

BLI HOLDINGS MIAMI BEACH KIDS SPF 50- 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.

Active ingredients

Avobenzone 3 %, Homosalate 10 %, Octisalate 5 %, Octocrylene 2.75 %, and 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 our risk of skin cancer and earl 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

Inactive Ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, Beta-Carotene, Butylphthalimide, C12-15 Alkyl Benzoate, Caprylic/ Capric Triglyceride, Carbomer, Crambe Maritima Extract, Disodium EDTA, Ethylhexyglycerin, Helianthus Annuus (Sunflower) Seed Oil, Hydroxypropyl Methylcellulose, Isopropylphthalimide, Phenoxyethanol, Polyethylene, Polysorbate 20, Propylene Glycol, Propylene Glycol, Prunus Ameniaca (Apricot) Kernel Oil, Pseudopterogorgia Elisabethae Plant Extract, Sodium Hydroxide, Solanum Lycopersicum (Tomato) Fruit/Leaf/Steam

Extract, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Water (Aqua), Zea Mays (Corn) Oil

Other information

- protect this product from excessive heat and direct sun. •may stain fabrics.

Questions or Comments?

Call 305.471.7989

PRINCIPAL DISPLAY PANEL - 177 mL Bottle Label

OFFICIAL SUNCARE
MB MIAMIBEACH™
MB LIFEGUARDS

Kids

Sunscreen Lotion
Broad Spectrum SPF 50

UVA/UVB Protection
Water Resistant (80 Minutes)
Dye-Free, Fragrance-Free
Hypoallergenic For Sensitive Skin

Made with Blend of Natural
Marine Extracts

6 FL OZ (177mL)

Drug Facts

Active Ingredients	Purpose
Avobenzone 3%, Homosalate 10%, Octisalate 5%, Octocrylene 2.75%, Oxybenzone 3%	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 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

Inactive ingredients Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, Beta-Carotene, Butylphthalimide, C12-15 Alkyl Benzoate, Caprylic/Capric Triglyceride, Carbomer, Crambe Maritima Extract, Disodium EDTA, Ethylhexylglycerin, Helianthus Annuus (Sunflower) Seed Oil, Hydroxypropyl Methylcellulose, Isopropylthalamide, Phenoxyethanol, Polyethylene, Polysorbate 20, Propylene Glycol, Prunus Armeniaca (Apricot) Kernel Oil, Pseudopterogorgia Elisabethae Plant Extract, Sodium Hydroxide, Solanum Lycopersicum (Tomato) Fruit/Leaf/Stem Extract, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Water, Zea Mays (Corn) Oil

Other information - protect this product from excessive heat and direct sun. - may stain fabrics.

Questions or comments?
Call 305.471.7989

Made in USA
Distributed by: Destination Brands International
8600 NW 41 Street, Miami, Florida 33166
www.MiamiBeachSun.com

Keep our beaches beautiful
Beach Cleanup Sponsorship

8 12604 02009 0

OFFICIAL SUNCARE

MB

MIAMIBEACH

MB LIFEGUARDS

KIDS

Sunscreen Lotion

Broad Spectrum SPF 50

UVA/UVB Protection

Water Resistant (80 Minutes)
 Dye-Free, Fragrance-Free
 Hypoallergenic for Sensitive Skin
 Made with Blend of Natural
 Marine Extracts
 6 FL OZ (177mL)



Sunscreen Lotion
 Broad Spectrum
 SPF 50

UVA/UVB Protection
 Water Resistant (80 Minutes)
 Dye-Free, Fragrance-Free
 Hypoallergenic For Sensitive Skin

Made with Blend of Natural
 Marine Extracts

0.25 FL OZ (7.4 mL)

Take a little of MIAMIBEACH™ with you!

www.MiamiBeachSun.com

Drug Facts

Active Ingredients	Purpose
Avobenzone 3%, Homosalate 10%, Octisalate 5%, Octocrylene 2.75%, Oxybenzone 3%	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 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

Inactive ingredients Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, Beta-Carotene, Butylphthalimide, C12-15 Alkyl Benzoate, Caprylic/Capric Triglyceride, Carbomer, Crambe Maritima Extract, Disodium EDTA, Ethylhexylglycerin, Helianthus Annuus (Sunflower) Seed Oil, Hydroxypropyl Methylcellulose, Isopropylthalamide, Phenoxyethanol, Polyethylene, Polysorbate 20, Propylene Glycol, Prunus Armeniaca (Apricot) Kernel Oil, Pseudopterogorgia Elisabethae Plant Extract, Sodium Hydroxide, Solanum Lycopersicum (Tomato) Fruit/Leaf/Stem Extract, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Water, Zea Mays (Corn) Oil

Other information - protect this product from excessive heat and direct sun. - may stain fabrics.

Questions or comments?

Call 305.471.7989

Made in USA

Distributed by:
 Destination Brands International
 8600 NW 41 Street, Miami, Florida 33166

Keep our beaches beautiful
 Beach Cleanup Sponsorship



OFFICIAL SUNCARE

MB

MIAMIBEACH

MB LIFEGUARDS

KIDS

Sunscreen Lotion

Broad Spectrum

SPF 50

UVA/UVB Protection

Water Resistant (80 Minutes)

Dye-Free, Fragrance-Free

Hypoallergenic for Sensitive Skin

Made with Blend of Natural

Marine Extracts

0.25 FL OZ (7.4mL)

BLI HOLDINGS MIAMI BEACH KIDS SPF 50

avobenzone, homosalate, octisalate, octocrylene, and oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0147
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	29.7 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	99 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	49.5 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	27.225 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	29.7 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
(C10-C30)ALKYL METHACRYLATE ESTER (UNII: XH2FQZ38D8)	
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
N-BUTYLPHTHALIMIDE (UNII: 5TH1DKT35E)	
ISOPROPYLPHTHALIMIDE (UNII: 1J1MM83329)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CAPRYLIC/CAPRIC ACID (UNII: DI775RT244)	
CRAMBE MARITIMA LEAF (UNII: NO0D2V62B)	

CARBOMER HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)
EDETATE DISODIUM (UNII: 7FLD91C86K)
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)
HYPROMELLOSES (UNII: 3NXW29V3WO)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
PSEUDOPTEROGORGIA ELISABETHAE (UNII: UDY3H1OUX5)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
APRICOT KERNEL OIL (UNII: 54JB35T06A)
WATER (UNII: 059QF0K00R)
SOLANUM LYCOPERSICUM (UNII: 0243Q4990L)
SODIUM HYDROXIDE (UNII: 55X04QC32I)
PEG-6 SORBITAN OLEATE (UNII: 58O7V09UCI)
COCOA BUTTER (UNII: 512OYT1CRR)
CORN OIL (UNII: 8470G57WFM)
.BETA.-CAROTENE (UNII: 01YAE03M7J)

Product Characteristics

Color	orange	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0147-4	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2015	
2	NDC:58443-0147-2	7.4 mL in 1 POUCH; Type 0: Not a Combination Product	03/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/01/2015	

Labeler - Prime Enterprises, Inc. (101946028)

Registrant - Prime Enterprises, Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	label(58443-0147) , pack(58443-0147) , manufacture(58443-0147) , analysis(58443-0147)

