

**COPPERTONE WATERBABIES SUNSCREEN SPF 50- avobenzene 3%,
homosalate 9%, octisalate 4.5%, octocrylene 9% lotion
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 SPF 50

Drug Facts

Active ingredients

Avobenzene 3%, Homosalate 9%, Octisalate 4.5%, Octocrylene 9%

Purpose

Sunscreen

Use

- helps prevent sunburn

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.

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

- 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
- may stain or damage some fabrics or surfaces

Inactive ingredients

water, aloe barbadensis leaf juice, C12-15 alkyl benzoate, neopentyl glycol diheptanoate, styrene/acrylates copolymer, butylene glycol,

VP/Eicosene copolymer, 1,2-hexanediol, hydroxyacetophenone, fragrance, tocopherol, acrylates/C10-30 alkyl acrylate crosspolymer, potassium hydroxide, disodium EDTA, sodium ascorbyl phosphate

Questions?

1-866-288-3330

#1 Pediatrician Recommended Brand

Coppertone Sunscreen Lotion

waterbabies

Fragrance Free

Hypoallergenic

Enriched with Vitamin E

50

Free Of oxybenzone, octinoxate, dyes & PABA

Water Resistant (80 Minutes)

Broad Spectrum SPF 50



COPPERTONE WATERBABIES SUNSCREEN SPF 50

avobenzone 3%, homosalate 9%, octisalate 4.5%, octocrylene 9% lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66800-4109
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	9 g in 100 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKWBC543X)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	

EICOSYL POVIDONE (UNII: XQQ9MKE2B)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
TOCOPHEROL (UNII: R0ZB2556P8)	
STYRENE/ACRYLAMIDE COPOLYMER (MW 500000) (UNII: 5Z4DPO246A)	
DISODIUM EDTA-COPPER (UNII: 6V475AX06U)	
FRAGRANCE CLEAN ORC0600327 (UNII: 329LCV5BTF)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
BUTYLENE GLYCOL (UNII: 3XUS85KORA)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	

Product Characteristics

Color	white (white to off-white)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66800-4109-1	30 g in 1 TUBE; Type 0: Not a Combination Product	11/02/2020	
2	NDC:66800-4109-2	59 g in 1 TUBE; Type 0: Not a Combination Product	11/02/2020	
3	NDC:66800-4109-3	88 g in 1 TUBE; Type 0: Not a Combination Product	11/02/2020	
4	NDC:66800-4109-6	177 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/02/2020	
5	NDC:66800-4109-8	237 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/02/2020	
6	NDC:66800-4109-0	296 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/02/2020	
7	NDC:66800-4109-9	315 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/02/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/02/2020	

Labeler - Beiersdorf Inc (001177906)