

**SPF 50 PLUS SUNSCREEN- titanium dioxide, octisalate, and zinc oxide lotion**  
**KAS Direct LLC dba BabyGanics**

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**SPF 50+ Sunscreen Lotion**

***Drug Facts***

**Active ingredients**

Octisalate 5.0%, Titanium Dioxide 3.0%, Zinc Oxide 6.0%

**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, butyloctyl salicylate, neopentyl glycol diethylhexanoate, caprylic/capric triglyceride, stearyl/octyldodecyl citrate crosspolymer, polyglyceryl-2 stearate, simmondsia chinensis (jojoba) seed oil<sup>1</sup>, hydrogenated dimer dilinoleyl/dimethylcarbonate copolymer, glyceryl stearate, cetyl alcohol, cocos nucifera (coconut) oil<sup>1</sup>, glycerin<sup>1</sup>, solanum lycopersicum (tomato) seed oil, helianthus annuus (sunflower) seed oil<sup>1</sup>, vaccinium macrocarpon (cranberry) seed oil, nigella sativa (black cumin) seed oil<sup>1</sup>, rubus idaeus (red raspberry) seed oil, butyrospermum parkii (shea) butter<sup>1</sup>, jojoba esters, stearyl alcohol, arachidyl alcohol, arachidyl glucoside, behenyl alcohol, polyhydroxystearic acid, xanthan gum, silica, alumina, ethylhexylglycerin, trisodium ethylenediamine disuccinate, phenoxyethanol

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<sup>1</sup> Certified Organic Ingredient

Unless otherwise specified, product not labeled as organic

dist. by KAS direct, LLC  
Westbury, NY 11590

## PRINCIPAL DISPLAY PANEL - 177 mL Tube Label

50+  
SPF

tear  
free

water  
resistant

babyganics

SPF 50+  
sunscreen  
lotion

broad spectrum SPF 50+  
UVA + UVB protection  
water resistant (80 minutes)  
non-allergenic • pediatrician  
& dermatologist tested

formulated with: Zinc Oxide,  
Octisalate, Titanium Dioxide\*

formulated without: PABA  
phthalates • parabens  
fragrances • nano-particles

Discover which of our

ingredients are Certified Organic on back panel.

6 FL OZ (177mL)

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**Other information** protect this product from excessive heat and direct sun

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†Certified Organic Ingredient  
Unless otherwise specified, product not labeled as organic  
\*Learn more about these and all our ingredients and the choices we make at babyganics.com/12108

Broad Spectrum UVA +UVB protection:

- Zinc Oxide
- Octisalate
- Titanium Dioxide

RECOMMENDED

ACTIVE

dist. by KAS direct, LLC  
Weesbury, NY 11590  
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1 800 378 7803  
please recycle  
(we do)

product  
not tested  
on animals

pediatrician &  
dermatologist  
tested

028-12108-801

8 13277 01210 8

**SPF 50+**  
**sunscreen**  
**lotion**

broad spectrum SPF 50+  
UVA + UVB protection  
water resistant (80 minutes)  
non-allergenic • pediatrician  
& dermatologist tested

**formulated with:** Zinc Oxide,  
Octisalate, Titanium Dioxide\*

**formulated without:** PABA  
phthalates • parabens  
fragrances • nano-particles

Discover which of our  
ingredients are Certified  
Organic on back panel.

6 FL OZ (177mL)

## SPF 50 PLUS SUNSCREEN

titanium dioxide, octisalate, and zinc oxide lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59062-1000
<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	30 mg in 1 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	60 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>Butyloctyl Salicylate</b> (UNII: 2EH13UN8D3)	
<b>Neopentyl Glycol Diethylhexanoate</b> (UNII: U68ZV6W62C)	
<b>Medium-Chain Triglycerides</b> (UNII: C9H2L21V7U)	
<b>Stearyl/Octyldodecyl Citrate Crosspolymer</b> (UNII: PN88NW0KPK)	
<b>Polyglyceryl-2 Stearate</b> (UNII: 253MC0P0YV)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>Jjoba Oil</b> (UNII: 724GKU717M)	
<b>Glyceryl Monostearate</b> (UNII: 230OU9XXE4)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>Coconut Oil</b> (UNII: Q9L0O73W7L)	
<b>Tomato Seed Oil</b> (UNII: 7N87T9C06T)	
<b>Sunflower Oil</b> (UNII: 3W1JG795YI)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>Cranberry Seed Oil</b> (UNII: 73KDS3BW5E)	
<b>Nigella Sativa Seed Oil</b> (UNII: CS4U38E731)	
<b>Raspberry Seed Oil</b> (UNII: 9S8867952A)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>Shea Butter</b> (UNII: K49155WL9Y)	
<b>JOJOBA OIL, RANDOMIZED</b> (UNII: 7F0EV20QYL)	
<b>Stearyl Alcohol</b> (UNII: 2KR89I4H1Y)	
<b>Arachidyl Alcohol</b> (UNII: 1QR1QRA9BU)	
<b>Arachidyl Glucoside</b> (UNII: 6JVB35JOOJ)	
<b>Docosanol</b> (UNII: 9G1OE216XY)	
<b>POLYHYDROXYSTEARIC ACID STEARATE</b> (UNII: 8KQ7I65XZE)	
<b>Silicon Dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>Aluminum Oxide</b> (UNII: LMI26O6933)	
<b>Trisodium Ethylenediamine Disuccinate</b> (UNII: YA22H34H9Q)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59062-1000-2	59 mL in 1 TUBE; Type 0: Not a Combination Product	07/24/2017	12/31/2025
2	NDC:59062-1000-6	177 mL in 1 TUBE; Type 0: Not a Combination Product	07/24/2017	12/31/2025
3	NDC:59062-1000-8	236 mL in 1 TUBE; Type 0: Not a Combination Product	07/24/2017	12/31/2026

4	NDC:59062-1000-1	354 mL in 1 TUBE; Type 0: Not a Combination Product	07/24/2017	12/31/2025
<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		07/24/2017	12/31/2026

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

Revised: 12/2024

KAS Direct LLC dba BabyGanics