

**COPPERSTONE WATER BABIES PURE AND SIMPLE WHIPPED SUNSCREEN
BROAD SPECTRUM SPF 50 SPF 50- avobenzone, homosalate, octisalate,
octocrylene, oxybenzone lotion
Formulated Solutions, LLC**

**Copperstone Water Babies Pure and Simple Whipped Sunscreen Broad
Spectrum SPF 50**

Drug Facts

Active ingredients

(To Deliver) Avobenzone 3%, Homosalate 10%, Octisalate 4.5%,
Octocrylene 4%, Oxybenzone 6%

Purpose

Sunscreen

Uses

- helps prevent sunburn
- if used as directed with other sun protection increases (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings

For external use only

Do not use on

damaged or broken skin

When using this product

- keep out of eyes. Rinse with water to remove.
- use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.
- do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120°F.

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

- apply liberally 15 minutes before sun exposure
- do not dispense or apply directly on face. Dispense into hands and apply to face
- use in well-ventillated areas
- reapply:
- after 80 minutes if swimming or sweating
- imediately after towel drying
- at least 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

Other Information

- protect this product from excessive heat and direct sun
- avoid long term storage above 40°C (104°F)
- may stain or damage some fabrics or surfaces

Inactive ingredients

Water, Aluminum Starch Octenylsuccinate, Behenyl Alcohol, Glycerin, Styrene/Acrylates Copolymer, Dicaprylyl Ether, Microcrystalline Cellulose, Glyceryl Stearate, Cetyl Alcohol, Benzyl Alcohol, Butylated PVP, Palmitic Acid, Stearic Acid, Myristyl Alcohol, Chlorphenesin, Tocopherol (Vitamin E), Cellulose Gum, Lecithin, Disodium EDTA, Lauryl Alcohol, Sodium Ascorbyl Phosphate, Fragrance, Nitrous Oxide.

Questions?

1-866-288-330

Package Labeling:

NEW!

Coppertone®
water
BABIES®

pure & simple

Whipped

SUNSCREEN

50

BROAD SPECTRUM SPF 50

Free of:
Fragrances,
Parabens & PABA

Water Resistant (80 Minutes)

#1 Pediatrician
Recommended Brand



5 OZ (142 g)

Coppertone® Water Babies® Pure & Simple Whipped Sunscreen offers broad spectrum protection in a gentle formula that spreads easily onto baby's delicate skin. Fragrance Free, Paraben Free, PABA Free, Dye Free, Oil Free. Trusted Coppertone® protection.

Drug Facts

Active ingredients

(To Deliver) Avobenzone 3%, Homosalate 10%, Octocrylene 4%, Oxybenzone 6%

Purpose

Octisalate 4.5%, 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

Do not use on damaged or broken skin

When using this product

■ keep out of eyes. Rinse with water to remove
■ use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.
■ do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120°F.

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

■ apply liberally 15 minutes before sun exposure ■ do not dispense or apply directly on face. Dispense into hands and apply to face ■ use in well-ventilated areas ■ reapply: ■ after 80 minutes of swimming or sweating ■ immediately after towel drying ■ at least 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

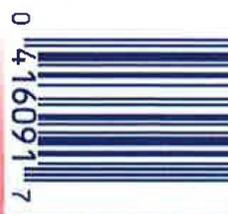
Other information

■ protect this product from excessive heat and direct sun
■ avoid long term storage above 40°C (104°F)
■ may stain or damage some fabrics or surfaces

Inactive ingredients

Water, Aluminum Starch Octenylsuccinate, Behenyl Alcohol, Glycerin, Styrene/Acrylates Copolymer, Dicaprylyl Ether, Microcrystalline Cellulose, Glyceryl Stearate, Cetyl Alcohol, Benzyl Alcohol, Butylated PVP, Palmitic Acid, Stearic Acid, Myristyl Alcohol, Chlorphenesin, Tocopherol (Vitamin E), Cellulose Gum, Lecithin, Disodium EDTA, Lauryl Alcohol, Sodium Ascorbyl Phosphate, Nitrous Oxide.

Questions? 1-866-288-3330



DOT-2P MS655/DOT-SP14/29

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C5324

Bayer



COPPERSTONE WATER BABIES PURE AND SIMPLE WHIPPED SUNSCREEN BROAD SPECTRUM SPF 50 SPF 50

avobenzone, homosalate, octisalate, octocrylene, oxybenzone lotion

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:23667-802

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	45 mg in 1 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	40 mg in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	60 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ006294)	
WATER (UNII: 059QF0KO0R)	
DOCOSANOL (UNII: 9G1OE216XY)	
GLYCERIN (UNII: PDC6A3C00X)	
DICAPRYLYL ETHER (UNII: 77JZM5516Z)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
PALMITIC ACID (UNII: 2V16EO95H1)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
MYRISTYL ALCOHOL (UNII: V42034O9PU)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
TOCOPHEROL (UNII: R0ZB2556P8)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
LAURYL ALCOHOL (UNII: 178A96NLP2)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
NITROUS OXIDE (UNII: K50XQU1029)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:23667-802-01	142 g in 1 CAN; Type 0: Not a Combination Product	02/09/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	02/09/2017	

Labeler - Formulated Solutions, LLC (143266687)