# KIDS SPF 50 SUNSCREEN- 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.

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#### Kids SPF 50 Sunscreen Lotion

## **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

Flammable: do not use near heat, flame, or while smoking

#### 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 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

alcohol denat. (36.8%), diisopropyl adipate, butyloctyl salicylate, isododecane, trimethylpentanediol/ adipic acid/glycerin crosspolymer, silica, myristyl lactate, hydroxypropylcellulose, fragrance

Questions?

1-877-978-6286

**Package Labeling:** 



#### KIDS SPF 50 SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene lotion

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:69039-660 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			
ALCOHOL (UNII: 3K9958V90M)				
DIISOPROPYL ADIPATE (UNII: P7E6YFV72X)				
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)				
ISODODECANE (UNII: A8289P68Y2)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
MYRISTYL LACTATE (UNII: 1D822OC34X)				
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)				

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:69039-660- 00	177 mL in 1 TUBE; Type 0: Not a Combination Product	10/25/2022	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	10/25/2022		

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

Revised: 10/2022 Sun Bum LLC