

**ECZEMA- oatmeal cream**  
**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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**ECZEMA CREAM**

***Drug Facts***

**Active ingredient**

Colloidal Oatmeal 1%

**Purpose**

Skin Protectant

**Uses**

Temporarily protects & helps relieve minor skin irritation and itching due to:

- Rashes
- Eczema
- Poison ivy, oak, or sumac
- Insect bites

**Warnings**

**For external use only**

**When using this product**

- Do not get into eyes.

**Stop use and ask a doctor if**

- Condition worsens
- Symptoms last more than 7 days or clear up and occur again within a few days

**Keep out of reach of children.** If swallowed, get medical help or contact Poison Control within the U.S. (1-800-222-1222)

**Directions**

Apply liberally onto desired area

- Reapply as needed. Children under 6 months: ask a doctor. Use in combination with our Eczema Shampoo & Bodywash.

**Other information**

You may report a serious adverse reaction event from using this product to: 5933 Bowcroft St. Los Angeles, CA 90016.

**Inactive ingredients**

Water, calendula officinalis flower extract, caprylic/capric triglyceride, cetyl alcohol, stearic acid, cetearyl olivate, sorbitan olivate, canola oil, allantoin, viola tricolor extract, yucca schidigera root extract, aloe barbadensis leaf juice, rosmarinus officinalis leaf extract, lavandula angustifolia (lavender) oil, salvia sclarea (clary) oil, phytic acid, caprylhydroxamic acid, glyceryl caprylate.

**PRINCIPAL DISPLAY PANEL - 133 mL Container Label**

CALIF♥RNIA BABY®  
TRUSTED SINCE 1995

therapeutic relief™

GLUTEN-FREE!  
ECZEMA  
CREAM  
SKIN PROTECTANT

OATMEAL & CALENDULA  
HELPS HEAL & PROTECT DELICATE SKIN  
FOR BABIES, KIDS & SENSITIVE ADULTS

ALLERGY  
TESTED

133 mL/4.5 fl. oz.

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*We've been obsessing for over 20 years (so you don't have to.)*

**PURE ESSENTIAL OILS  
FACE & BODY**

Our certified organic oatmeal is processed in a single-source facility. This means it's not processed on the same equipment that handles raw materials with gluten like wheat, rye or barley so there is no cross-contamination. This super-rich, concentrated, creamy blend of natural emollients relieves skin irritation due to eczema and rashes.

Free of gluten, soy, dairy and nuts (except for coconut). Blended, packaged & manufactured in our FDA registered & certified organic U.S.A. facility.

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California Baby®  
Los Angeles, CA 90016  
www.californiababy.com

UPC/FPO  
792692 33472 2

**CERTIFIED ORGANIC INGREDIENTS:** COLLOIDAL OATMEAL, CANOLA OIL, CALENDULA, VIOLA TRICOLOR EXTRACT AND ALOE BARBADENSIS LEAF JUICE. EMOLLIENTS SOURCED FROM COCONUT OR OLIVE.

## ECZEMA

oatmeal cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:529 15-120
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OATMEAL (UNII: 8 PI54V663Y) (OATMEAL - UNII:8 PI54V663Y)	OATMEAL	10 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0K00R)	
medium-chain triglycerides (UNII: C9H2L21V7U)	
cetyl alcohol (UNII: 936JST6JCN)	
stearic acid (UNII: 4ELV7Z65AP)	
cetearyl olivate (UNII: 58B69Q84JO)	
sorbitan olivate (UNII: MDL271E3GR)	
canola oil (UNII: 331KBJ17RK)	
allantoin (UNII: 344S277G0Z)	
calendula officinalis flower (UNII: P0M7O4Y7YD)	
VIOLA TRICOLOR WHOLE (UNII: 9Q24RAI43V)	
yucca schidigera root (UNII: E2H9ET15AT)	
aloe vera leaf (UNII: ZY8 1Z83H0 X)	
rosemary (UNII: IJ67X351P9)	
lavender oil (UNII: ZBP1YXW0H8)	
clary sage oil (UNII: 87L0D4U3M0)	
phytic acid (UNII: 7IGF0S7R8I)	
caprylhydroxamic acid (UNII: UPY805K99W)	
GLYCERYL MONOCAPRYLATE (UNII: TM2TZD4G4A)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:529 15-120-45	133 mL in 1 CONTAINER; Type 0: Not a Combination Product	12/01/2012	
2	NDC:529 15-120-05	14 mL in 1 TUBE; Type 0: Not a Combination Product	12/01/2012	
3	NDC:529 15-120-02	57 mL in 1 JAR; Type 0: Not a Combination Product	12/01/2012	
4	NDC:529 15-120-19	562 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	12/01/2012	07/31/2017

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part347	12/01/2012	

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

Revised: 11/2020

ORGANIC &amp; SUSTAINABLE BEAUTY