

**SPF30 CALENDULA SUNSCREEN- titanium dioxide lotion**  
**ORGANIC & SUSTAINABLE BEAUTY**

*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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**SPF30 CALENDULA™ SUNSCREEN LOTION**

***Drug Facts***

**Active ingredient**

Titanium Dioxide 12%

**Purpose**

Sunscreen

**Uses**

Helps prevent sunburn

- higher SPF gives more sunburn protection
- retains SPF after 80 minutes of activity in the water

**Warnings**

**For external use only**

**Do not use:** on damaged or broken skin.

**Stop use and ask a doctor if**

- rash or irritation develops and lasts.

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

**Keep out of reach of children.** If 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
- Children under 6 months of age: ask a doctor
- **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

### **Other information**

Protect the product in this container from excessive heat and direct sunlight. Report serious adverse reactions to: 5933 Bowcroft St. Los Angeles, CA 90016

### **Inactive ingredients**

Water, calendula officinalis extract (calendula), isoamyl laurate, coco-caprylate, viola tricolor extract (pansy), polyglyceryl-2 dipolyhydroxystearate, euphorbia cerifera (candelilla) wax, glyceryl starch, carthamus tinctorius (safflower) oleosomes, polyglyceryl-3 diisostearate, levulinic acid, glycerin, tapioca starch, rosmarinus officinalis (rosemary) leaf extract, cocos nucifera (coconut) oil, squalane, magnesium stearate, p-anisic acid, lavandula angustifolia (lavender) oil, salvia sclarea (clary) oil, allantoin, panthenol.

### **PRINCIPAL DISPLAY PANEL - 82 g Tube Label**

CALIF♥RNIA BABY®  
TRUSTED SINCE 1995

calendula™

30+

SUNSCREEN LOTION

HIGH PROTECTION

SUPER GENTLE & SOOTHING

BROAD SPECTRUM

SPF 30+ SUNSCREEN

WATER RESISTANT (80 MINUTES)

FOR BABIES, KIDS + ADULTS

WITH SENSITIVE SKIN

ALLERGY

TESTED

© 2018

NET WT 82 g/2.9 oz.

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CALIFORNIA NATURAL LIVING, INC.  
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Los Angeles, CA 90016  
(310) 815-8201 • www.californiababy.com

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BLENDED, MANUFACTURED & PACKAGED IN OUR FDA REGISTERED & CERTIFIED ORGANIC U.S.A. FACILITY

**CALIFORNIA BABY®**  
TRUSTED SINCE 1995



calendula™

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**SPF30 CALENDULA SUNSCREEN**

titanium dioxide lotion

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:529 15-067
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	120 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0K00R)	
isoamyl laurate (UNII: M1SLX00M3M)	
coco-caprylate (UNII: 4828G836N6)	
calendula officinalis flower (UNII: P0M7O4Y7YD)	
VIOLA TRICOLOR WHOLE (UNII: 9Q24RAI43V)	
polyglyceryl-2 dipolyhydroxystearate (UNII: 9229XJ4V12)	
CANDELILLA WAX (UNII: WL0328HX19)	
STARCH, RICE (UNII: 4DGK8B7I3S)	
CARTHAMUS TINCTORIUS SEED OLEOSOMES (UNII: 9S60Q72309)	
polyglyceryl-3 diisostearate (UNII: 46P231IQV8)	
levulinic acid (UNII: RYX5QG61E1)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
STARCH, TAPIOCA (UNII: 24SC3U704I)	
ROSEMARY (UNII: IJ67X351P9)	
COCONUT OIL (UNII: Q9L0O73W7L)	
squalane (UNII: GW89575KF9)	
magnesium stearate (UNII: 70097M6I30)	
p-anisic acid (UNII: 4SB6Y7DMM3)	
allantoin (UNII: 344S277G0Z)	
CLARY SAGE OIL (UNII: 87L0D4U3M0)	
TEA TREE OIL (UNII: VIF565UC2G)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
GARDENIA TAITENSIS FLOWER (UNII: T0OCU8201Y)	
panthenol (UNII: WV9CM0O67Z)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52915-067-29	82 g in 1 TUBE; Type 0: Not a Combination Product	12/01/2012	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	12/01/2012	

**Labeler** - ORGANIC & SUSTAINABLE BEAUTY (020085717)

Revised: 11/2020

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