

**OUTDOOR ADVENTURE SET- zinc oxide, titanium dioxide, and octisalate**  
**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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**outdoor adventure set**

***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.

637 Commercial Street, Suite 300

San Francisco, CA 94111

## PRINCIPAL DISPLAY PANEL - Kit Package

babyganics

outdoor

adventure set

mosquito bites?

sun burns? we've

got you covered

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

natural insect

repellent

5 FL OZ (142 g)

SPF 50+

sunscreen lotion

2 FL OZ (59 mL)

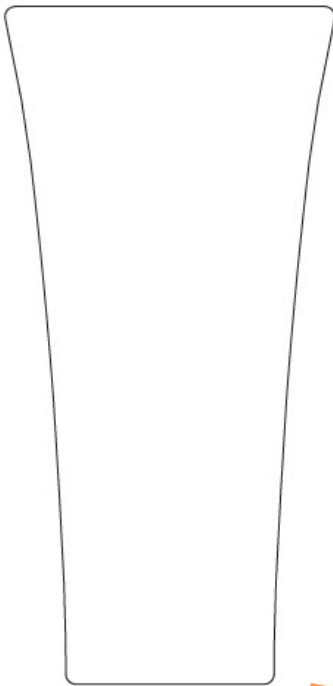
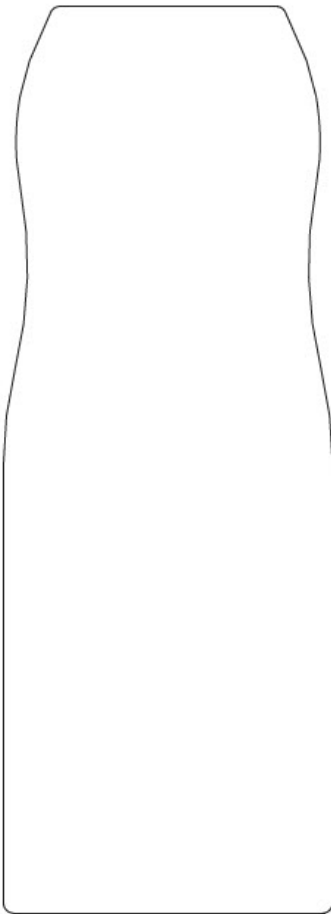


# outdoor adventure set



# outdoor adventure set

mosquito bites?  
sun burns? we've  
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## natural insect repellent

5 FL OZ (142 g)

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

## SPF 50+ sunscreen lotion

2 FL OZ (59 mL)



# natural insect repellent & SPF 50+ sunscreen lotion



Strong rays and pesky mosquitoes are no match for this powerfully protective duo. Bring on the fun in the sun.



## natural insect repellent

plant and essential oils help keep mosquitoes away formulated without parabens, sulfates, phthalates or synthetic ingredients

### Active Ingredients:

Soybean Oil .....	95.25%
Rosemary Oil .....	1.50%
Citronella Oil .....	0.95%
Geranium Oil .....	0.75%
Cedarwood Oil .....	0.70%
Peppermint Oil .....	0.60%
Lemongrass Oil .....	0.25%
<b>Total</b> .....	<b>100.00%</b>

## KEEP OUT OF REACH OF CHILDREN CAUTION

See additional precautionary statements below

**Directions for Use:** Shake well before each use. Hold can 4-6 inches away from skin. Apply just enough product to evenly cover exposed skin. Do not spray directly on face. Do not apply under clothing, diapers or underarm area. Avoid applying on cuts, wounds or irritated skin. Do not allow children to handle this product. When using on children, apply to your own hands and apply on child; being careful to avoid eyes, mouth and hands. Reapply every 90 minutes. After returning indoors, bathe child and wash clothes with soap and water.

**Storage and Disposal:** Store in a cool, dry place inaccessible to children and pets. Non-refillable container; do not reuse or refill this container. Recycle empty container or put in trash.

