

URBAN OUTFITTERS SUNSCREEN SHIMMER BROAD SPECTRUM SPF 30- avobenzene, homosalate, octisalate, octocrylene, 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.

Urban Outfitters Sunscreen Shimmer Lotion 30 Broad Spectrum SPF 30

Active Ingredients

Avobenzene 3%

Homosalate 7.5%

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.

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

Inactive ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Allantoin, Aloe Barbadensis Leaf Juice, Butylphthalimide, Butyrospermum Parkii (Shea) Butter, C12-15 Alkyl Benzoate, Camellia Sinensis (Green Tea) Leaf Extract, Carbomer, Disodium EDTA, Ethylhexylglycerin, Fragrance, Hydroxypropyl Methylcellulose, Isopropylphthalimide, Mangifera Indica (Mango) Seed Butter, Mica, Phenoxyethanol, Polyester-8, Polyethylene, Polysorbate 20, Propylene Glycol, Silk Amino Acids, Sodium Hydroxide, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Titanium Dioxide, Tocopheryl Acetate, Water

Other information

- Protect this product from excessive heat and direct sun

Questions or comments?

Call toll free 1-800-282-2200

Urban Outfitters Sunscreen Shimmer Lotion 30 Broad Spectrum SPF 30

<p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active Ingredients</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Avobenzone 3% Homosalate 7.5% Octisalate 5% Octocrylene 2.75% Oxybenzone 2%</td> <td>Sunscreen</td> </tr> </tbody> </table> <p>Uses</p> <ul style="list-style-type: none"> ■ helps prevent sunburn ■ if used as directed with other sun protection measures (see <i>Directions</i>), decreases the risk of skin cancer and early skin aging caused by the sun <p>Warnings</p> <p>For external use only</p> <p>Do not use on damaged or broken skin</p> <p>When using this product keep out of eyes. Rinse with water to remove.</p> <p>Stop use and ask a doctor if rash occurs</p> <p>Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none"> ■ apply liberally 15 minutes before sun exposure ■ reapply: <ul style="list-style-type: none"> ■ 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: <ul style="list-style-type: none"> ■ 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 <p>Inactive ingredients</p> <p>Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Allantoin, Aloe Barbadensis Leaf Juice, Butylphthalimide, Butyrospermum Parkii (Shea) Butter, C12-15 Alkyl Benzoate, Camellia Sinensis (Green Tea) Leaf Extract, Carbomer, Disodium EDTA, Ethylhexylglycerin, Fragrance, Hydroxypropyl Methylcellulose, Isopropylphthalimide, Mangifera Indica (Mango) Seed Butter, Mica, Phenoxyethanol, Polyester-8, Polyethylene, Polysorbate 20, Propylene Glycol, Silk Amino Acids, Sodium Hydroxide, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Titanium Dioxide, Tocopheryl Acetate, Water</p> <p>Other information</p> <ul style="list-style-type: none"> ■ protect this product from excessive heat and direct sun <p>Questions or comments?</p> <p>Call toll free 1-800-282-2200</p>	Active Ingredients	Purpose	Avobenzone 3% Homosalate 7.5% Octisalate 5% Octocrylene 2.75% Oxybenzone 2%	Sunscreen	<p>SUNSCREEN SHIMMER LOTION 30</p>
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Avobenzone 3% Homosalate 7.5% Octisalate 5% Octocrylene 2.75% Oxybenzone 2%	Sunscreen				
<p>MADE IN USA FROM US AND IMPORTED INGREDIENTS DISTRIBUTED BY URBAN OUTFITTERS, INC. 5000 S. Broad St. Philadelphia, PA 19112 Urbanoutfitters.com</p>	<p>URBAN OUTFITTERS</p> <p>BROAD SPECTRUM SPF 30 Sunscreen with Aloe Vera, Shea Butter, Cocoa Butter, Mango Butter, Vitamin E</p> <p>Water Resistant (80 minutes)</p> <p>6 fl. oz. / 177 mL</p>				

URBAN OUTFITTERS SUNSCREEN SHIMMER BROAD SPECTRUM SPF 30

avobenzone, homosalate, octisalate, octocrylene, oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0259
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	20.2 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30.3 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50.5 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	27.78 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	75.75 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
AMINO ACIDS, SILK (UNII: V0L00EX11A)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CARBOMER HOMO POLYMER TYPE C (UNII: 4Q93RCW27E)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MANGIFERA INDICA SEED BUTTER (UNII: 4OXD9M35X2)	
POLYESTER-8 (1400 MW, CYANO DIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
ALLANTOIN (UNII: 344S277G0Z)	
N-BUTYLPHTHALIMIDE (UNII: 5TH1DKT35E)	
SHEA BUTTER (UNII: K49155WL9Y)	
COCOA BUTTER (UNII: 512OYT1CRR)	
CARBOMER 1342 (UNII: 809Y72KV36)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ISOPROPYLPHTHALIMIDE (UNII: 1J1MM83329)	
MICA (UNII: V8A1AW0880)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	white (Off-white)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0259-4	177 mL in 1 TUBE; Type 0: Not a Combination Product	03/02/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/02/2018	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0259) , manufacture(58443-0259) , label(58443-0259) , analysis(58443-0259)

Revised: 1/2020

Prime Enterprises Inc.