BANANA BOAT- avobenzone, 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 Ingredient

Avobenzone 3%, Homosalate 9%, Octisalate 4.5%, Octocrylene 6%

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.

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

Shake well. 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. **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

Inactive Ingredients

Water, Isobutane, Isohexadecane, C12-15 Alkyl 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

BANANA

BOAT

Simply

Protect

KIDS

SUNSCREEN LOTION SPRAY

UVA/UVB BROAD SPECTRUM SPF 50+

50+

25% FEWER INGREDIENTS

MADE WITHOUT OXYBENZONE & PARABENS

tear free

No Added Oils & Fragrances

Water Resistant

(80 Minutes)

SHAKE WELL BEFORE USE







25% FEWER INGREDIENTS*

MADE WITHOUT OXYBENZONE & PARABENS

tear free

No Added Oils & Fragrances

Water Resistant (80 Minutes)

SHAKE WELL BEFORE USE

NET WT 9.5 OZ. (269 g)

SUN SAFETY DIRECTIONS







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

About 4 applications per 170g can

Drug Facts

Active Ingredients

Active Ingresseries
Avaberzone 3,0%, Homosalate 9,0%
Octisalate 4,5%, Octoorylene 6,0%
Sunscreen

Purpose

USES II helps prevent surburn III 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

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 dector if rash occurs.

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May stain some fabrics.

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Directions

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Increating Increations: Water Reductors Inchesseserne, CI2-15 Akril Benzoste,

Inactive Ingredients: Water, Isobutane, Isoberadecane, C12-15 Alkyl Benzoste, Cetyl PEG-PD-101 Dimetricone, Lauryl PEG-B Dimetricone, Myrica Cerriera (Bayberry) Fruit Wax, Ethylhecyl Methosycrylene, Sodium Chloride, Glycarin, Phenosyethanol, Caprylyl Glycol, Sodium Chrote.

Other Information

protect this product from excessive heat

Questions or comments? Call 1400-SafeSur, Mon-Fri

Distributed by: EDGEWELL PERSONAL CARE BRANDS, LLC Shelton, CT 06484 www.bungnaboot.com 2018 Edgewell.

Edgewell* 93027834

DOT 29 M5655



SUNSCREM LOTION SPRAY
UVA/UVB BROAD SPECTRUM SPF 50+



25% FEWER INGREDIENTS*

MADE WITHOUT OXYBENZONE & PARABENS

tear free

No Added Oils & Fragrances

Water Resistant (80 Minutes)

SHAKE WELL BEFORE USE

NET WT 6 OZ. (170 g)

SUN SAFETY DIRECTIONS

SHAKE WELL BEFORE USE





15 min





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

About 4 applications per 170g can

Drug Facts

Active Ingredients Purpose
Avobenzone 3.0%, Homosalate 9.0%
Octisalate 4.5%, Octoorylene 6.0%. Sunscreen

Uses II helps prevent sunburn III 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

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Inactive Ingredients: Water, Isobutane, Isohexadecane, C12-15 Aleyl Benzaste, Catyl PEG-PDG-101 Dimethicone, Lauryl PEG-8 Dimethicone, Myrica Cerifera (Bayberryl Fruit Wax, Ethylhexyl Methoxycryfene, Sodium Chloride, Glycerin, Phenoxyethanol, Caprylyl Glycol, Sodium Citrate.

Other Information protect this product from excessive heat and direct sun

Questions or comments? Cal 1-900-SafeSun, Mon-Fri

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Edgewell 93027652

DOT 29 M5655





*by number vs. Banana Boat Kids Sport Sunscreen Lotion Spray SPF 50+ SHAKE WELL BEFORE USE

Drug Facts

Active Ingredients

Purpose

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

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■ Shake well ■ 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 ■ 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

Inactive Ingredients Water, Isobutane, Isohexadecane, C12-15 Alkyl 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

Distributed by: EDGEWELL PERSONAL CARE BRANDS, LLC SHELTON, CT 06484

www.bananaboat.com



DOT 20 M5655 93027633

BANANA BOAT

avobenzone, homosalate, octisalate, octocrylene spray

Product Information

HUMAN OTC DRUG NDC:63354-039 **Product Type** Item Code (Source)

TOPICAL Route of Administration

Active Ingredient/Active Moiety

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

| Inactive Ingredients | |
|-----------------------------------------------------------|----------|
| Ingredient Name | Strength |
| MORELLA CERIFERA FRUIT WAX (UNII: L41B20QT0M) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| SODIUM CITRATE (UNII: 1Q73Q2JULR) | |
| WATER (UNII: 059QF0KO0R) | |
| ISOBUTANE (UNII: BXR49TP611) | |
| ETHYLHEXYL METHOXYCRYLENE (UNII: S3KFG6Q5X8) | |
| ISOHEXADECANE (UNII: 918X1OUF1E) | |
| ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ) | |
| CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | |

| Packaging | | | | | |
|-----------|----------------------|---------------------------------------------------|-------------------------|-----------------------|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 | NDC:63354-039- 31 | 51 g in 1 CAN; Type 0: Not a Combination Product | 10/15/2018 | | |
| 2 | NDC:63354-039- 34 | 170 g in 1 CAN; Type 0: Not a Combination Product | 10/15/2018 | | |
| 3 | NDC:63354-039- 37 | 269 g in 1 CAN; Type 0: Not a Combination Product | 10/15/2018 | | |

| Marketing Information | | | | |
|-------------------------|---------------------------------------------|-------------------------|-----------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph not final | part352 | 10/15/2018 | | |
| | | | | |

Labeler - Edgewell Personal Care Brands, LLC (151179769)