# OUTDOOR EXPLORER SET- titanium dioxide, octisalate, and zinc oxide 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.

-----

### outdoor explorer 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

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

dist. by KAS direct, LLC 1600 Stewart Avenue Westbury, NY 11590

# PRINCIPAL DISPLAY PANEL - Kit Package

bites? burns? we've got you covered

babyganics

outdoor explorer set

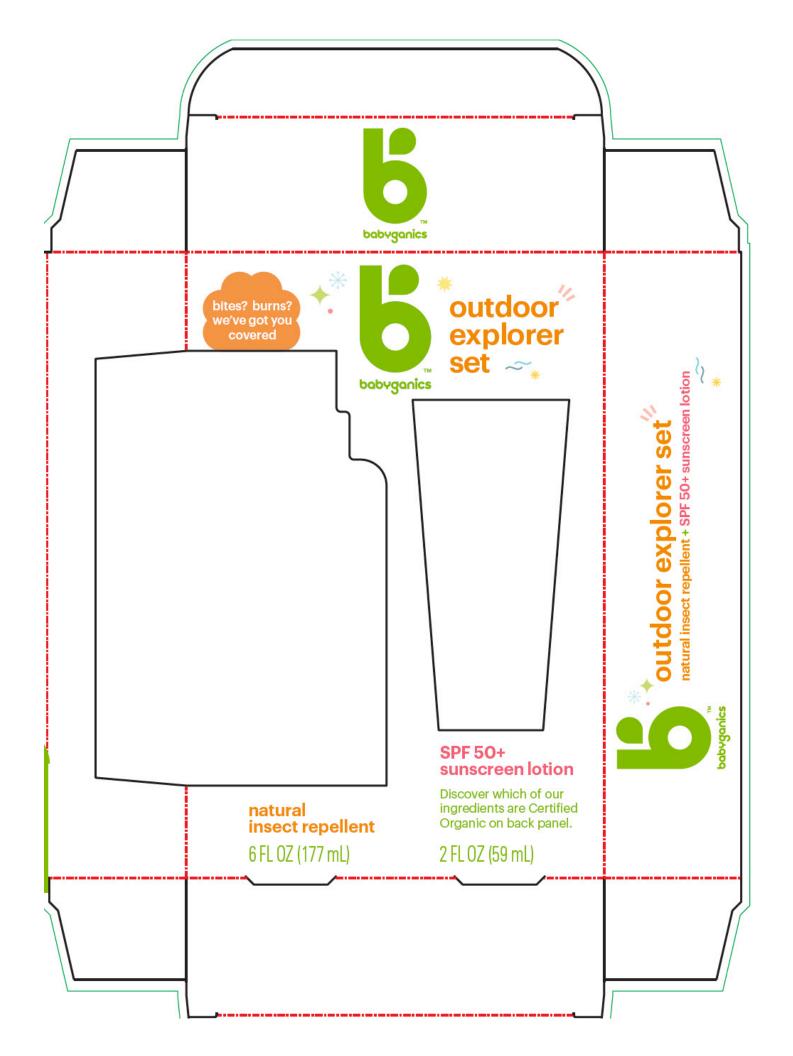
natural insect repellent

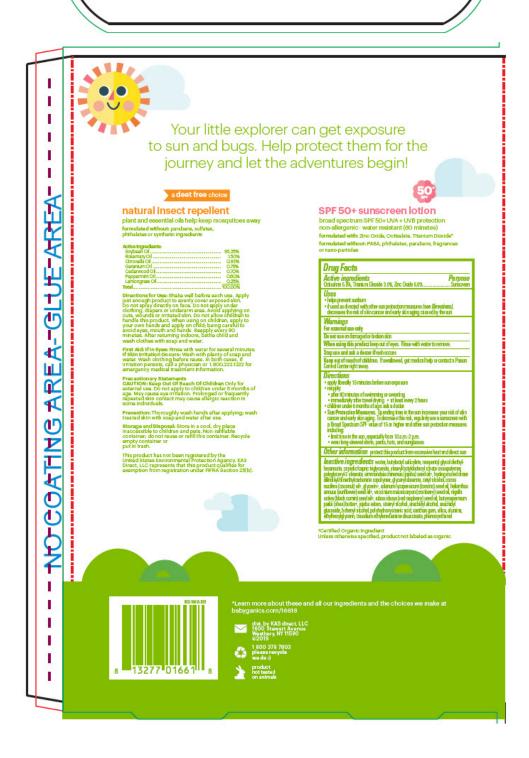
6 FL OZ (177 mL)

SPF 50+ sunscreen lotion

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

2 FL OZ (59 mL)





### **OUTDOOR EXPLORER SET**

titanium dioxide, octisalate, and zinc oxide kit

I I UM	acc	rmation	

Product Type HUMAN OTC DRUG Item Code (Source) NDC:59062-5300

P	Packaging					
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>		
1	NDC:59062-5300-1	1 in 1 PACKAGE	01/01/2018			

Quant	Quantity of Parts		
Part #	Package Quantity	Total Product Quantity	
Part 1	1 TUBE	59 mL	
Part 2	1 BOTTLE, SPRAY	177 mL	

# Part 1 of 2

# **SPF 50 PLUS SUNSCREEN**

titanium dioxide, octisalate, and zinc oxide lotion

Product Information	
Item Code (Source)	NDC:59062-1000
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	<b>Basis of Strength</b>	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	30 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
ZINC OXIDE (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: 2300U9XXE4)		
Glycerin (UNII: PDC6A3C0OX)		
COCONUT OIL (UNII: Q9L0O73W7L)		
TOMATO SEED OIL (UNII: 7N87T9C06T)		
SUNFLOWER OIL (UNII: 3W1JG795YI)		
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: 2KR89I4H1Y)	
Arachidyl Alcohol (UNII: 1QR1QRA9BU)	
Arachidyl Glucoside (UNII: 6JVW35JOOJ)	
DOCOSANOL (UNII: 9G10E216XY)	
POLYHYDROXYSTEARIC ACID STEARATE (UNII: 8KQ7I65XZE)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ALUMINUM OXIDE (UNII: LMI2606933)	
Trisodium Ethylenediamine Disuccinate (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		

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)	

l	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		01/01/2018			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	01/01/2018		
	part352	01/01/2018		

Labeler - KAS Direct LLC dba BabyGanics (002764605)

Revised: 7/2021 KAS Direct LLC dba BabyGanics