

**SPF 50 MINERAL SUNSCREEN BABYGANICS- titanium dioxide and zinc oxide lotion**

**SPF 50 MINERAL SUNSCREEN BKIDS- titanium dioxide and zinc oxide lotion**

**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.*

-----

## **SPF 50 Mineral Sunscreen**

### **Drug Facts**

#### **Active ingredients**

Titanium dioxide 3%, 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** 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, ethylhexyl palmitate, butyloctyl salicylate, caprylic/capric triglyceride, trimethylpentanediol/adipic acid/glycerin crosspolymer, cetearyl olivate, glycerin, sorbitan olivate, tocopheryl acetate, phenoxyethanol, cetearyl alcohol, cetearyl glucoside, propanediol, alumina, xanthan gum, jojoba esters, 1,2-hexanediol, bisabolol, helianthus annuus (sunflower) seed oil<sup>1</sup>, solanum lycopersicum (tomato) seed oil, lecithin, polyhydroxystearic acid, caprylhydroxamic acid, citric acid, isopropyl myristate, isostearic acid, polyglyceryl-3 polyricinoleate, vaccinium macrocarpon (cranberry) seed oil, nigella sativa (black cumin) seed oil<sup>1</sup>, rubus idaeus (red raspberry) seed oil

---

1 Certified Organic Ingredient • Unless otherwise specified, product not labeled as organic • \*Learn about these and all our ingredients and the choices we make at [babyganics.com/products](http://babyganics.com/products)

dist. by KAS Direct, LLC  
san francisco, ca 94111

### **PRINCIPAL DISPLAY PANEL - 59 mL Tube Label - 59062-1001**

non  
allergenic

tear  
free

babyganics®

SPF 50  
mineral  
sunscreen

pediatrician tested

broad spectrum SPF 50  
water resistant (80 minutes)

made without oxybenzone, octinoxate,  
parabens, fragrance, nano-particles

Discover which of our ingredients are  
certified organic on the back panel.

2 FL OZ (59 mL)



**SPF 50  
mineral  
sunscreen**

**pediatrician tested**

broad spectrum SPF 50  
water resistant (80 minutes)

 made without oxybenzone, octinoxate, parabens, fragrance, nano-particles

Discover which of our ingredients are certified organic on the back panel.

2 FL OZ (59 mL)

|   |                             |
|---|-----------------------------|
| <b>Drug Facts</b>   |                             |
| <b>Active ingredients</b><br>Titanium dioxide 3%, Zinc oxide 12%.....   | <b>Purpose</b><br>Sunscreen |
| <b>Uses</b><br>• helps prevent sunburn • if used as directed with other sun protection measures (see <i>Directions</i> ), decreases the risk of skin cancer and early skin aging caused by the sun  |                             |
| <b>Warnings</b><br>For external use only<br><b>Do not use</b> on damaged or broken skin<br><b>When using this product</b> keep out of eyes. Rinse with water to remove.<br><b>Stop use and ask a doctor</b> if rash occurs<br><b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.   |                             |
| <b>Directions</b><br>• 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 • <b>Sun Protection Measures.</b> 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  |                             |
| <b>Other information</b> protect this product from excessive heat and direct sun  |                             |
| <b>Inactive ingredients</b> water, ethylhexyl palmitate, butyloctyl salicylate, caprylic/capric triglyceride, trimethylpentanediol/adipic acid/glycerin crosspolymer, cetearyl olivate, glycerin, sorbitan olivate, tocopheryl acetate, phenoxyethanol, cetearyl alcohol, cetearyl glucoside, propanediol, alumina, xanthan gum, jojoba esters, 1,2-hexanediol, bisabolol, helianthus annuus (sunflower) seed oil†, solanum lycopersicum (tomato) seed oil, lecithin, polyhydroxystearic acid, caprylhydroxamic acid, citric acid, isopropyl myristate, isostearic acid, polyglyceryl-3 polyricinoleate, vaccinium macrocarpon (cranberry) seed oil, nigella sativa (black cummin) seed oil†, rubus idaeus (red raspberry) seed oil |                             |



†Certified Organic Ingredient • Unless otherwise specified, product not labeled as organic • \*Learn about these and all our ingredients and the choices we make at [babyganics.com/products](http://babyganics.com/products)



 reef safe  
made without oxybenzone & octinoxate

dist. by KAS Direct, LLC  
san francisco, ca 94111  
©2021 • 1 800 378 7803

1118921

**PRINCIPAL DISPLAY PANEL - 59 mL Tube Label - 59062-1101**

tear free  
kids by babyganics®  
easy rub-in  
SPF 50 mineral sunscreen  
dermatologist tested  
broad spectrum SPF 50 water & sweat resistant (80 minutes)  
made without oxybenzone, octinoxate, parabens, fragrance

Discover which of our ingredients are certified organic on the back panel.

