

SUN BUM HAND CREAM SPF15- avobenzone, homosalate, octisalate, octocrylene cream
Sun Bum LLC

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.

Sun Bum Hand Cream SPF15

Drug Facts

Active ingredients

Avobenzone 2%,
Homosalate 5%,
Octisalate 2%,
Octocrylene 10%

Purpose

Sunscreen

Uses

- helps prevent sunburn
- Keep outer carton for full information
- 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 swallowed, get medical help or contact a Poison Control Center immediately.

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
- children under 6 months of age: ask a doctor

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 value 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-sleeved shirts, pants, hats and sunglasses

Other information

protect this product from excessive heat and direct sun

Inactive ingredients

water, isoamyl cocoate, cetearyl alcohol, arachidyl alcohol, dimethicone, glycerin, behenyl alcohol, styrene/acrylates copolymer, cetearyl glucoside, arachidyl glucoside, fragrance, polyester-8, saccharide isomerate, apyrylyl glycol, phenoxyethanol, sorbic acid, xanthan gum xanthan gum, phenoxyethanol, ethylhexylglycerin

Questions?

1-877-978-6286

Package Labeling:



SUN
BUM



Trust The Bum®

Hand Cream

Broad Spectrum SPF 15 Sunscreen
Water Resistant (80 Minutes)
2 FL OZ / 59 mL

15



Sun Bum® Sunscreens are carefully formulated to help protect those of us who live and love in the sun.

Trust The Bum®

● Moisturizing ● For All Skin Types ● Dermatologist Tested

Drug Facts

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Avobenzone 2%, Homosalate 5%	Sunscreen
Octisalate 2%, Octocrylene 10%	

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Stop use and ask a doctor if rash occurs
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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
• children under 6 months of age: ask a doctor
• **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 value of 15 or higher and other sun protection measures including:
• limit time in the sun, especially from 10 a.m. - 2 p.m.
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Other information protect this product from excessive heat and direct sun

Inactive ingredients water, isoamyl cocoate, cetearyl alcohol, arachidyl alcohol, dimethicone, glycerin, behenyl alcohol, styrene/acrylates copolymer, cetearyl glucoside, arachidyl glucoside, fragrance, polyester-8, saccharide isomerate, caprylyl glycol, phenoxyethanol, sorbic acid, xanthan gum

Questions? 1-877-978-6286

Mfg. for and Dist. by Sun Bum, LLC, PO Box 320598 Cocoa Beach, FL 32932 USA.
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Premium Sunscreen Hand Cream



Hand Cream

**Broad Spectrum SPF 15
Water Resistant (80 Minutes)**

Moisturizing & Protecting

Vegan • Gluten Free
Dermatologist Tested

2 FL OZ / 59 mL

Drug Facts

Active ingredients

Avobenzone 2%, Homosalate 5%,
Octisalate 2%, Octocrylene 10% Sunscreen

Purpose

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 swallowed, get medical help or contact a Poison Control Center immediately.

Directions

- shake well
- apply liberally 15 minutes before sun exposure
- reapply:
 - after 80 minutes of swimming or sweating
 - immediately after towel drying
 - at least every 2 hours
- children under 6 months of age: ask a doctor

Sun Protection Measures

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SUN BUM HAND CREAM SPF15

avobenzone, homosalate, octisalate, octocrylene cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69039-637
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
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	50 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	20 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6VM) (OCTOCRYLENE - UNII:5A68WGF6VM)	OCTOCRYLENE	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISOAMYL COCOATE (UNII: 14OG46E98E)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERIN (UNII: PDC6A3C0OX)	
DOCOSANOL (UNII: 9G1OE216XY)	
STYRENE/ACRYLAMIDE COPOLYMER (500000 MW) (UNII: 5Z4DPO246A)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
ARACHIDYL GLUCOSIDE (UNII: 6JVW35JOOJ)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SORBIC ACID (UNII: X045WJ989B)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69039-637-01	59 mL in 1 CARTON; Type 0: Not a Combination Product	05/19/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/19/2021	

Labeler - Sun Bum LLC (028642574)