

**SUNTONE KIDS BROAD SPECTRUM SPF 50 SUNSCREEN- 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.*

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**Suntone Kids Broad Spectrum SPF 50 Sunscreen**

***Active Ingredients***

Avobenzone 3%

Homosalate 10%

Octisalate 5%

Octocrylene 2.75%

Oxybenzone 3%

***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 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

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, 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, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Triethanolamine, Water (Aqua)

***Other Information***

- protect this product from excessive heat and direct sun

***Questions or Comments?***

Biocycle Laboratories. Inc.

16363 NW 49 Avenue, Miami, FL 33014

**SUntone Kids Broad Spectrum SPF 50 Sunscreen**



## SUNTONE KIDS BROAD SPECTRUM SPF 50 SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene, and oxybenzone lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58 443-0 138
<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	30 mg in 1 mL
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL
<b>OCTISALATE</b> (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	50 mg in 1 mL

<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	27.5 mg in 1 mL
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	30 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>ISOPROPYLPHthalimide</b> (UNII: 1J1MM83329)	
<b>COCOA BUTTER</b> (UNII: 512OYT1CRR)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>HIGH DENSITY POLYETHYLENE</b> (UNII: UG00KM4WR7)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SORBITAN MONOOLEATE</b> (UNII: 06XEA2VD56)	
<b>CARBOMER 940</b> (UNII: 4Q93RCW27E)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>(C10-C30)ALKYL METHACRYLATE ESTER</b> (UNII: XH2FQZ38D8)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>N-BUTYLPHthalimide</b> (UNII: 5TH1DKT35E)	
<b>METHYLISOTHIAZOLINONE</b> (UNII: 229D0E1QFA)	
<b>METHYLPARABEN</b> (UNII: A2J8C7HI9T)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0138-4	177 mL in 1 TUBE; Type 0: Not a Combination Product	03/17/2014	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/17/2014	

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

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

## Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0138) , manufacture(58443-0138) , label(58443-0138) , analysis(58443-0138)

Revised: 1/2020

Prime Enterprises Inc.