

CONCEPT II SOLSCENTS BROAD SPECTRUM SPF 15 VANILLA SILK- avobenzone, octisalate, and 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.

Concept II SolScents Broad Spectrum SPF 15 Vanilla Silk

Active Ingredients

Avobenzone 2%

Octisalate 5% Octocrylene 1.85%

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 excessive heat and direct sun.

Questions or comments?

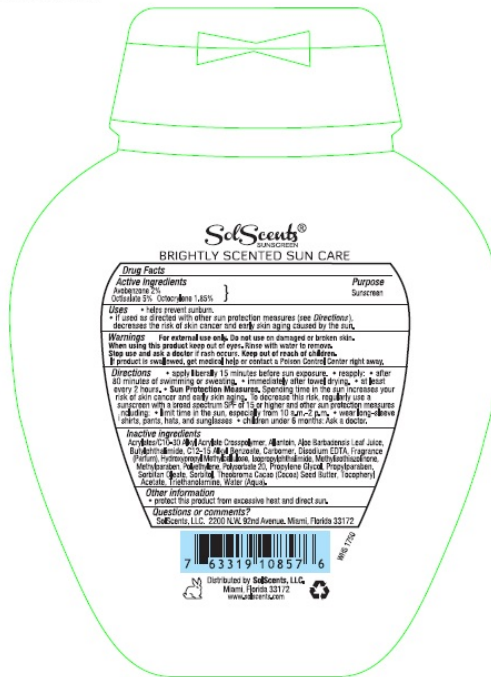
SolScents, LLC. 2200 N.W. 92nd Avenue. Miami, Florida 33172

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Note: Only UPC Code (Print Black Ink)



- Peach Pantone Color N° 1645
- White (shown as black color)
- White (shown as light blue)



CONCEPT II SOLSCENTS BROAD SPECTRUM SPF 15 VANILLA SILK

avobenzene, octisalate, and octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58 443-0214
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	20 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	50 mg in 1 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	18.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
METHYL PARABEN (UNII: A2I8C7HI9T)	
COCOA BUTTER (UNII: 512OYT1CRR)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SORBITOL (UNII: 506T60A25R)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
ISOPROPYL PHTHALIMIDE (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-BUTYL PHTHALIMIDE (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: 059QF0K00R)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0214-4	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/20/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	05/20/2013	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0214) , manufacture(58443-0214) , label(58443-0214)

Revised: 1/2020

Prime Enterprises Inc.