

**BABYGANICS SUNSCREEN 50 SPF- octinoxate, octisalate, and zinc oxide spray**  
**KAS Direct LLC dba BabyGanics**

*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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**babyganics® Sunscreen Spray 50 SPF**

***Drug Facts***

**Active ingredients**

Octinoxate 7.5%, Octisalate 5.0%, Zinc oxide 11.2%

**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

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

**Stop use and ask a doctor** if rash occurs

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

**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.** 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 a.m.-2 p.m.
  - wear long-sleeved shirts, pants, hats, and sunglasses

**Other information**

protect this product from excessive heat and direct sun

## **Inactive ingredients**

water, caprylic/capric triglyceride, glycerin, aloe barbadensis leaf juice, vp/hexadecene copolymer, glyceryl stearate, hexaglyceryl polyricinoleate, polysorbate 80, phenethyl alcohol, glyceryl caprylate, sodium magnesium silicate, xanthan gum, hydroxyethyl acrylate/sodium acryloyldimethyltaurate copolymer, citric acid, squalane, lecithin, polysorbate 60, sorbitan isostearate.

Dist. by:

KAS Direct, LLC.

Hicksville, NY 11801

## **PRINCIPAL DISPLAY PANEL - 177 mL Bottle Label**

**50+**

**SPF**

**tear**

**free**

**water**

**resistant**

**babyanics®**

**mineral-based**

**sunscreen spray**

**broad spectrum SPF 50+**

UVA + UVB protection

water resistant (80 minutes)

non-allergenic

**no:** PABA, phthalates, parabens,  
fragrances or nano-particles

6 FL OZ (177mL)

040-12078-01

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pediatrician + dermatologist tested

to learn more, please visit [babyganics.com](http://babyganics.com)

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1 800 378 7803 please recycle we do :)

made in the USA never tested on animals

041-12078-01

<b>BABYGANICS SUNSCREEN 50 SPF</b>			
octinoxate, octisalate, and zinc oxide spray			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59062-1207
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			

Ingredient Name	Basis of Strength	Strength
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL
<b>OCTISALATE</b> (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	50 mg in 1 mL
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	112 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>HEXADECYL POVIDONE</b> (UNII: AG75W62QYU)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>PHENYLETHYL ALCOHOL</b> (UNII: ML9LGA7468)	
<b>GLYCERYL MONOCAPRYLATE</b> (UNII: TM2TZD4G4A)	
<b>SODIUM MAGNESIUM FLUORO SILICATE</b> (UNII: U1QJ22MC8E)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (10000 MPAS AT 1.5%)</b> (UNII: 86FQE96TZ4)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>SQUALANE</b> (UNII: GW89575KF9)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)	
<b>SORBITAN ISOSTEARATE</b> (UNII: 01S2G2C1E4)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59062-1207-1	177 mL in 1 BOTTLE, DISPENSING; 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	06/21/2013	

**Labeler** - KAS Direct LLC dba BabyGanics (002764605)