

## **OUTDOOR ESSENTIALS- zinc oxide, octocrylene, 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 essentials**

### **Drug Facts**

#### **Active ingredients**

Zinc Oxide 11.20%, Octocrylene 6.0%, Octisalate 5.0%

#### **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
  - do not spray directly into face. Spray on hands then apply to face.
- 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, butyloctyl salicylate, stearyl/octyldodecyl citrate crosspolymer, aloe barbadensis leaf juice, glyceryl stearate, polyglyceryl-6 polyricinoleate, helianthus annuus (sunflower) seed oil, solanum lycopersicum (tomato) seed oil, lecithin, polysorbate 60, vaccinium macrocarpon (cranberry) seed oil, nigella sativa (black cumin) seed oil organic, rubus idaeus (raspberry) seed oil, squalane, xanthan gum, polysorbate 80, phenethyl alcohol, glyceryl caprylate, lithium magnesium sodium silicate, hydroxyethyl acrylate/sodium acryloyldimethyltaurate copolymer, sorbitan isostearate, citric acid

dist. by KAS direct, LLC  
San Francisco, CA 94111

## **PRINCIPAL DISPLAY PANEL - Kit Carton**

outdoor essentials

babyganics

SPF 50+

sunscreen spray

broad spectrum SPF 50+

UVA + UVB protection • non-allergenic

water resistant (80 minutes)

natural

insect repellent

plant and essential oils help keep

mosquitoes away

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

6 FL OZ (177 mL)

6 FL OZ (177 mL)



# ☀️ outdoor essentials ❄️



a deet free choice

natural insect repellent



SPF 50+ sunscreen spray

**b** outdoor essentials  
babyganics

## SPF 50+ sunscreen spray

broad spectrum SPF 50+  
UVA + UVB protection · non-allergenic  
water resistant (80 minutes)

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plant and essential oils help keep  
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## outdoor essentials

a deet free choice

### 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%
Total	100.00%

**Directions for Use:** Shake well before each use. 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.

**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.

**Precautionary Statements**  
**CAUTION: Keep Out Of Reach Of Children** 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.

**Prevention:** Thoroughly wash hands after applying; wash treated skin with soap and water after use.

**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.

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 spray

broad spectrum SPF 50+ UVA + UVB protection  
non-allergenic · water resistant (80 minutes)

formulated with: Zinc Oxide, Octocrylene, Octisalate\*  
formulated without: PABA, phthalates, parabens, fragrances or nano-particles



#### Drug Facts

Active ingredients	Purpose
Zinc Oxide 11.20%, Octocrylene 6.0%, Octisalate 5.0%	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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  - after 80 minutes of swimming or sweating
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  - 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, butylcetyl salicylate, steryl octyldodecyl diolate or copolymer, aloë barbadensis leaf juice, glyceryl stearate, polyglyceryl-6 polydicosete, helianthus annuus (sunflower) seed oil, solanum lycopersicum (tomato) seed oil, lactin, polysorbate 60, vaccinium macrocarpon (cranberry) seed oil, nigella arvensis (black currant) seed oil, rubus idaeus (raspberry) seed oil, squalane, xanthan gum, polysorbate 80, phenethyl alcohol, glyceryl caprylate, lithium magnesium sodium silicate, hydroxyethyl acrylate/sodium acryloyldimethyltaurate copolymer, sorbitan laurate, citric acid

