

BANANA BOAT- avobenzone, homosalate, octisalate, octocrylene spray
Edgewell Personal Care 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.

Drug Facts

Active Ingredients

Avobenzone 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 are

- 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	Purpose
Active Ingredients Avobenzone 3.0%, Homosalate 10.0%, Octisalate 5.0%, Octocrylene 6.0%	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. Flammable: Contents under pressure. Do not puncture or incinerate container. Do not expose to heat or flames 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. 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. May stain some fabrics.	
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 30 minutes of swimming or sweating ■ immediately after towel drying ■ reapply every 2 hours ■ 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-sleeve shirts, pants, hats, and sunglasses ■ children under 6 months: Ask a doctor	
Inactive Ingredients: Isobutane, Water, butylacrylate, Ethylhexyl Benzoate, Cetyl PEG/PPG-10/1 Dimethicone, Dibutyl Adipate, Lauryl PEG-8 Dimethicone, Ethylhexyl Methacrylate, Sodium Chloride, PEG-8, Phenoxethanol, Caprylyl Glycol, Glycerin, Sodium Citrate, Methylparaben, Butylparaben, Ethylparaben, butylparaben, Propylparaben, PEG-8 Dimethicone, Aloe Barbados Leaf Juice, Octyldecylalcohol, Retinyl Palmitate, Silica, Tocopheryl Acetate, Ascorbic Acid, Sodium Propoxyhydroxypropyl Thioureate, Silica.	
Other Information ■ protect this product from excessive heat and direct sun	
Questions or comments? Call 1-800-SafeSun, Mon-Fri	

Distributed by:
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Shelton, CT 06484
www.bananaboat.com
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BANANA BOAT

avobenzone, homosalate, octisalate, octocrylene spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63354-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
ISOBUTANE (UNII: BXR49TP611)	
WATER (UNII: 059QF0KO0R)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
DIBUTYL ADIPATE (UNII: F4K100DXP3)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
OCTYLDOECANOL (UNII: 461N1O614Y)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
ETHYL PARABEN (UNII: 14255EXE39)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
BUTYL PARABEN (UNII: 3QPIU3FV8)	
ISOBUTYL PARABEN (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	

