DESERT ESSENCE DONT BE RASH DIAPER CREAM- zinc oxide cream
Autumn Harp, 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.

Desert Essence Dont Be Rash Diaper Cream

Active Ingredient

Zinc Oxide 12%

Purpose:

Skin Protectant

Uses:

• Helps treat and prevent diaper rash

• Helps seal out wetness

• Protects chafed skin due to diaper rash

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 a physician.

Directions for Use:

• Apply to clean, dry skin by massaging a thick layer on baby's bottom.

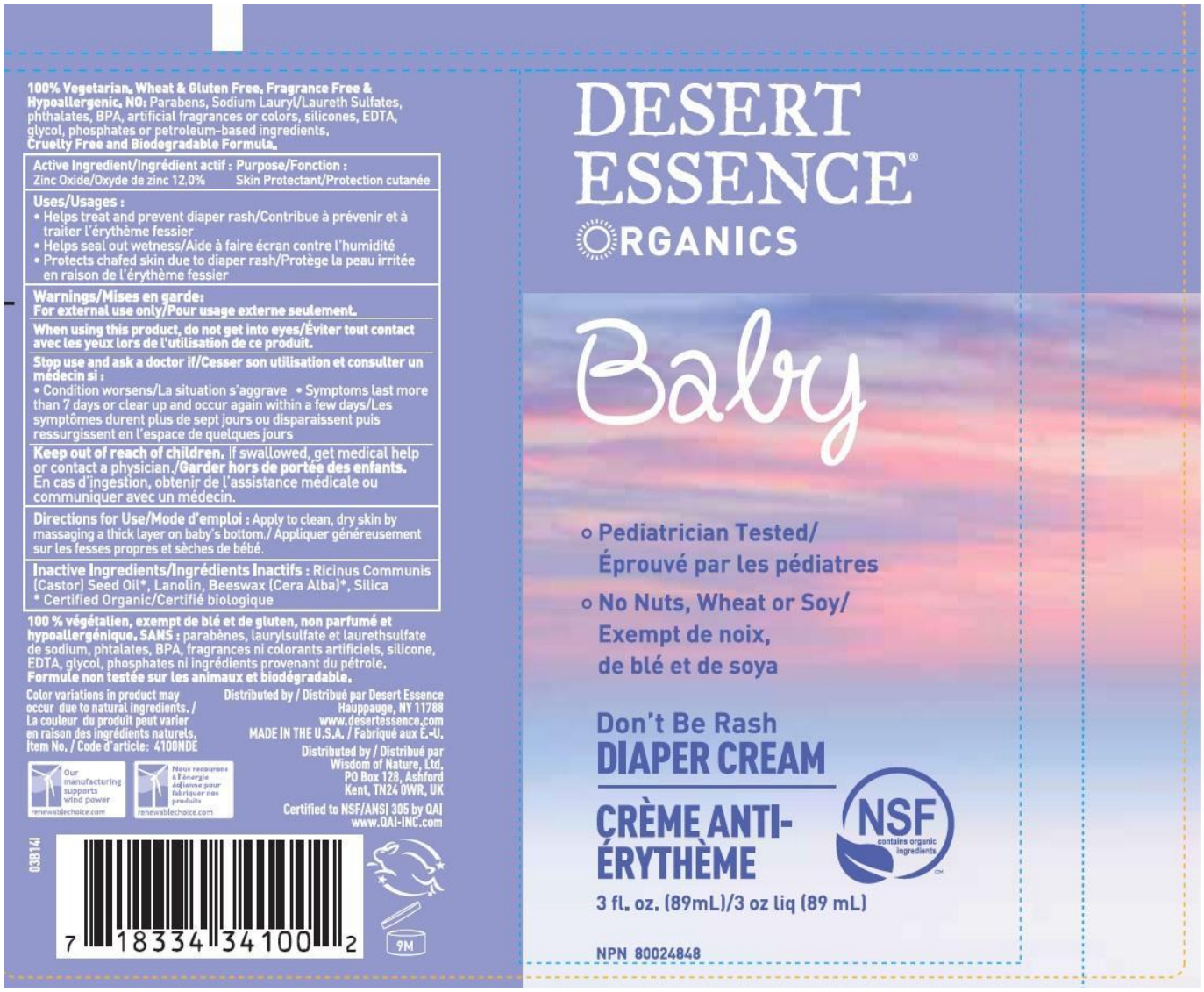
Inactive Ingredients:

Ricinus Communis (Castor) Seed Oil*, Lanolin, Beeswax (Cera Alba)*, Silica

* Certified Organic

Principal Display Panel

Image Components



DESERT ESSENCE DONT BE RASH DIAPER CREAM

zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51514-0338
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	12 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CASTOR OIL (UNII: D5340Y2I9G)	
LANOLIN (UNII: 7EV65EAW6H)	
YELLOW WAX (UNII: 2ZA36H0S2V)	

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics			
Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51514-0338-1	89 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	06/09/2011	

Labeler - Autumn Harp, Inc. (064187883)

Establishment

Name	Address	ID/FEI	Business Operations
Autumn Harp, Inc.		064187883	manufacture(51514-0338)

Revised: 5/2014 Autumn Harp, Inc.