## COPPERTONE PURE AND SIMPLE BABY SPF 50- zinc oxide stick Bayer HealthCare 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.

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#### Coppertone Pure & Simple Baby SPF 50 Stick UI 1614115

#### **Drug Facts**

#### Active ingredients

Zinc Oxide 20%

#### **Purpose**

Sunscreen

#### Uses

#### 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

Stop use and ask a doctor if rash occurs

**When using this product** keep out of eyes. Rinse with water to remove.

**Keep out of reach of children.** If product is swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

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- 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

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- protect this product from excessive heat and direct sun
- may stain or damage some fabrics or surfaces

*Inactive ingredients* cocos nucifera (coconut) oil, behenyl behenate, helianthus annuus (sunflower) seed oil, theobroma cacao (cocoa) seed butter, polyhydroxystearic acid, ricinus communis (castor) seed oil, squalane, helianthus annuus (sunflower) seed wax, butyrospermum parkii (shea butter), euphorbia cerifera (candelilla) wax, tocopherol, caprylic/capric triglyceride, simmondsia chinensis (jojoba) seed oil, aloe barbadensis leaf extract

**Questions?** 1-866-288-3330

#### Package label

New

Formula

#1 Pediatrician

Recommended Brand

Coppertone®

SUNSCREEN STICK

Pure

& Simple

baby + cocoa butter

50

Hypoallergenic & genlte

No PABA, Parabens,

Phthalates, Fragrances,

Dyes, Oxybenzone

Water Resistant

(80 Minutes)

**Broad Spectrum** 

**SPF 50** 





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Bayer

#### **COPPERTONE PURE AND SIMPLE BABY SPF 50**

zinc oxide stick

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Product	Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:11523-7475

Route of Administration TOPICAL

# Active Ingredient/Active Moiety Ingredient Name Basis of Strength ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) ZINC OXIDE (200 mg in 1 g

Inactive Ingredients		
Ingredient Name	Strength	
SHEA BUTTER (UNII: K49 155WL9 Y)		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
TOCOPHEROL (UNII: R0ZB2556P8)		
COCONUT OIL (UNII: Q9L0O73W7L)		
BEHENYL BEHENATE (UNII: K8NU647RJ0)		
COCOA BUTTER (UNII: 512OYT1CRR)		
SUNFLOWER OIL (UNII: 3W1JG795YI)		
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)		
CASTOR OIL (UNII: D5340 Y2I9 G)		
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)		
CANDELILLA WAX (UNII: WL0328 HX19)		
JOJOBA OIL (UNII: 724GKU717M)		
SQUALANE (UNII: GW89575KF9)		
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)		

Product Characteristics		
Color	white (off white to light yellow)	Score
Shape		Size
Flavor		Imprint Code
Contains		

ı	P	ackaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:11523-7475-1	13.9 g in 1 BLISTER PACK; Type 0: Not a Combination Product	11/0 1/20 19	09/01/2021

Marketing Information				
	Marketing Category	Application Number or Managraph Citation	Marketing Start Date	Marketing End Da

OTC monograph not final	part352	11/0 1/20 19	09/01/2021

## Labeler - Bayer HealthCare LLC. (112117283)

Revised: 12/2019 Bayer HealthCare LLC.