2 FL OZ (59 mL)



**kids**  
by babyganics®

easy rub-in

**SPF 50**

**mineral**

**sunscreen**

**dermatologist tested**

broad spectrum SPF 50  
water & sweat resistant (80 minutes)

made without oxybenzone, octinoxate, parabens, fragrance

Discover which of our ingredients are certified organic on the back panel.

2 FL OZ (59 mL)

**Drug Facts**

|   |                             |
|---|-----------------------------|
| <b>Active ingredients</b><br>Titanium dioxide 3%, Zinc oxide 12%.....   | <b>Purpose</b><br>Sunscreen |
| <b>Uses</b><br>• 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  |                             |
| <b>Warnings</b><br>For external use only<br>Do not use on damaged or broken skin<br>When using this product keep out of eyes. Rinse with water to remove.<br>Stop use and ask a doctor if rash occurs<br>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.   |                             |
| <b>Directions</b><br>• 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   |                             |
| <b>Other information</b> protect this product from excessive heat and direct sun  |                             |
| <b>Inactive ingredients</b> water, ethylhexyl palmitate, butyloctyl salicylate, caprylic/capric triglyceride, trimethylpentanediol/adipic acid/glycerin crosspolymer, cetearyl olivate, glycerin, sorbitan olivate, tocopheryl acetate, phenoxyethanol, cetearyl alcohol, cetearyl glucoside, propanediol, alumina, xanthan gum, jojoba esters, 1,2-hexanediol, bisabolol, helianthus annuus (sunflower) seed oil <sup>†</sup> , solanum lycopersicum (tomato) seed oil, lecithin, polyhydroxystearic acid, caprylhydroxamic acid, citric acid, isopropyl myristate, isostearic acid, polyglyceryl-3 polyricinoleate, vaccinium macrocarpon (cranberry) seed oil, nigella sativa (black cummin) seed oil <sup>†</sup> , rubus idaeus (red raspberry) seed oil |                             |

<sup>†</sup>Certified Organic Ingredient - Unless otherwise specified, product not labeled as organic • \*Learn about these and all our ingredients and the choices we make at [babyganics.com/products](http://babyganics.com/products)



reef safe  
made without oxybenzone & octinoxate

dist. by KAS Direct, LLC  
san francisco, ca 94111  
©2021 • 1800 378 7803

1118952

## SPF 50 MINERAL SUNSCREEN BABYGANICS

titanium dioxide and zinc oxide lotion

### Product Information

|                                |                |                           |                |
|--------------------------------|----------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:59062-1001 |
| <b>Route of Administration</b> | TOPICAL        |                           |                |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength        |
|---|-------------------|-----------------|
| <b>Titanium Dioxide</b> (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP) | Titanium Dioxide  | 31.6 mg in 1 mL |
| <b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)             | ZINC OXIDE        | 120 mg in 1 mL  |

## Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| <b>WATER</b> (UNII: 059QF0KO0R)  |          |
| <b>Ethylhexyl Palmitate</b> (UNII: 2865993309)   |          |
| <b>Butyloctyl Salicylate</b> (UNII: 2EH13UN8D3)  |          |
| <b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)   |          |
| <b>TRIMETHYLPENTANEDIOL/ADIPIC ACID/GLYCERIN CROSSPOLYMER (25000 MPA.S)</b> (UNII: 587WKM3S9Q) |          |
| <b>Cetearyl Olivat</b> (UNII: 58B69Q84JO)  |          |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)   |          |
| <b>Sorbitan Olivat</b> (UNII: MDL271E3GR)  |          |
| <b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)   |          |
| <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)   |          |
| <b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)  |          |
| <b>Cetearyl Glucoside</b> (UNII: 09FUA47KNA)   |          |
| <b>Propanediol</b> (UNII: 5965N8W85T)  |          |
| <b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)   |          |
| <b>XANTHAN GUM</b> (UNII: TTV12P4NEE)  |          |
| <b>JOJOBA OIL, RANDOMIZED</b> (UNII: 7F0EV20QYL)   |          |
| <b>1,2-Hexanediol</b> (UNII: TR046Y3K1G)   |          |
| <b>.ALPHA.-BISABOLOL, (+/-)-</b> (UNII: 36HQN158VC)  |          |
| <b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)  |          |
| <b>TOMATO SEED OIL</b> (UNII: 7N87T9C06T)  |          |
| <b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)                                    |          |
| <b>Caprylhydroxamic Acid</b> (UNII: UPY805K99W)  |          |
| <b>Isopropyl Myristate</b> (UNII: 0RE8K4LNJS)  |          |
| <b>Isostearic Acid</b> (UNII: X33R8U0062)  |          |
| <b>POLYGLYCERYL-3 PENTARICINOLEATE</b> (UNII: 7Q0OK5DOT4)                                      |          |
| <b>CRANBERRY SEED OIL</b> (UNII: 73KDS3BW5E)   |          |
| <b>Nigella Sativa Seed Oil</b> (UNII: CS4U38E731)  |          |
| <b>RASPBERRY SEED OIL</b> (UNII: 9S8867952A)   |          |
| <b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)  |          |
| <b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)  |          |

