# BADGER KIDS SPF 30 SUNSCREEN- zinc oxide lotion 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.

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#### Badger Kids SPF 30 Sunscreen

#### **Active Ingredient**

Non-Nano Uncoated Zinc Oxide 12%

#### 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

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

#### When using this product

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

#### Keep out of reach of children

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

#### **Directions:**

**Directions:** • For full protection, apply liberally (2 mg/cm2 of skin) 15 minutes before sun exposure • Use a water resistant sunscreen if swimming or sweating **Reapply:** • 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 10 am - 2 pm • Wear long sleeved shirts, pants, hats, and sunglasses • For children under 6 months: ask a doctor.

#### **Ingredients**

\*Aloe Barbadensis (**Aloe**) Leaf Juice, \*Helianthus Annuus (**Sunflower**) Oil, Carthamus Tinctorius (**Safflower**) Oleosomes, \*Sucrose Cocoate (from **Coconut**), Water, \*Citrus Aurantium Dulcis (**Sweet Orange**) Essential Oil, Microcrystalline Cellulose, Citric Acid (from Non-GMO **Corn**), Leuconostoc

Ferment Filtrate (from **Radish**), \*Glycerin (from Sustainable **Palm**), \*Citrus Tangerina (**Tangerine**) Essential Oil, \*Aloe Barbadensis (**Aloe**) Extract, Tocopherol (**Sunflower Vitamin E**), Gluconolactone (from Non-GMO **Corn**), \*Vanilla Planifolia (**Vanilla**) CO<sub>2</sub> Extract, Xanthan Gum, \*Lecithin (from **Soybean**), Cellulose Gum. \*=Certified Organic

#### Other Information:

Store at temperatures below 90°F.

#### **Principal Display Panel**

Image Components



### **BADGER KIDS SPF 30 SUNSCREEN**

zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:51514-0302
Route of Administration	TOPICAL	DEA Schedule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ZINC OXIDE (ZINC OXIDE)	ZINC OXIDE	12 g in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
WATER			
SUNFLO WER O IL			
CARTHAMUS TINCTORIUS (SAFFLOWER) OLEOSOMES			
SUCROSE CO CO ATE			
ORANGE OIL			
CELLULOSE, MICRO CRYSTALLINE			
CITRIC ACID MONO HYDRATE			
MANDARIN O IL			
ALOE VERA LEAF			
GLYCERIN			
TOCOPHEROL			
GLUCONOLACTONE			
VANILLA			
XANTHAN GUM			
LECITHIN, SO YBEAN			
CARBO XYMETHYLCELLULO SE SODIUM			

Product Characteristics				
Color	white	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51514-0302-1	118 mL in 1 TUBE		

<b>Marketing Infor</b>	mation		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

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OTC monograph final	part352		0 3/0 1/20 13	

## Labeler - Autumn Harp, Inc. (064187883)

Establishment				
Name	Address	ID/FEI	Business Operations	
Autumn Harp, Inc.		064187883	manufacture(51514-0302)	

Revised: 9/2013 Autumn Harp, Inc.