

**BABYGANICS SUNSCREEN 30 SPF- zinc oxide, octinoxate, and octisalate spray**  
**KAS Direct LLC dba BabyGanics**

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**babyganics® Sunscreen Spray 30 SPF**

***Drug Facts***

**Active ingredients**

Octinoxate 5.0%, Octisalate 4.0%, 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, vp/hexadecene copolymer, aloe barbadensis leaf juice, glyceryl stearate, hexaglyceryl polyricinoleate, polysorbate 80, phenethyl alcohol, glyceryl caprylate, sodium magnesium silicate, xanthan gum, hydroxyethyl acrylate/sodium acryloyldimethyltaurate copolymer, squalane, citric acid, lecithin, polysorbate 60, sorbitan isostearate.

Dist. by:

KAS Direct, LLC.

Hicksville, NY 11801

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

**30  
SPF**

**tear  
free**

**water  
resistant**

**babyganics®**

**mineral-based  
sunscreen spray**

**broad spectrum SPF 30**

UVA + UVB protection

water resistant (80 minutes)

non-allergenic

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

6 FL OZ (177mL)

040-12290-01

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pediatrician + dermatologist tested  
 to learn more, please visit [babyganics.com](http://babyganics.com)  
 © 2014 dist. by KAS Direct, LLC Westbury, NY 11590  
 1800 378 7803 please recycle we do :)  
 made in the USA never tested on animals

**BABYGANICS SUNSCREEN 30 SPF**  
zinc oxide, octinoxate, and octisalate spray

| Product Information     |                |                    |                |
|-------------------------|----------------|--------------------|----------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:59062-1229 |
| Route of Administration | TOPICAL        |                    |                |

| <b>Active Ingredient/Active Moiety</b>                              |                          |                 |
|---|--------------------------|-----------------|
| <b>Ingredient Name</b>  | <b>Basis of Strength</b> | <b>Strength</b> |
| <b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE               | 112 mg in 1 mL  |
| <b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE               | 50 mg in 1 mL   |
| <b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | OCTISALATE               | 40 mg in 1 mL   |

| <b>Inactive Ingredients</b>  |                 |
|--|-----------------|
| <b>Ingredient Name</b>   | <b>Strength</b> |
| <b>WATER</b> (UNII: 059QF0KO0R)  |                 |
| <b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)   |                 |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)   |                 |
| <b>HEXADECYL POVIDONE</b> (UNII: AG75W62QYU)   |                 |
| <b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)   |                 |
| <b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)  |                 |
| <b>POLYGLYCERYL-6 DIOLEATE</b> (UNII: 062SZD3F3X)  |                 |
| <b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)   |                 |
| <b>PHENYLETHYL ALCOHOL</b> (UNII: ML9LGA7468)  |                 |
| <b>GLYCERYL MONOCAPRYLATE</b> (UNII: TM2TZD4G4A)   |                 |
| <b>SODIUM MAGNESIUM FLUOROSILICATE</b> (UNII: U1QJ22MC8E)  |                 |
| <b>XANTHAN GUM</b> (UNII: TTV12P4NEE)  |                 |
| <b>HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%)</b> (UNII: 86FQE96TZ4) |                 |
| <b>SQUALANE</b> (UNII: GW89575KF9)   |                 |
| <b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)  |                 |
| <b>SOYBEAN LECITHIN</b> (UNII: 1DI56QDM62)   |                 |
| <b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)   |                 |
| <b>SORBITAN ISOSTEARATE</b> (UNII: 01S2G2C1E4)   |                 |

| <b>Packaging</b> |                  |   |                             |                           |
|------------------|------------------|---|-----------------------------|---------------------------|
| <b>#</b>         | <b>Item Code</b> | <b>Package Description</b>  | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
| 1                | NDC:59062-1229-1 | 177 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product | 06/21/2013                  | 12/31/2026                |

| <b>Marketing Information</b> |   |                             |                           |
|------------------------------|---|-----------------------------|---------------------------|
| <b>Marketing Category</b>    | <b>Application Number or Monograph Citation</b> | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
| OTC monograph drug           | M020  | 06/21/2013                  | 12/31/2026                |

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