## Packaging

| # | Item Code        | Package Description                                 | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:59062-1001-2 | 59 mL in 1 TUBE; Type 0: Not a Combination Product  | 03/01/2021           |                    |
| 2 | NDC:59062-1001-6 | 177 mL in 1 TUBE; Type 0: Not a Combination Product | 03/01/2021           |                    |
| 3 | NDC:59062-1001-8 | 226 mL in 1 TUBE; Type 0: Not a Combination Product | 03/01/2021           |                    |

## Marketing Information

| Marketing | Application Number or Monograph | Marketing Start | Marketing End |
|-----------|---------------------------------|-----------------|---------------|
|-----------|---------------------------------|-----------------|---------------|

| Category                | Citation | Date       | Date |
|-------------------------|----------|------------|------|
| OTC monograph not final | part352  | 03/01/2021 |      |

## SPF 50 MINERAL SUNSCREEN BKIDS

titanium dioxide and zinc oxide lotion

### Product Information

|                         |                |                    |                |
|-------------------------|----------------|--------------------|----------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:59062-1101 |
| Route of Administration | TOPICAL        |                    |                |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength        |
|---|-------------------|-----------------|
| <b>Titanium Dioxide</b> (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP) | Titanium Dioxide  | 31.6 mg in 1 mL |
| <b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)             | ZINC OXIDE        | 120 mg in 1 mL  |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| <b>WATER</b> (UNII: 059QF0KO0R)  |          |
| <b>Ethylhexyl Palmitate</b> (UNII: 2865993309)   |          |
| <b>Butyloctyl Salicylate</b> (UNII: 2EH13UN8D3)  |          |
| <b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)   |          |
| <b>TRIMETHYLPENTANEDIOL/ADIPIC ACID/GLYCERIN CROSSPOLYMER (25000 MPA.S)</b> (UNII: 587WKM3S9Q) |          |
| <b>Cetearyl Olivat</b> e (UNII: 58B69Q84JO)  |          |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)   |          |
| <b>Sorbitan Olivat</b> e (UNII: MDL271E3GR)  |          |
| <b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)   |          |
| <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)   |          |
| <b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)  |          |
| <b>Cetearyl Glucoside</b> (UNII: 09FUA47KNA)   |          |
| <b>Propanediol</b> (UNII: 5965N8W85T)  |          |
| <b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)   |          |
| <b>XANTHAN GUM</b> (UNII: TTV12P4NEE)  |          |
| <b>JOJOBA OIL, RANDOMIZED</b> (UNII: 7F0EV20QYL)   |          |
| <b>1,2-Hexanediol</b> (UNII: TR046Y3K1G)   |          |
| <b>.ALPHA.-BISABOLOL, (+/-)-</b> (UNII: 36HQN158VC)  |          |
| <b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)  |          |
| <b>TOMATO SEED OIL</b> (UNII: 7N87T9C06T)  |          |
| <b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)                                    |          |
| <b>Caprylhydroxamic Acid</b> (UNII: UPY805K99W)  |          |
| <b>Isopropyl Myristate</b> (UNII: ORE8K4LNJS)  |          |
| <b>Isostearic Acid</b> (UNII: X33R8U0062)  |          |
| <b>POLYGLYCERYL-3 PENTARICINOLEATE</b> (UNII: 7Q0OK5DOT4)                                      |          |
| <b>CRANBERRY SEED OIL</b> (UNII: 73KDS3BW5E)   |          |
| <b>Nigella Sativa Seed Oil</b> (UNII: CS4U38E731)  |          |

|   |  |
|---|--|
| <b>RASPBERRY SEED OIL</b> (UNII: 9S8867952A)      |  |
| <b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)       |  |
| <b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP) |  |

### Packaging

| # | Item Code        | Package Description                                 | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:59062-1101-2 | 59 mL in 1 TUBE; Type 0: Not a Combination Product  | 03/01/2021           |                    |
| 2 | NDC:59062-1101-6 | 177 mL in 1 TUBE; Type 0: Not a Combination Product | 03/01/2021           |                    |

### Marketing Information

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part352                                  | 03/01/2021           |                    |

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

### Establishment

| Name        | Address | ID/FEI    | Business Operations   |
|-------------|---------|-----------|---|
| Autumn Harp |         | 064187883 | MANUFACTURE(59062-1001, 59062-1101) , LABEL(59062-1001, 59062-1101) |

Revised: 2/2021

KAS Direct LLC dba BabyGanics