

**COPPERTONE WATERBABIES SUNSCREEN SPF 50- avobenzene 3%, homosalate 9%, octisalate 4.5%, octocrylene 9% aerosol, spray
Beiersdorf Inc**

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.

Coppertone Waterbabies Lotion Spray SPF 50

Drug Facts

Active ingredients

(To Deliver) Avobenzene 3%, Homosalate 9%, Octisalate 4.5%, Octocrylene 9%

Purpose

Sunscreen

Use

- helps prevent sunburn

Warnings

For external use only

Flammable: Do not use near heat, flame, or while smoking

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.
- 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

- shake well before each use

- spray liberally and spread evenly by hand 15 minutes before sun exposure
- hold container 4 to 6 inches from the skin to apply
- do not spray directly into face. Spray on hands 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

■ **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
- store between 20° to 25°C (68° to 77°F)
- may stain or damage some fabrics or surfaces

Inactive ingredients

water, dimethyl ether, aloe barbadensis leaf juice, C12-15 alkyl benzoate, neopentyl glycol diheptanoate, butylene glycol, styrene/acrylates copolymer, VP/eicosene copolymer, 1,2-hexanediol, hydroxyacetophenone, fragrance, tocopherol, acrylates/C10-30 alkyl acrylate crosspolymer, potassium hydroxide, disodium EDTA

Questions?

1-866-288-3330

Coppertone® Sunscreen Lotion Spray

#1 Pediatrician Recommended Sunscreen Brand

water babies

50

Hypoallergenic

With Aloe and Nourishing Vitamin E

Free of Oxybenzone, Octinoxate, Dyes & PABA

Water Resistant (80 Minutes)

Broad Spectrum SPF 50

Coppertone[®]
SUNSCREEN LOTION SPRAY



**water
babies**

50

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WITH ALOE AND
NOURISHING VITAMIN E**

Free of Oxybenzone,
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Water Resistant (80 Minutes)
Broad Spectrum SPF 50

NET WT 6 OZ (170 g)

Broad Spectrum UVA/UVB protection that is specially formulated to be gentle on baby's delicate skin. #1 Pediatrician Recommended Sunscreen Brand
• Dermatologist Tested

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www.coppertone.com



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Beiersdorf

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COPPERTONE WATERBABIES SUNSCREEN SPF 50

avobenzone 3%, homosalate 9%, octisalate 4.5%, octocrylene 9% aerosol, spray

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:66800-4232

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	9 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
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
STYRENE/ACRYLAMIDE COPOLYMER (MW 500000) (UNII: 5Z4DPO246A)	
DISODIUM EDTA-COPPER (UNII: 6V475AX06U)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
WATER (UNII: 059QF0KO0R)	
DIMETHYL ETHER (UNII: AM13FS69BX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKWBC543X)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
CARBOMER INTERPOLYMER TYPE C (ALLYL SUCROSE CROSSLINKED) (UNII: U990QE4LKP)	
TOCOPHEROL (UNII: R0ZB2556P8)	
VINYLPYRROLIDONE/EICOSENE COPOLYMER (UNII: 035MV9S1C3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66800-4232-6	170 g in 1 CAN; Type 0: Not a Combination Product	11/01/2021	
2	NDC:66800-4232-9	269 g in 1 CAN; Type 0: Not a Combination Product	11/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/01/2021	

Labeler - Beiersdorf Inc (001177906)