

SUN BUM PREMIUM SPF 15 SUNSCREEN TANNING- avobenzone, homosalate, octisalate, octocrylene oil
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 Premium SPF 15 Sunscreen Tanning Oil

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 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 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

mineral oil, aloe barbadensis leaf extract, prunus armeniaca (apricot) kernel oil, simmondsia chinensis (jojoba) seed oil, prunus amygdalus dulcis (sweet almond) oil, helianthus annuus (sunflower) seed oil, cocos nucifera (coconut) oil, linum usitatissimum (linseed) seed oil, persea gratissima (avocado) oil, argania spinosa kernel oil, macadamia ternifolia seed oil, olea europaea (olive) fruit oil, passiflora edulis seed oil, rosa canina fruit oil, camellia oleifera seed oil, theobroma cacao (cocoa) seed butter, camellia sinensis leaf powder, sclerocarya birrea seed oil, hydrogenated vegetable oil, fragrance

Questions?

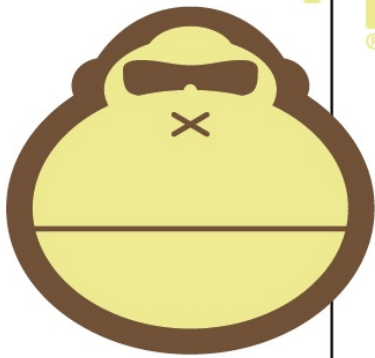
Call 1-877-978-6286

Package Labeling:



Premium Sunscreen Tanning Oil

SUN
BUM



Tanning Oil

15

Broad Spectrum SPF 15
UVA / UVB Protection
Water Resistant (80 Minutes)

Dark Tanning Oil with Marula Oil, Argan Oil,
Coconut Oil, Avocado Oil, Green Tea and Aloe Vera
Dermatologist Tested

8.5 FL OZ / 250 mL

Trust The Bum®

- Paraben Free
- PABA Free
- Gluten Free
- Hypoallergenic
- Phthalate Free
- Cruelty Free
- Oxybenzone Free
- Non-Comedogenic
- Retinyl Palmitate Free

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69039-278
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Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	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
MINERAL OIL (UNII: T5L8T28FGP)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
APRICOT KERNEL OIL (UNII: 54JB35T06A)	
JOJOBA OIL (UNII: 724GKU717M)	
ALMOND OIL (UNII: 66YXD4DKO9)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
COCONUT OIL (UNII: Q9L0O73W7L)	
LINSEED OIL (UNII: 84XB4DV00W)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
ARGAN OIL (UNII: 4V59G5UW9X)	
MACADAMIA OIL (UNII: 515610SU8C)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
PASSIFLORA EDULIS SEED OIL (UNII: F3VOA31UHQ)	
ROSA CANINA FRUIT OIL (UNII: CR7307M3QZ)	
CAMELLIA OIL (UNII: T1PE06G0VE)	
COCOA BUTTER (UNII: 512OYT1CRR)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
SCLEROCARYA BIRREA SEED OIL (UNII: WDO4TLS35F)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69039-278-00	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/01/2019	

