

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.

Active Ingredients

AVOBENZONE 3%, HOMOSALATE 9%, OCTISALATE 4.5%, OCTOCRYLENE 6%

Purpose

Sunscreen

Uses

Helps prevent sunburn

Warnings

For external use only

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.

Do not use

on damaged or broken skin

When using this product

keep out of eyes. Keep away from face to avoid breathing it. 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 and then apply to face.
•Do not apply in windy conditions •Use in a well-ventilated area •Reapply: •after 80 minutes of swimming or sweating •immediately after towel drying •at least every 2 hours •Children under 6 months: Ask a doctor

Inactive Ingredients

Water, Isobutane, Isohexadecane, Ethylhexyl Benzoate, Cetyl PEG/PPG-10/1 Dimethicone, Lauryl PEG-8 Dimethicone, Myrica Cerifera (Bayberry) Fruit Wax, Ethylhexyl Methoxycrylene, Sodium Chloride, Glycerin, Phenoxyethanol, Caprylyl Glycol, Sodium Citrate.

Other Information

Protect this product from excessive heat and direct sun

Questions or Comments?

Call 1-800-SAFESUN, Mon-Fri

Principal Display Panel

Banana

Boat

simply

protect

Kids

sunscreens lotion spray

50+

25% fewer ingredients*

made without oxybenzone & parabens

no added oils & fragrances

broad spectrum SPF 50+

water resistant (80 minutes)

NEW!

**25% MORE
VALUE SIZE**

**25% MORE
VALUE SIZE**

tear free



**simply
protect™
KIDS**
SUNSCREEN LOTION SPRAY

50+

25% fewer ingredients*
MADE WITHOUT OXYBENZONE & PARABENS
NO ADDED OILS & FRAGRANCES

BROAD SPECTRUM SPF 50+
WATER RESISTANT (80 MINUTES)

NET WT 7.5 OZ. (212 g)

Introducing new **Banana Boat® Simply Protect™ Kids Sunscreen SPF 50+**. It gives you the broad spectrum UVA/UVB sun protection your kids need with 25% fewer ingredients* in a mild formula that goes on quickly and easily so your kids can get straight to the fun.

*by number vs. Banana Boat Kids Sport Lotion Spray Sunscreen SPF 50+

Drug Facts

Active Ingredients
Avobenzone 3.0%, Homosalate 9.0%, Octisalate 4.5%, Octocrylene 6.0% ... 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.

Flammable: Contents under pressure. Do not puncture or incinerate container. Do not expose to heat or store 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.

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May stain some fabrics.

Directions

- Shake well
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- Use in a well-ventilated area
- Reapply: • after 80 minutes of swimming or sweating
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- At least every 2 hours
- Children under 6 months: 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

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Other information

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Questions or comments?
Call 1-800-SafeSun, Mon-Fri

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EDGEWELL PERSONAL CARE
BRANDS, LLC
SHELTON, CT 06484
www.bananaboat.com



Recommended as an effective broad spectrum sunscreen



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NEW!

tear  free



simply
protect™

KiDS

SUNSCREEN LOTION SPRAY

50+

25% fewer ingredients*
MADE WITHOUT OXYBENZONE & PARABENS
NO ADDED OILS & FRAGRANCES

BROAD SPECTRUM SPF 50+
WATER RESISTANT (80 MINUTES)

NET WT 1.8 OZ. (51g)

*by number vs. Banana Boat Kids Sport Spray Sunscreen SPF 50+

Drug Facts

Active Ingredients	Purpose
Avobenzene 3.0%, Homosalate 9.0%	Sunscreen
Octisalate 4.5%, Octocrylene 6.0%	

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Recommended as an effective broad spectrum sunscreen
DOT 20 M6655 93022870



NEW!

tear free



simply protect™

KIDS

SUNSCREEN LOTION SPRAY

50+

25% fewer ingredients*

MADE WITHOUT OXYBENZONE & PARABENS
NO ADDED OILS & FRAGRANCES

BROAD SPECTRUM SPF 50+
WATER RESISTANT (80 MINUTES)

NET WT 6 OZ. (170 g)

Introducing new **Banana Boat® Simply Protect™ Kids Sunscreen SPF 50+**. It gives you the broad spectrum UVA/UVB sun protection your kids need with 25% fewer ingredients* in a mild formula that goes on quickly and easily so your kids can get straight to the fun.

*by number vs. Banana Boat Kids Sport Lotion Spray Sunscreen SPF 50+

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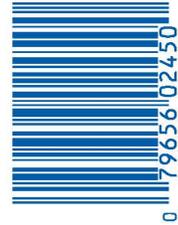


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DOT 20 M5655



Recommended as an effective broad spectrum sunscreen



9302666

OVER 55% MORE
FAMILY SIZE

OVER 55% MORE
FAMILY SIZE

tear free



simply
protect™
KIDS
SUNSCREEN LOTION SPRAY



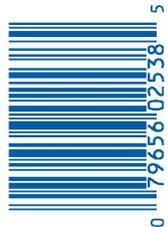
25% fewer ingredients*
MADE WITHOUT OXYBENZONE & PARABENS
NO ADDED OILS & FRAGRANCES

BROAD SPECTRUM SPF 50+
WATER RESISTANT (80 MINUTES)

NET WT 9.5 OZ. (269g)

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BANANA BOAT

avobenzone, homosalate, octisalate, octocrylene spray

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:63354-925

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	6 g in 100 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	9 g in 100 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
MORELLA CERIFERA FRUIT WAX (UNII: L41B20QT0M)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
ISOBUTANE (UNII: BXR49TP611)	
ETHYLHEXYL METHOXYCRYLENE (UNII: S3KFG6Q5X8)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
WATER (UNII: 059QF0KO0R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
2-ETHYLHEXYL BENZOATE (UNII: R63ZWW1A13)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63354-925-34	170 g in 1 CAN; Type 0: Not a Combination Product	01/02/2018	
2	NDC:63354-925-31	51 g in 1 CAN; Type 0: Not a Combination Product	01/02/2018	
3	NDC:63354-925-37	269 g in 1 CAN; Type 0: Not a Combination Product	01/02/2018	
4	NDC:63354-925-36	212 g in 1 CAN; Type 0: Not a Combination Product	04/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/02/2018	

Labeler - Edgewell Personal Care Brands LLC (151179769)

Establishment

Name	Address	ID/FEI	Business Operations
KIK Custom Product		243547333	manufacture(63354-925)