

**BROAD SPECTRUM SPF 50 BABY SUNSCREEN PREFERRED PLUS PHARMACY-
avobenzone, homosalate, octisalate, octocrylene, oxybenzone lotion
Kinray 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.

Drug Facts

Active ingredients

Avobenzone 3.0%, Homosalate 13.0%, Octisalate 5.0%, Octocrylene 7.0%, Oxybenzone 4.0%

Uses

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.

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 of 15 or higher and other sun protection measures including: limit time in the sun, specially from 10am - 2pm, wear long-sleeve shirts, pants, hats, and sunglasses.

Children under 6 months: ask a doctor.

Inactive ingredients

Aluminum Starch Octenylsuccinate, Benzyl Alcohol, Carbomer, Dimethicone, Disodium EDTA, Fragrance, Methylparaben, Polyglyceryl-3 Distearate, Propylparaben, Sorbitan Isostearate, Sorbitol, Stearic Acid, Tocopherol, Triethanolamine, VP/Eicosene Copolymer, Water.

Purpose

Sunscreen.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Preferred Plus Pharmacy

Broad Spectrum SPF 50

Baby Sunscreen Lotion

Water Resistant (80 Minutes)



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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61715-027
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL

HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	13 g in 100 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 g in 100 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	7 g in 100 mL
OXYBENZONE (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y)	OXYBENZONE	4 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
POLYGLYCERYL-3 DISTEARATE (UNII: Z11LK470XV)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
SORBITOL (UNII: 506T60A25R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TOCOPHEROL (UNII: R0ZB2556P8)	
TRIETHANOLAMINE BENZOATE (UNII: M3EN4GC19W)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61715-027-08	237 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/15/2013	

Labeler - Kinray Inc. (012574513)