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



# outdoor essentials

## SPF 50+ sunscreen spray



## natural insect repellent

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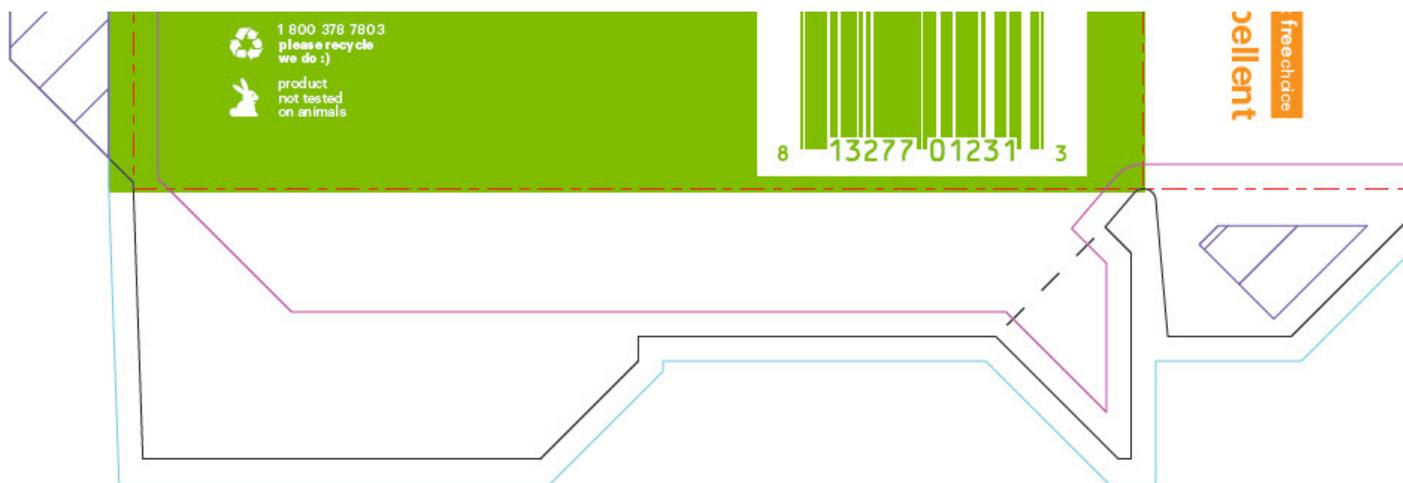


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\*Learn about all our ingredients  
and the choices we make at  
[bobogenics.com/12313](http://bobogenics.com/12313)

050-12313-802





## OUTDOOR ESSENTIALS

zinc oxide, octocrylene, and octisalate kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59062-5400
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59062-5400-1	1 in 1 PACKAGE	01/01/2020	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
<b>Part 1</b>	1 BOTTLE, SPRAY	177 mL
<b>Part 2</b>	1 BOTTLE, SPRAY	177 mL

## Part 1 of 2

### BABYGANICS SPF 50 PLUS SUNSCREEN

zinc oxide, octisalate, and octocrylene spray

### Product Information

<b>Item Code (Source)</b>	NDC:59062-0120
<b>Route of Administration</b>	TOPICAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	112 mg in 1 mL

<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	60 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0K00R)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>STEARYL/OCTYLDODECYL CITRATE CROSSPOLYMER</b> (UNII: PN88NW0KPK)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>POLYGLYCERYL-6 POLYRICINOLEATE</b> (UNII: YPM0ZOC2HR)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>PHENYLETHYL ALCOHOL</b> (UNII: ML9LGA7468)	
<b>GLYCERYL MONOCAPRYLATE</b> (UNII: TM2TZD4G4A)	
<b>LAPONITE</b> (UNII: D703131383)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%)</b> (UNII: 86FQE96TZ4)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>SQUALANE</b> (UNII: GW89575KF9)	
<b>TOMATO SEED OIL</b> (UNII: 7N87T9C06T)	
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>CRANBERRY SEED OIL</b> (UNII: 73KDS3BW5E)	
<b>RASPBERRY SEED OIL</b> (UNII: 9S8867952A)	
<b>NIGELLA SATIVA SEED OIL</b> (UNII: CS4U38E731)	
<b>SORBITAN ISOSTEARATE</b> (UNII: 01S2G2C1E4)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59062-0120-6	177 mL in 1 BOTTLE, SPRAY; 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	07/01/2019	

**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	<b>SOYBEAN OIL</b> (UNII: 241ATL177A)	
INGR	<b>ROSEMARY OIL</b> (UNII: 8LGU7VM393)	
INGR	<b>CITRONELLA OIL</b> (UNII: QYO8Q067D0)	
INGR	<b>GERANIUM OIL, ALGERIAN TYPE</b> (UNII: 5Q1I94P4WG)	
INGR	<b>JUNIPERUS VIRGINIANA OIL</b> (UNII: PAD4FN7P2G)	
INGR	<b>PEPPERMINT OIL</b> (UNII: AV092KU4JH)	
INGR	<b>WEST INDIAN LEMONGRASS OIL</b> (UNII: 5BIA40E9ED)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		177 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		01/01/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/01/2020	

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

Revised: 7/2021

KAS Direct LLC dba BabyGanics