

DIAPER RASH BALM- skin protectant ointment

Skinfix, 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.

Diaper Rash Balm

Package Label Principal Display

Treats rash, redness & Irritation

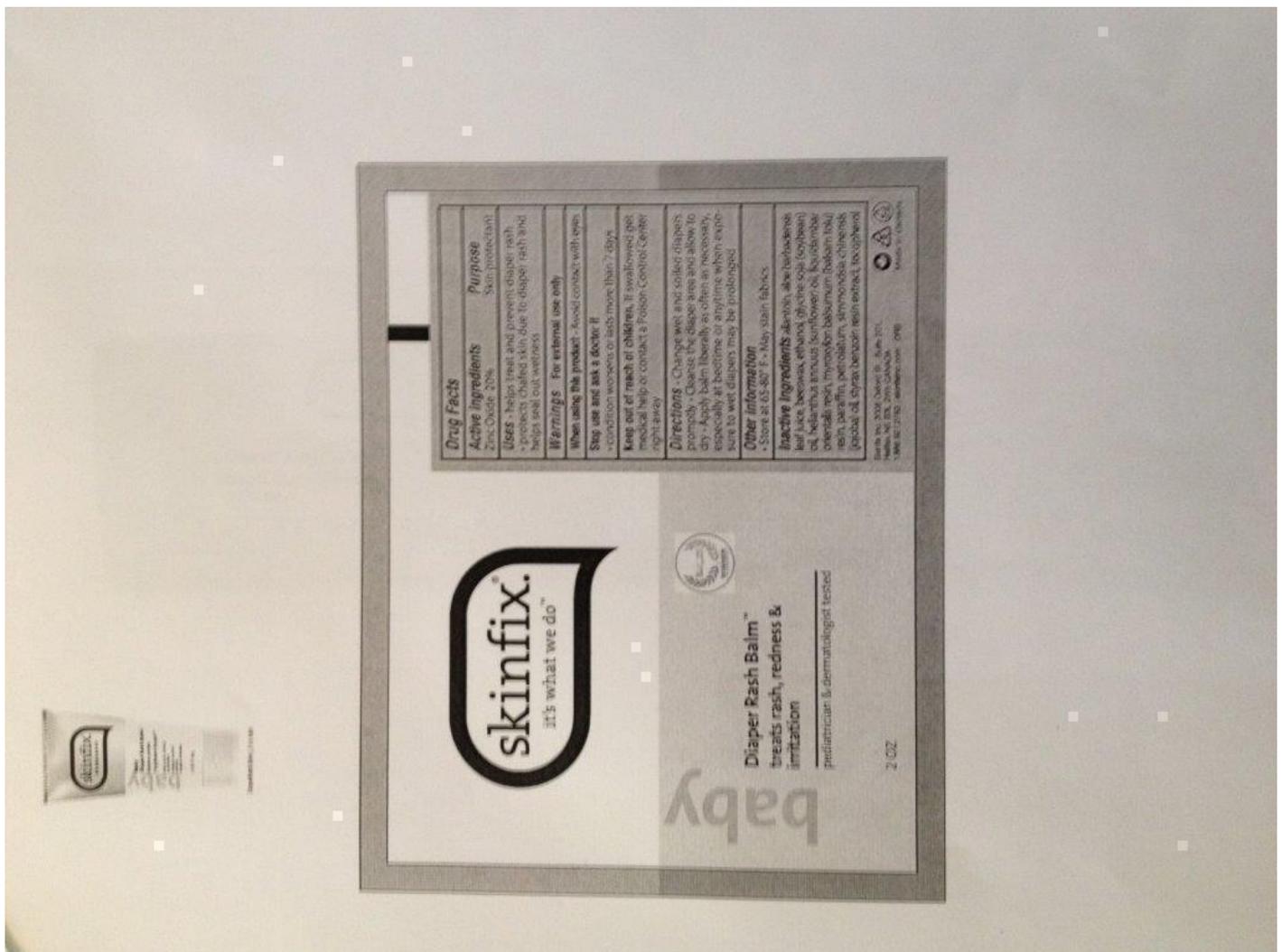
Uses - helps treat and prevent diaper rash. protects chafed skin due to diaper rash and helps seal out wetness.

Warnings - For external use only

When using this product . Avoid contact with eyes

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

Directions - Change wet and soiled diapers promptly. Cleanse the diaper area and allow to dry. Apply balm liberally as often as necessary, especially at bedtime or anytime when exposure to wet diapers may be prolonged.



DIAPER RASH BALM

skin protectant ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61328-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.2 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
ALCOHOL (UNII: 3K9958V90M)	
SOYBEAN OIL (UNII: 241ATL177A)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
JOJOBA OIL (UNII: 724GKU717M)	
WHITE WAX (UNII: 7G1J5DA97F)	
PARAFFIN (UNII: I9O0E3H2ZE)	
ALLANTOIN (UNII: 344S277G0Z)	
BENZOIN RESIN (UNII: GK21SBA74R)	
LIQUIDAMBAR ORIENTALIS RESIN (UNII: 63V91G4W93)	
TOLU BALSAM (UNII: TD2LE91MBE)	
ALOE (UNII: V5VD430YW9)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61328-001-01	60 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	12/09/2013	

Labeler - Skinfix, Inc. (203158183)

Registrant - Product Integrity Laboratory, LLC (783863694)

Establishment

Name	Address	ID/FEI	Business Operations
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Canadian Custom Packaging Company		207062514	manufacture(61328-001)
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Revised: 12/2013

Skinfix, Inc.