

**BIG LOTS SOUNDBODY SPF 50 ULTRA SHIELD 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.

Big Lots Soundbody SPF 50 Ultra Shield Sunscreen Lotion

Active ingredients

Avobenzone 3.0%

Homosalate 15.0%

Octisalate 5.0%

Octocrylene 7.0%

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, sorbitol, stearic acid, aluminum starch octenylsuccinate, triethanolamine, polyethyloxazoline, carbomer, dimethicone, tocopherol, disodium EDTA, polyglyceryl-3 distearate, caprylyl glycol, phenoxyethanol, ethylhexyl glycerin, sorbitan isostearate, benzyl alcohol, fragrance

Label



Sound Body™ Ultra Shield Sunscreen Lotion SPF 50 provides hypoallergenic, non-comedogenic broad spectrum protection against the sun's harmful UVA/UVB rays. This water-resistant, non-greasy formula absorbs quickly. Great for those on-the-go, anytime, anywhere.

Drug Facts	
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Questions or comments?	
Call toll free 1-877-485-0385	

*This product is not manufactured or distributed by BAYER HEALTHCARE, LLC, owner of the registered trademarks Coppertone® and Coppertone Sport®.

**No parabens separately added to preserve this product.

†Formula is compliant with HI SB2571

Manufactured for Big Lots Stores, Inc.

By: FOTE Fruit of the Earth, Inc., Grand Prairie, TX 75050

V#5005299 ITEM#BIG24405



50^{SPF}

ultra shield sunscreen lotion

BROAD SPECTRUM SPF 50
UVA/UVB protection

- Water Resistant (80 minutes)
- Dermatologist Tested
- Paraben Free**
- Non Greasy



8 FL OZ (237 mL)

BIG LOTS SOUNDBODY SPF 50 ULTRA SHIELD SUNSCREEN

avobenzone homosalate octisalate octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50594-157
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	150 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6VM) (OCTOCRYLENE - UNII:5A68WGF6VM)	OCTOCRYLENE	70 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
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WATER (UNII: 059QF0KO0R)
TRIDECYL SALICYLATE (UNII: AZQ08K38Z1)
SORBITOL (UNII: 506T60A25R)
STEARIC ACID (UNII: 4ELV7Z65AP)
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ006294)
POLYETHYLOXAZOLINE (200000 MW) (UNII: I765I75FT2)
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)
DIMETHICONE (UNII: 92RU3N3Y1O)
.ALPHA.-TOCOPHEROL, DL- (UNII: 7QWA1RIO01)
EDETATE DISODIUM (UNII: 7FLD91C86K)
POLYGLYCERYL-3 DISTEARATE (UNII: ZI1LK470XV)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)
BENZYL ALCOHOL (UNII: LKG8494WBH)
TROLAMINE (UNII: 903K93S3TK)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50594-157-11	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/16/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/16/2019	

Labeler - BIG LOTS STORES, INC. (017885351)

Revised: 12/2022

BIG LOTS STORES, INC.