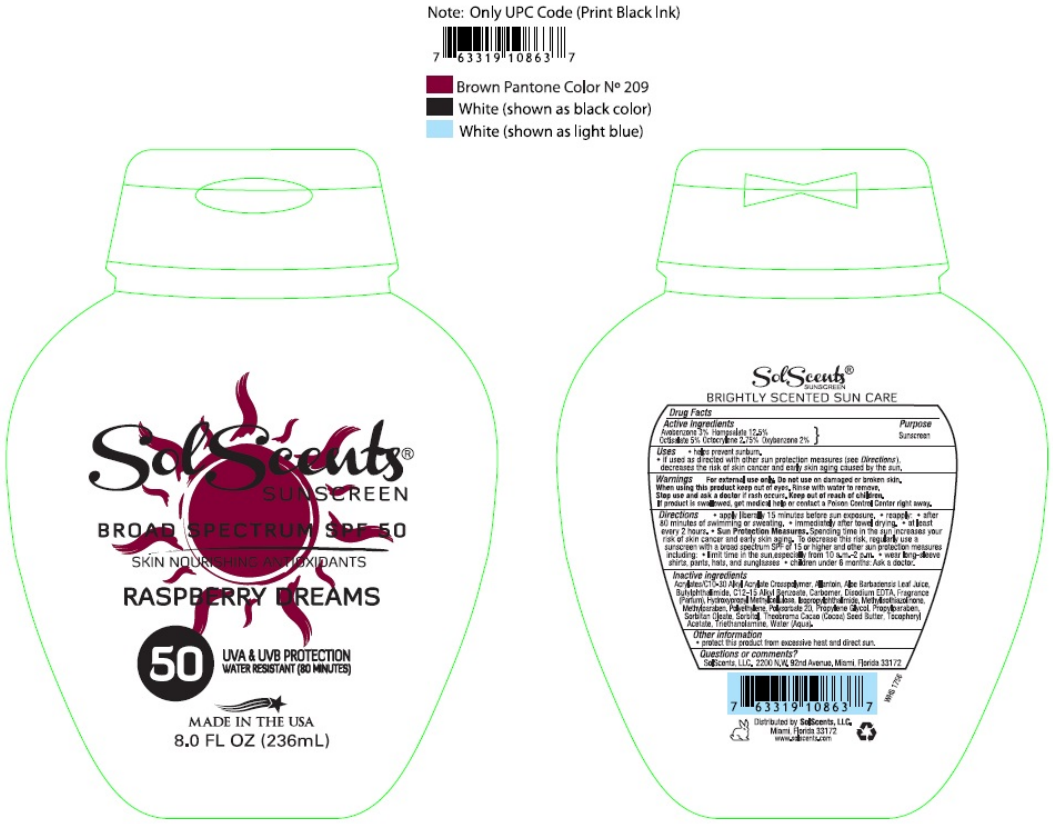

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Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58443-0217
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	20 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	125 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL

OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	27.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
ISOPROPYLPHTHALIMIDE (UNII: 1J1MM83329)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
N-BUTYLPHTHALIMIDE (UNII: 5TH1DKT35E)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALLANTOIN (UNII: 344S277G0Z)	
(C10-C30)ALKYL METHACRYLATE ESTER (UNII: XH2FQZ38D8)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
COCOA BUTTER (UNII: 512OYT1CRR)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Product Characteristics

Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0217-4	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/23/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	05/23/2013	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0217) , manufacture(58443-0217) , label(58443-0217)