# BADGER BABY SPF 30 SUNSCREEN- zinc oxide cream Norwood Packaging Ltd.

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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#### $Badger_{ extsf{R}}$ Baby SPF 30 Sunscreen Cream

**Drug** Facts

#### **Active Ingredient**

Non-Nano Uncoated Zinc Oxide 18.75%

#### Purpose

Sunscreen

#### Uses

- Helps prevent sunburn
- If used as directed with other sun protection measures (see *Directions*), decreases the risk of skin cancer and early skin aging caused by the sun.

#### Warnings

#### For external use only

**Do not use** on damaged or broken skin. Stop and ask a doctor if rash occurs.

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

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

#### Directions

• For full protection, apply liberally (2mg/cm<sup>2</sup> of skin) to all exposed skin 15 minutes before sun exposure, then rub in to reduce whitening effect.

#### Reapply

- After 40 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 10am-2pm
  - Wear long-sleeved shirts, pants, hats, and sunglasses
- For children under 6 months of age: ask a doctor.

#### Ingredients

<sup>1</sup>Helianthus Annuus (**Sunflower**) Oil, <sup>1</sup>Cera Alba (**Beeswax**), Tocopherol (**Sunflower Vitamin E**), CO<sub>2</sub> Extracts of <sup>1</sup>Hippophae Rhamnoides (**Seabuckthorn**) and <sup>1</sup>Calendula Officinalis (**Calendula**), <sup>1</sup>Anthemis Nobilis (**Chamomile**) Essential Oil.

1 = Certified Organic

#### **Other Information**

Store at temperatures below 90°F.

#### PRINCIPAL DISPLAY PANEL - 87 mL Tube Label

Active

 $BADGER_{\mathbb{R}}$ 

Chamomile & Calendula

Broad Spectrum SPF 30

Baby

ZINC OXIDE SUNSCREEN CREAM

Safe • Effective • Pediatrician Tested

WATER RESISTANT 40min

UVA UVB

NON NANO

#### BIO DEGRADABLE

NATURAL PRODUCTS ASSOCIATION  $\bullet$  CERTIFIED  $\bullet$   $_{\ensuremath{\mathbb{R}}}$ 

100% CERTIFIED NATURAL 98% ORGANIC INGREDIENTS

NSF contains organic ingredients <sub>CM</sub>

87ml/2.9 fl.oz



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

zinc oxide cream

Product Information									
Product T ype	HUMAN OTC DRUG	Item Code (Source)	NDC:55143-105						
Route of Administration	TOPICAL								
Active Ingredient/Active Moiety									
Active ingretient/Active molety									
Ingred	ient Name	Basis of Strength	Strength						
ZINC OXIDE (UNII: SOI2LOH54Z) (ZIN	COXIDE - UNII:SOI2LOH54Z)	ZINC O XIDE	18.75 g in 100 mL						
Inactive Ingredients									
macuve mgreutents									
	Ingredient Name		Strength						
SUNFLOWER OIL (UNII: 3W1JG795YI)									

YELLOW WAX (UNII: 2ZA36H0S2V)								
TOCOPHEROL (UNII: R0ZB2556P8)								
HIPPOPHAE RHAMNO IDES FRUIT (UNII: AVL0R9111T)								
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)								
CHAMAEMELUM NOBILE FLOWER OIL (UNII: UB27587839)								
Packaging								
#	Item Code	Package Description	Marketing Start Date		Marketing End Date			
1 NDC	C:55143-105-01	87 mL in 1 TUBE						
Marketing Information								
Μ	arketing Category	Application Number or Mo	nograph Citation	Marketing Star	rt Date	Marketing End Date		
OTC MONOGRAPH NOT FINAL		AL part352	part352					

# Labeler - Norwood Packaging Ltd. (243693926)

## Establishment

Name	Address	ID/FEI	Business Operations
Norwood Packaging Ltd.		243693926	MANUFACTURE(55143-105)

Revised: 1/2014

Norwood Packaging Ltd.