## BABYGANICS SPF 50- octinoxate, octisalate, and zinc spray 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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#### **Drug Facts**

#### **Active Ingredients**

Active Ingredients

Purpose

Octinoxate 7.5%, Octisalate 5.0%, Zinc Oxide 11.2% Sunscreen

#### Uses

Uses

helps prevent sunburn

if used as directed with other sun protection measures (see Directions), decrease the risk of skin cancer and early skin aging caused by the sun

#### Warnings

Warnings

For external use only

#### Do not use

Do not use on damaged or broken skin

#### When using this product

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

#### Stop use and ask a doctor

Stop use and ask a doctor if rash occurs

#### Keep out of reach of children

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

#### **Directions**

Directions

apply liberally 15 minutes before sun exposure

reapply

after 80 minutes of swimming or sweating

immediately after towel drying at least every 2 hours children under 6 months of age: ask a doctor

#### **Sun Protection Measures**

Sun Protection measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk of skin cancer and early skin aging. To decrease this risk sunscreen with 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

#### Other Information

Other information protect from excessive heat and direct sun

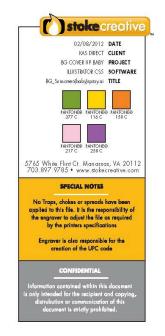
#### **Inactive ingredients**

Inactive Ingredients: Water, Glycerin, Caprylic/Capric Triglyceride, Aloe Barbadensis Leaf Juice, VP/hexadecene copolymer, Cetearyl Glucoside, Phenethyl Alcohol, Glyceryl Caprylate, Polyacrylate Crosspolymer-6, Cetearyl Alcohol, Citric Acid.

#### Label







#### **BABYGANICS SPF 50**

octinoxate, octisalate, and zinc spray

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:51514-0235

Route of Administration TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	112 mg in 1 mL		
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL		
OCTISALATE (UNII: 4X49 Y0 59 6 W) (OCTISALATE - UNII:4X49 Y0 59 6 W)	OCTISALATE	50 mg in 1 mL		

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	

#### CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)

GLYCERIN (UNII: PDC6A3C0OX)

ı	# Item Code Package Description		Package Description	<b>Marketing Start Date</b>	Marketing End Date
ı	1	NDC:51514-0235-1	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/21/2013	

### **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part352	02/23/2012			

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

Establishment				
Name	Address	ID/FEI	Business Operations	
Autumn Harp, Inc.		064187883	manufacture(51514-0235)	

Revised: 11/2018 Autumn Harp, Inc.