### Precautionary Statements

#### CAUTION: KEEP OUT OF REACH OF CHILDREN

Only for external use. Do not apply to children under 6 months of age. May cause eye irritation. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Thoroughly wash hands after applying; wash treated skin with soap and water after use.

**First Aid:** If in Eyes: Rinse with water for several minutes.

If Skin Irritation Occurs: Wash with plenty of soap and water. Wash clothing before reuse. In both cases, if irritation persists, call a physician or 1.800.222.1222 for emergency medical treatment information.

This product has not been registered by the United States Environmental Protection Agency. KAS Direct, LLC represents that this product qualifies for exemption from registration under FIFRA Section 25(b).

## SPF 50+ sunscreen lotion

broad spectrum SPF 50+ UVA + UVB protection non-allergenic • water resistant (80 minutes) formulated with Zinc Oxide, Octisalate, Titanium Dioxide\* formulated without PABA, phthalates, parabens, fragrances or nano-particles reef safe; formulated without oxybenzone and octinoxate

### Drug Facts

Active ingredients	Purpose
Octisalate 5.0%, Titanium Dioxide 3.0%, Zinc Oxide 8.0%	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
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- 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

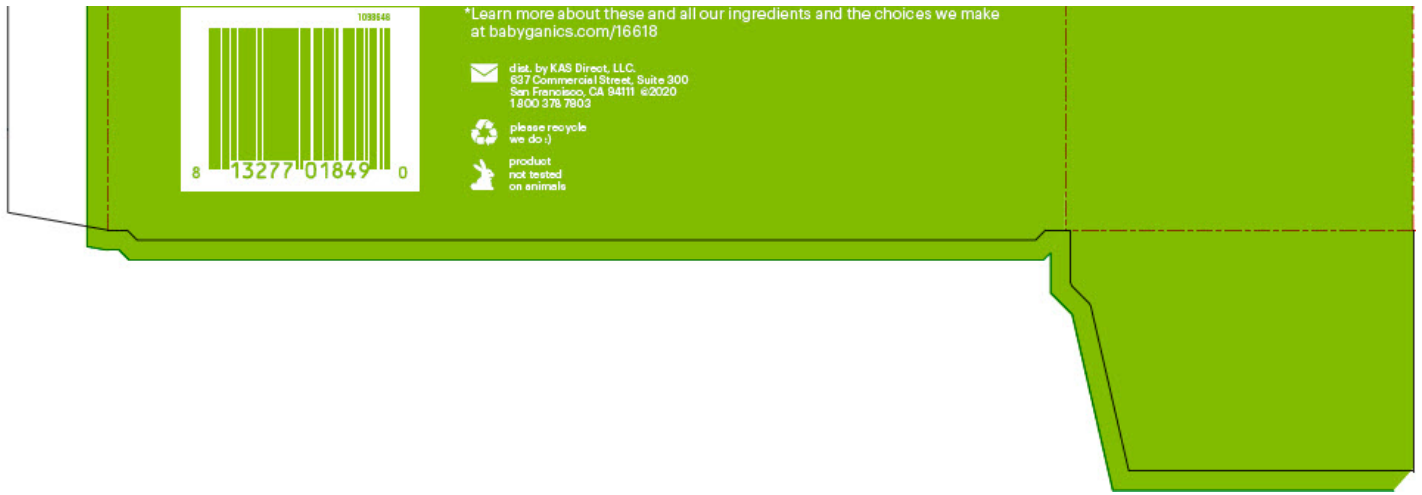
**Inactive ingredients** water, butyloctyl salicylate, neopentyl glycol diethylhexanoate, caprylic/capric triglyceride, stearyl octyldodecyl citrate crosspolymer, polyglyceryl-2 stearate, simmondsia chinensis (jojoba) seed oil†, hydrogenated dimethylsiloxane (dimethylsiloxane copolymer, glyceryl stearate, cetyl alcohol, cocos nucifera (coconut) oil†, glycerin†, solanum lycopersicum (tomato) seed oil, helianthus annuus (sunflower) seed oil†, vaccinium macrocarpon (cranberry) seed oil, nigella arvensis (black cumin) seed oil†, rubus idaeus (red raspberry) seed oil, butyrospermum parkii (shea) butter†, jojoba esters, stearyl alcohol, arachidyl alcohol, arachidyl glucoside, behenyl alcohol, polyhydroxyisostearic acid, xanthan gum, silica, alumina, ethylhexylglycerin, tosedium ethylhexadecane disuccinate, phenoxyethanol

