SUN BUM PREMIUM MOISTURIZING SUNSCREEN ROLL ON SPF 50- avobenzone, homosalate, octisalate, octocrylene lotion
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 Moisturizing Sunscreen Roll On Lotion SPF 50

Drug Facts

Active ingredients

Avobenzone 3%, Homosalte 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

• shake well before use • apply liberally and spread by hand15 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

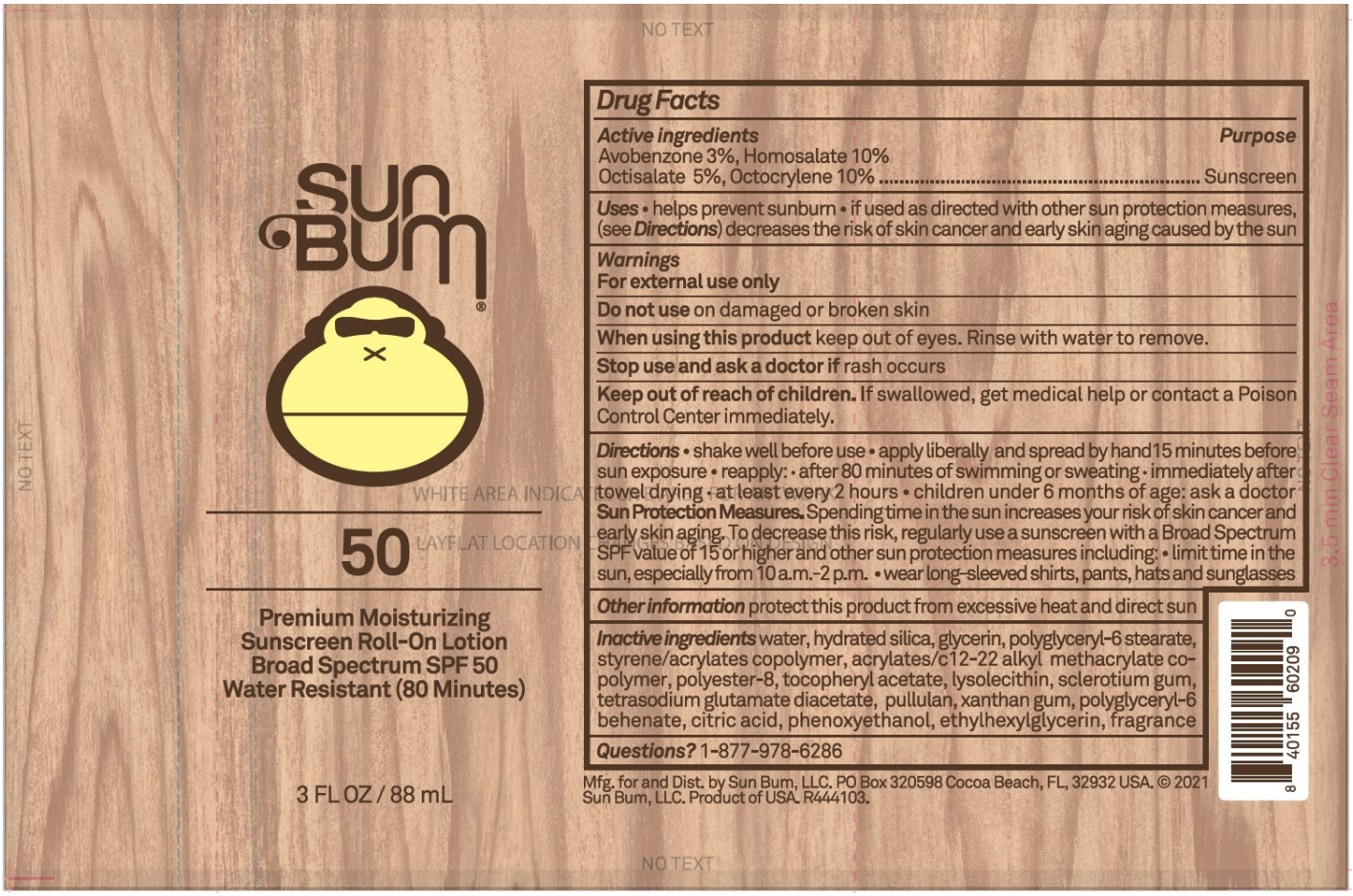
Inactive ingredients

water, hydrated silica, glycerin, polyglyceryl-6 stearate, styrene/acrylates copolymer, acrylates/c 12-22 alkyl methacrylate copolymer, polyster-8, tocopheryl acetate, lysolecithin, sclerotium gum, tetrasodium glutamate diacetate, pullulan, xanthan gum, polyglyceryl-6 behenate, citric acid, phenoxyethanol, ethylhexylglycerin, fragrance

Questions?

1-877-978-6286

Package Labeling:



SUN BUM PREMIUM MOISTURIZING SUNSCREEN ROLL ON SPF 50

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69039-642
Route of Administration	TOPICAL		

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
WATER (UNII: 059QF0KO0R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYGLYCERYL-6 STEARATE (UNII: ETY9Q81E2T)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

LYSOPHOSPHATIDYLCHOLINE, SOYBEAN (UNII: CQD833204Z)	
BETASIZOFIRAN (UNII: 2X51AD1X3T)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
PULLULAN (UNII: 8ZQ0AYU1TT)	
XANTHAN GUM (UNII: TTV12P4NEE)	
POLYGLYCERYL-6 BEHENATE (UNII: 4T2L7QI313)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69039-642-01	88 mL in 1 TUBE; Type 0: Not a Combination Product	01/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/01/2022	

Labeler - Sun Bum LLC (028642574)

Revised: 2/2022 Sun Bum LLC