

**BIG LOTS SOUNDBODY SPF 30 ULTRA SPORT SUNSCREEN- avobenzone  
homosalate 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 30 Ultra Sport Sunscreen Lotion**

***Active ingredients***

Avobenzone 1.8%  
Homosalate 7.0%  
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 this product from excessive heat and direct sun
- may stain or damage some fabrics/materials or surfaces

## ***Inactive ingredients***

water, cetearyl alcohol, stearyl alcohol, glycerin, acrylates/C12-22 alkyl methacrylate copolymer, cetyl alcohol, carbomer, ceteth-10 phosphate, dicetyl phosphate, coco-glucoside, xanthan gum, disodium EDTA, methyl dihydroabietate, lauryl PEG-8 dimethicone, phenylisopropyl dimethicone, polyglyceryl-3 stearate/isostearate/dimer dilinoleate crosspolymer, sodium ascorbyl phosphate, tocopheryl acetate, aloe barbadensis leaf juice, phenoxyethanol, triethanolamine, propylene glycol, hydroxyacetophenone

## **Label**



## BIG LOTS SOUNDBODY SPF 30 ULTRA SPORT SUNSCREEN

avobenzone homosalate octocrylene lotion

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:50594-156 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

**Active Ingredient/Active Moiety**

| Ingredient Name   | Basis of Strength | Strength      |
|---|-------------------|---------------|
| <b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)   | AVOBENZONE        | 18 mg in 1 mL |
| <b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)   | HOMOSALATE        | 70 mg in 1 mL |
| <b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE       | 50 mg in 1 mL |

**Inactive Ingredients**

| Ingredient Name  | Strength |
|--|----------|
| <b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)   |          |
| <b>WATER</b> (UNII: 059QF0KO0R)  |          |
| <b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)  |          |
| <b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)  |          |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)   |          |
| <b>BUTYL ACRYLATE/C16-C20 ALKYL METHACRYLATE/METHACRYLIC ACID/METHYL METHACRYLATE COPOLYMER</b> (UNII: 7K68DGG29P) |          |
| <b>CARBOMER 940</b> (UNII: 4Q93RCW27E)   |          |
| <b>CETETH-10 PHOSPHATE</b> (UNII: 4E05O5N49G)  |          |
| <b>DIHEXADECYL PHOSPHATE</b> (UNII: 2V6E5WN99N)  |          |
| <b>COCO GLUCOSIDE</b> (UNII: ICS790225B)   |          |
| <b>XANTHAN GUM</b> (UNII: TTV12P4NEE)  |          |
| <b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)   |          |
| <b>METHYL DIHYDROABIETATE</b> (UNII: 7666FJ0J9F)   |          |
| <b>LAURYL PEG/PPG-18/18 METHICONE</b> (UNII: ZJ5S27D9NX)   |          |
| <b>SODIUM ASCORBYL PHOSPHATE</b> (UNII: 836SJG51DR)  |          |
| <b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)   |          |
| <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)   |          |
| <b>TROLAMINE</b> (UNII: 9O3K93S3TK)  |          |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)   |          |
| <b>HYDROXYACETOPHENONE</b> (UNII: G1L3HT4CMH)  |          |
| <b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)  |          |

**Packaging**

| # | Item Code        | Package Description                                   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:50594-156-11 | 237 mL in 1 BOTTLE; Type 0: Not a Combination Product | 09/19/2019           |                    |

**Marketing Information**

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part352                                  | 09/19/2019           |                    |

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

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BIG LOTS STORES, INC.