# SUN BUM SKIN CARE ESSENTIALS KIT- avobenzone, homosalate, octisalate, octocrylene 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.

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### Sun Bum Skin Care Essentials Kit

### **Drug Facts**

### Active ingredients

Avobenzone 3%, Homosalate 10%, Octisalate 5%, Octocrylene 10%

### **Purpose**

Sunscreen

#### Uses

- helps prevent sunburn
- If used as directed with other sun protection measuress ( **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 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
- 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 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 (SPF 30 moisturizing sunscreen lotion)

water, polyglyceryl-6 stearate, dimethicone, cetearyl alcohol, capryloyl glycerin/sebacic acid copolymer, hydrated silica, hibiscus sabdariffa fruit extract, niacinamide, cocos nucifera (coconut) fruit extract, helianthus annuus (sunflower) extract, lactobacillus, lactobacillus ferment, musa sapientum (banana) flower extract, musa sapientum (banana) fruit extract, musa sapientum (banana) leaf extract, musa sapientum (banana) peel extract, musa sapientum (banana) pulp extract, lysolecithin, erythritol, glucose, glycerin, arachidyl alcohol, arachidyl glucoside, behenyl alcohol, cetearyl glucoside, fragrance, polyglyceryl-6 behenate, pullulan, sclerotium gum, tocopherol, xanthan gum, phenoxyethanol, ethylhexylglycerin

Questions?

1-877-978-6286

Package Labeling:







- Sulfates ParabensMineral Oil
- Phthalates
   Formaldehyde
   Synthetic Fragrance







Pestoring Face Mask (0.5 FL OZ / 15 mL)

Product Description: Our Restoring Face Mask helps hydrate and soothe skin after a day in the sun or when skin just needs some extra love. This cooling mask helps give skin an extra boost of hydration and helps to calim redness and irritation.

Daily Sunscreen Moisturizer SPF30 (0.5 FL 0Z/15 mL)

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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 right away.

Other information protect this product from excessive heat and direct sun

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# Trust The Bum®



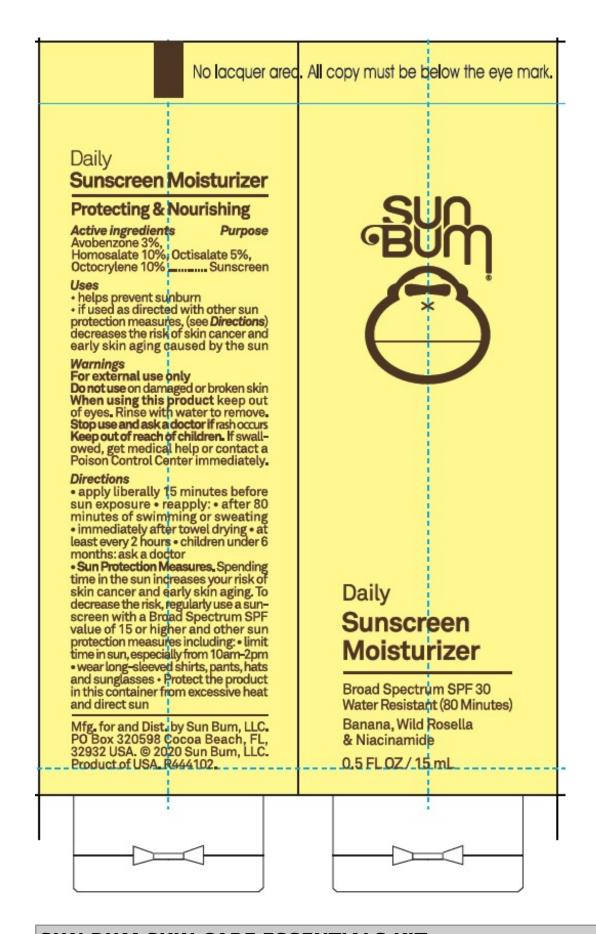






Mfg. for and Dist. by Sun Burn, LLC. PO Box 320598 Cocoa Beach, FL, 32932 USA. © 2020 Sun Burn, LLC. Product of USA. Bag: Made in China. R444103.





#### SUN BUM SKIN CARE ESSENTIALS KIT

avobenzone, homosalate, octisalate, octocrylene kit

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:69039-645

P	Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date	
1	NDC:69039-645-01	1 in 1 KIT	08/17/2021		

Quant	Quantity of Parts			
Part #	Package Quantity	Total Product Quantity		
Part 1	1 TUBE	15 mL		

# Part 1 of 1

# **DAILY SUNSCREEN MOISTURIZER SPF 30**

avobenzone, homosalate, octisalate, octocrylene lotion

## **Product Information**

Item Code (Source) NDC:69039-646

Route of Administration TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL		
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S)	HOMOSALATE	100 mg in 1 mL		
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL		
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	100 mg in 1 mL		

Inactive Ingredients	
Ingredient Name	Strength
HIBISCUS SABDARIFFA WHOLE (UNII: UH3Z91Y49Y)	
LACTOBACILLUS FERMENTUM (UNII: 2C1F12C6AP)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-6 STEARATE (UNII: ETY9Q81E2T)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CAPRYLOYL GLYCERIN/SEBACIC ACID COPOLYMER (2000 MPA.S) (UNII: N7YC58165T)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
NIACINAMIDE (UNII: 25X5118RD4)	
COCONUT (UNII: 3RT3536DHY)	
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)	
MUSA X PARADISIACA FLOWER (UNII: DG5B0M0NGY)	
BANANA (UNII: 4AJZ4765R9)	

MUSA X PARADISIACA LEAF (UNII: 2UIJ27N6ED)	
BANANA PEEL (UNII: 04CM0T683C)	
LYSOPHOSPHATIDYLCHOLINE, SOYBEAN (UNII: CQD833204Z)	
ERYTHRITOL (UNII: RA96B954X6)	
ANHYDROUS DEXTROSE (UNII: 5SL0G7R0OK)	
GLYCERIN (UNII: PDC6A3C0OX)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
ARACHIDYL GLUCOSIDE (UNII: 6JVW35JOOJ)	
DOCOSANOL (UNII: 9G10E216XY)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
POLYGLYCERYL-6 BEHENATE (UNII: 4T2L7QI313)	
PULLULAN (UNII: 8ZQ0AYU1TT)	
BETASIZOFIRAN (UNII: 2X51AD1X3T)	
TOCOPHEROL (UNII: R0ZB2556P8)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:69039-646- 01	15 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/17/2021	

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OTC monograph not final	part352	08/17/2021	

# **Labeler -** Sun Bum LLC (028642574)

Revised: 8/2021 Sun Bum LLC