

**BANANA BOAT ULTRA DEFENSE SPF 85- avobenzone and homosalate and octocrylene and oxybenzone spray**  
**Accra-Pac, 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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**Banana Boat Ultra Defense SPF 85**

***Drug Facts***

***Active Ingredients***

Avobenzone 0.03mL / 1mL

Homosalate 0.15mL / 1mL

Octocrylene 0.10mL / 1mL

Oxybenzone 0.06mL / 1mL

***Purpose***

Sunscreen

***Use***

helps prevent sunburn

***Warnings***

- **For external use only**
- Do not spray directly into face
- **Flammable:** do not use near heat, flame, or while smoking

***When using this product***

- avoid spraying in eyes. If contact occurs, rinse thoroughly with water.
- do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120°F.

***Stop use and ask a doctor if***

irritation or rash develops

***Keep out of reach of children.***

If swallowed, get medical help or contact a Poison Control Center right away.

***Directions***

- apply generously and evenly to all areas 15 minutes before sun exposure
- spray on hands to apply to face
- use in well-ventilated area
- reapply at frequent intervals and after swimming or towel drying
- ask a doctor before use on children under six months of age

### ***Other Information***

Sun Alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer and other harmful effects of the sun.

- May stain some fabrics.

### ***Inactive Ingredients***

SD Alcohol 40-B, Cyclopentasiloxane, Cyclohexasiloxane, C12-C15 Alkyl Lactate, Trimethylolpropane Tricaprylate/Tricaprate, Dicaprylyl Carbonate, Acrylates/Octylacrylamide Copolymer, Caprylyl Glycol, Dimethyl Capramide, Aloe Barbadensis Leaf Extract, Retinyl Palmitate (Vitamin A), Tocopherol, Fragrance.

### ***Questions or Comments?***

Call 1-800 SafeSun, Mon-Fri

Dist. by:

SUN PHARMACEUTICALS, LLC  
SHELTON, CT 06484

### **PRINCIPAL DISPLAY PANEL**

**CLEAR**

**UltraMist®**

**BANANA**

**BOAT®**

**Ultra**

**Defense™**

**Sheer Protect**

**Continuous Spray Sunscreen**

**SPF/UVB 85**

**with Aloe Vera**

**AvoTriplex™**

**High UVA**

**Long-Lasting Protection**

**Sun-Tested, Sun-Proven™**

**Lightweight & Rub-Free**

**Skin Cancer Foundation Recommended**

**Very Water Resistant**

**6 FL. OZ. (177mL)**



## BANANA BOAT ULTRA DEFENSE SPF 85

avobenzone and homosalate and octocrylene and oxybenzone spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:17630-2015
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.03 mL in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	0.15 mL in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	0.10 mL in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.06 mL in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	

CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17630-2015-1	177 mL in 1 CAN		
2	NDC:17630-2015-2	236 mL in 1 CAN		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	06/01/2009	

**Labeler** - Accra-Pac, Inc. (024213616)

### Establishment

Name	Address	ID/FEI	Business Operations
Accra-Pac, Inc.		024213616	MANUFACTURE

Revised: 3/2010

Accra-Pac, Inc.