# BIG LOTS SOUNDBODY SPF 50 BABY SUNSCREEN- avobenzone, homosalate, octisalate, octocrylene lotion BIG LOTS STORES, INC.

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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## **Big Lots Soundbody SPF 50 Baby Sunscreen Lotion**

## **Active ingredients**

Avobenzone 3.0%, Homosalate 15.0%, Octisalate 5.0%, Octocrylene 5.0%

### **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 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 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 the product in this container from excessive heat and direct sun
- may stain or damage some fabrics, materials or surfaces

# **Inactive ingredients**

water, tridecyl salicylate, propylene glycol, styrene/acrylates copolymer, polyamide-8, neopentyl glycol diheptanoate, oleth-3, acrylates/C10-30 alkyl acrylate crosspolymer, triethanolamine, tocopherol, disodium EDTA, chlorphenesin, benzyl alcohol, fragrance

#### Label



#### Drug Facts

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Inactive ingredients Water, Tridecyl Salicylate, Propylene Glycol Styrene/Acrylates Copolymer, Polyamide-8, Neopentyl Glycal Diheplancate, Oleth-3, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Triethanolamine, Tocogheni, Disodium EDTA, Chlorphenesin, Senzyl Mochol, Fragranca,

Questions or comments? Call 1-800-527-7731

No parabens separately added to preserve this product.

†Formula is compliant with HI SB2571

Manufactured for Big Lots Stores, Inc., By: Fruit of the Earth, Inc.; Grand Prairie, TX 75050 V#5005299 ITEM#BIG24415





#### **BROAD SPECTRUM SPF 50 UVA/UVB** protection

- Sweat and Wate



8 FL OZ (237 mL)

#### **BIG LOTS SOUNDBODY SPF 50 BABY SUNSCREEN**

avobenzone, homosalate, octisalate, octocrylene lotion

#### **Product Information**

**Product Type HUMAN OTC DRUG** Item Code (Source) NDC:50594-158

**Route of Administration TOPICAL** 

#### **Active Ingredient/Active Moiety Ingredient Name Basis of Strength** Strength OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) **OCTOCRYLENE** 50 mg in 1 mL OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) **OCTISALATE** 50 mg in 1 mL **HOMOSALATE** (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S) **HOMOSALATE** 150 mg in 1 mL AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) **AVOBENZ ONE** 30 mg in 1 mL

#### **Inactive Ingredients**

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
CHLORPHENESIN (UNII: 1670DAL4SZ)	
.ALPHATOCOPHEROL, DL- (UNII: 7QWA1RIO01)	
OLETH-3 (UNII: BQZ26235UC)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
WATER (UNII: 059QF0KO0R)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
TRIDECYL SALICYLATE (UNII: AZ Q08K38Z1)	
TROLAMINE (UNII: 903K93S3TK)	
POLYAMIDE-8 (4500 MW) (UNII: 77723GV81A)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
<b>BUTYL METHACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID/STYRENE CROSSPOLYMER</b> (UNII: V5RS026Q0H)	

l	P	ackaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
	1	NDC:50594-158- 11	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/07/2020			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	12/07/2020		

# Labeler - BIG LOTS STORES, INC. (017885351)

Revised: 2/2023 BIG LOTS STORES, INC.