†Certified Organic Ingredient  
Unless otherwise specified, product not labeled as organic

babyorganics™



natural insect repellent & SPF 50+ sunscreen lotion



## OUTDOOR ADVENTURE SET

zinc oxide, titanium dioxide, and octisalate kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59062-5200
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59062-5200-1	1 in 1 PACKAGE; Type 0: Not a Combination Product	01/01/2019	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	59 mL
Part 2	1 CAN	142 g

## Part 1 of 2

### KIDS SPF 50 PLUS SUNSCREEN

titanium dioxide, octisalate, and zinc oxide lotion

### Product Information

<b>Route of Administration</b>	TOPICAL
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### 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
WATER (UNII: 059QF0KO0R)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
Neopentyl Glycol Diethylhexanoate (UNII: U68ZV6W62C)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
Stearyl/Octyldodecyl Citrate Crosspolymer (UNII: PN88NW0KPK)	
Polyglyceryl-2 Stearate (UNII: 253MC0P0YV)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
JOJOBA OIL (UNII: 724GKU717M)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
GLYCERIN (UNII: PDC6A3C0OX)	
COCONUT OIL (UNII: Q9L0O73W7L)	
TOMATO SEED OIL (UNII: 7N87T9C06T)	
SUNFLOWER OIL (UNII: 3W1JG795Y)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
CRANBERRY SEED OIL (UNII: 73KDS3BW5E)	
Nigella Sativa Seed Oil (UNII: CS4U38E731)	
RASPBERRY SEED OIL (UNII: 9S8867952A)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SHEA BUTTER (UNII: K49155WL9Y)	
JOJOBA OIL, RANDOMIZED (UNII: 7F0EV20QYL)	
Stearyl Alcohol (UNII: 2KR89I4HIY)	
Arachidyl Alcohol (UNII: 1QR1QRA9BU)	
Arachidyl Glucoside (UNII: 6JVVW35JOOJ)	
DOCOSANOL (UNII: 9G1OE216XY)	
POLYHYDROXYSTEARIC ACID STEARATE (UNII: 8KQ7I65XZE)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ALUMINUM OXIDE (UNII: LM26O6933)	
Trisodium Ethylenediamine Disuccinate (UNII: YA22H34H9Q)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59062-1100-2	59 mL in 1 TUBE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	07/24/2017	

## Part 2 of 2

## NATURAL INSECT REPELLENT

lotions, oils, powders, and creams spray

### Product Information

**Route of Administration** TOPICAL

### Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	soybean oil (UNII: 241ATL177A)	
INGR	rosemary oil (UNII: 8LGU7VM393)	
INGR	Citronella Oil (UNII: QYO8Q067D0)	
INGR	GERANIUM OIL, ALGERIAN TYPE (UNII: 5Q1I94P4WG)	
INGR	JUNIPERUS VIRGINIANA OIL (UNII: PAD4FN7P2G)	
INGR	Peppermint Oil (UNII: AV092KU4JH)	
INGR	WEST INDIAN LEMONGRASS OIL (UNII: 5BIA40E9ED)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		142 g in 1 CAN; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		01/01/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/01/2019	

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

Revised: 11/2020

KAS Direct LLC dba BabyGanics