# BABY SUNSCREEN SPF 30- zinc oxide lotion SEVENTH GENERATION 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.

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#### **BABY SUNSCREEN**

ZINC OXIDE 20%

**SUNSCREEN** 

Other Information

• protect the product in this container from excessive heat and direct 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.

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-sleeved shirts, pants, hats, and sunglasses
- CHILDREN UNDER 6 MONTHS OF AGE: ASK A DOCTOR

Inactive ingredients Aloe barbadensis leaf juice, anthemis nobilis flower oil, caprylic/capric triglycerides, helianthus annuus seed oil, hydrogenated methyl abietate, lavandula angustifolia flower oil, magnesium sulfate, olea europaea fruit oil, polyaminopropyl biguanide, polyglycerol-10 laurate, ricinus communis seed oil, simmondsia chinensis seed oil, sorbitan stearate, tocopherol, water.

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SEVENTH GENERATION

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BABY SUNSCREEN BROAD SPECTRUM SPF 30



### **DRUG FACTS**

## Active ingredient

Zinc Oxide 20%

Purpose

Sunscreen

Uses

· helps prevent sunburn

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MADE IN USA/MANUFACTURED FOR: SEVENTH GENERATION, INC., BURLINGTON, YT 05401 1-800-456-1191



#### **BABY SUNSCREEN SPF 30**

zinc oxide lotion

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:42263-101

Route of Administration TOPICAL

#### **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	20 g in 100 g

#### **Inactive Ingredients**

Ingredient Name	Strength
ALOE (UNII: V5VD430 YW9)	
CHAMAEMELUM NOBILE FLOWER OIL (UNII: UB27587839)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
LAVENDER O IL (UNII: ZBP1YXW0H8)	
MAGNESIUM SULFATE (UNII: DE08037SAB)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
POLYAMINO PRO PYL BIGUANIDE (UNII: 322U039 GMF)	
POLYGLYCERYL-10 OLEATE (UNII: 55C81W76DH)	
CASTOR OIL (UNII: D5340 Y2I9 G)	
JOJOBA OIL (UNII: 724GKU717M)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0 H58 X)	
TOCOPHEROL (UNII: R0ZB2556P8)	
WATER (UNII: 059QF0KO0R)	

Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:42263-101-13	85 g in 1 TUBE				

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph final	part352	12/30/2011				

# Labeler - SEVENTH GENERATION INC (178161212)

# **Registrant** - SEVENTH GENERATION INC (178161212)

Revised: 3/2012 SEVENTHGENERATION INC