

**BANANA BOAT- avobenzene, homosalate, octisalate, octocrylene spray**  
**Edgewell Personal Care Brands 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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**Active Ingredients**

Avobenzene 3%

Homosalate 10%

Octisalate 5%

Octocrylene 6%

**Purpose**

Sunscreen

**Uses**

helps prevent sunburn

**Warnings**

- **For external use only**
- **Flammable:** Do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120°F. Do not use in presence of a flame or spark. Keep away from sources of ignition - No smoking.
- **Intentional misuse** by deliberately concentrating and inhaling the contents can be harmful or fatal.
- **Do not use** on damaged or broken skin

**When using this product**

- keep away from face to avoid breathing it
- 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 product is swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- hold container 4 to 6 inches from the skin to apply
- spray liberally and spread evenly by hand 15 minutes before sun exposure
- **do not spray directly into face.** Spray on hands then apply to face.
- do not apply in windy conditions
- use in well ventilated area
- reapply: after 80 minutes of swimming or sweating • immediately after towel drying • at least every

2 hours

### **Other Information**

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 of 15 or higher and other sun protection measures including:

- limit time in the sun, especially from 10 am - 2 pm
- wear long-sleeve shirts, pants, hats and sunglasses
- May stain some fabrics.

### **Inactive Ingredients**

Isobutane, Water, Isohexadecane, Ethylhexyl Benzoate, Cetyl PEG/PPG-10/1 Dimethicone, Dibutyl Adipate, Lauryl PEG-8 Dimethicone, Ethylhexyl Methoxycrylene, Sodium Chloride, PEG-8, Caprylyl Glycol, Glycerin, Sodium Citrate, PEG-8 Dimethicone, Aloe Barbadensis Leaf Juice, Octyldodecanol, Retinyl Palmitate, Silica, Tocopheryl Acetate, Ascorbic Acid, Sodium Propoxyhydroxypropyl Thiosulfate Silica, Phenoxyethanol, Methylparaben, Butylparaben, Ethylparaben, Isobutylparaben, Propylparaben.

### **Questions or Comments?**

Call 1-800 SafeSun, Mon-Fri

### **Principal Display Panel**

LOTION

UltraMist®

Tear-Free

Sting-Free

BANANA  
BOAT®

KIDS

UVA/UVB PROTECTION

CONTINUOUS SPRAY SUNSCREEN

50+

BROAD SPECTRUM  
SPF 50+

WATER RESISTANT  
(80 MINUTES)

NO ADDED FRAGRANCE

SWIM•SPLASH•SPORT

NET WT.

**LOTION**  
UltraMist®

**55% MORE FAMILY SIZE**

**Tear-Free Sting-Free**

**BANANA BOAT**

**KIDS**

• **UVA/UVB PROTECTION**  
**CONTINUOUS SPRAY SUNSCREEN**

**50+**

**BROAD SPECTRUM SPF 50+**

**WATER RESISTANT (80 MINUTES)**

**NO ADDED FRAGRANCE**

**SWIM • SPLASH • SPORT**

**NET WT 9.5 OZ. (269 g)**

**55% MORE FAMILY SIZE**

**Tear-Free Sting-Free**

Banana Boat® UltraMist® Lotion Spray Sunscreen for Kids SPF 50+ is an ultra-gentle formula that is non-stinging to eyes and is clinically tested to be mild to kids' skin. It protects against sunburn and long-term skin damage by providing broad spectrum UVA/UVB protection. The convenient, one touch spray goes on easily for "struggle-free" application.

- Non-Stinging to Eyes • Alcohol-Free
- Hypoallergenic • Ideal for Pool & Beach

Drug Facts	
<b>Active Ingredients</b>	<b>Purpose</b>
Avobenzone 3.0%, Homosalate 10.0%, Octisalate 5.0%, Octocrylene 6.0%	Sunscreen
<b>Uses</b> ■ helps prevent sunburn ■ if used as directed with other sun protection measures (see <b>Directions</b> ), decreases the risk of skin cancer and early skin aging caused by the sun.	
<b>Warnings</b>	
<b>For external use only.</b>	
Flammable. Contents under pressure. Do not puncture or incinerate container. Do not expose to heat or flame at temperatures above 120°F. Do not use in the presence of a flame or spark. Keep away from sources of ignition—No smoking. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.	
<b>Do not use</b> on damaged or broken skin.	
<b>When using this product</b> ■ Keep away from face to avoid breathing it ■ keep out of eyes. Rinse with water to remove.	
<b>Stop use and ask a doctor</b> if rash occurs.	
<b>Keep out of reach of children.</b> If product is swallowed, get medical help or contact a Poison Control Center right away.	
May stain some fabrics.	
<b>Directions</b> ■ Hold container 4 to 6 inches from the skin to apply ■ spray liberally and spread evenly by hand 15 minutes before sun exposure ■ Do not spray directly into face. Spray on hands then apply to face ■ Do not apply in windy conditions ■ use in well-ventilated area ■ apply ■ after 80 minutes of exercising or sweating ■ immediately after towel drying ■ at least every 2 hours ■ <b>Sun Protection Measures.</b> 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. to 2 p.m. ■ wear long-sleeve shirts, pants, hats, and sunglasses ■ children under 6 months: Ask a doctor	
<b>Inactive Ingredients:</b> Isobutane, Water, butylacrylate, Ethylhexyl Stearate, Cetyl PEGPPS-101 Dimethicone, Dibutyl Adipate, Lauryl PEG-8 Dimethicone, Ethylhexyl Methoxycrylate, Sodium Chloride, PEG-8, Phenoxethanol, Caprylyl Glycol, Glyceryl, Sodium Citrate, Methylparaben, Butylparaben, Ethylparaben, Isobutylparaben, Propylparaben, PEG-8 Dimethicone, Aloe Barbadosis Leaf Juice, Octyldecyl, Retinyl Palmitate, Silica, Tocopheryl Acetate, Ascorbic Acid, Sodium Propoxyhydroxypropyl Thioisolate Silica.	
<b>Other information</b>	
■ protect this product from excessive heat and direct sun	
<b>Questions or comments?</b>	
Call 1-800-SafeSun, Mon-Fri	

Distributed by:  
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## BANANA BOAT

avobenzone, homosalate, octisalate, octocrylene spray

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:63354-0 10

**Route of Administration**

TOPICAL

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 100 g
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	6 g in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>ISOBUTANE</b> (UNII: BXR49TP611)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>ISOHEXADECANE</b> (UNII: 918X10UF1E)	
<b>DIBUTYL ADIPATE</b> (UNII: F4K100DXP3)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>OCTYLDODECANOL</b> (UNII: 461N1O614Y)	
<b>VITAMIN A PALMITATE</b> (UNII: 1D1K0N0VVC)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>METHYL PARABEN</b> (UNII: A2I8C7HI9T)	
<b>ETHYL PARABEN</b> (UNII: 14255EXE39)	
<b>PROPYL PARABEN</b> (UNII: Z8IX2SC1OH)	
<b>BUTYL PARABEN</b> (UNII: 3QPIIU3FV8)	
<b>ISOBUTYL PARABEN</b> (UNII: 0QQJ25X58G)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63354-010-34	177.42 g in 1 CAN; Type 0: Not a Combination Product	01/11/2012	
2	NDC:63354-010-36	236.56 g in 1 CAN; Type 0: Not a Combination Product	01/11/2012	
3	NDC:63354-010-37	269 g in 1 CAN; Type 0: Not a Combination Product	01/11/2012	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/11/2012	

