## KIDS SPF50 PLUS MINERAL SUNSCREEN CONTINUOUS TOTALLY TROPICALzinc oxide and titanium dioxide spray 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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## Kids SPF50+ Mineral Sunscreen Spray Continuous Totally Tropical Drug Facts

#### **Active ingredients**

Titanium dioxide 3.5%, Zinc oxide 7.25%

#### **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.
- keep away from face to avoid breathing it
- use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.
- do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120°F.

## 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**

- shake well before each use
- hold can 4-6 inches away from the skin to apply

- spray liberally and spread evenly by hand 15 minutes before sun exposure
- do not spray directly into face. Spray on hands then apply to face.
- do not apply in windy conditions
- use in a well-ventilated area
- 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
- may stain or damage some fabrics, materials or surfaces

#### **Inactive ingredients**

water, isododecane, caprylic/capric triglyceride, isohexadecane, C12-15 alkyl benzoate, neopentyl glycol diheptanoate, shea butter ethyl esters, carthamus tinctorius (safflower) seed oil, C30-38 olefin/isopropyl maleate/MA copolymer, butyloctyl salicylate, cocoglucoside, cetearyl alcohol, cetearyl glucoside, cetearyl olivate, sorbitan olivate, ethylhexylglycerin, simmondsia chinensis (jojoba) seed oil<sup>1</sup>, sodium hydroxide, chlorphenesin, xanthan gum, tocopherol, glycerin<sup>1</sup>, sodium phytate, helianthus annuus (sunflower) seed oil<sup>1</sup>, solanum lycopersicum (tomato) seed oil, vaccinium macrocarpon (cranberry) seed oil, nigella sativa (black cumin) seed oil<sup>1</sup>, rubus idaeus (raspberry) seed oil, citric acid, fragrance<sup>2</sup>

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

Dist. by KAS Direct, LLC 1525 Howe St., Racine, WI 53403

## PRINCIPAL DISPLAY PANEL - 170 g Can Blister Pack Label

twin pack

tear

free

kids

by babyganics<sub>®</sub>

easy rub-in

<sup>2</sup> Product formulated with plant-derived fragrance and ingredients chosen with kids in mind. Learn about these and all our ingredients and the choices we make at babyganics.com/products

SPF 50 mineral sunscreen totally tropical

dermatologist tested

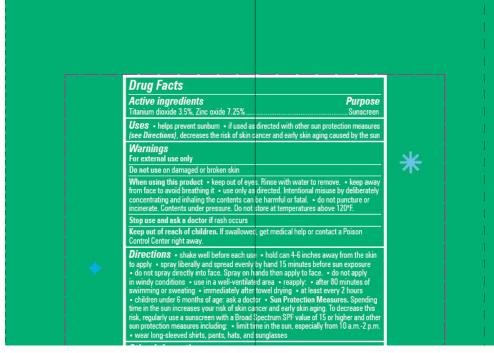
broad spectrum SPF 50 water & sweat resistant (80 minutes)

made without oxybenzone, octinoxate, parabens

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

2 - NET WT 6 OZ (170 g) each







# KIDS SPF50 PLUS MINERAL SUNSCREEN CONTINUOUS TOTALLY TROPICAL

zinc oxide and titanium dioxide spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59062-2400
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	7.25 g in 100 g	
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	3.5 g in 100 g	

Inactive Ingredients	
Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Isododecane (UNII: A8289P68Y2)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
Isohexadecane (UNII: 918X1OUF1E)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
Neopentyl Glycol Diheptanoate (UNII: 5LKW3C543X)	
Shea Butter Ethyl Esters (UNII: V2CI786FPG)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
DIDECYLDIMONIUM CHLORIDE (UNII: JXN4009Y9B)	
Butyloctyl Salicylate (UNII: 2EH13UN8D3)	
Coco Glucoside (UNII: ICS790225B)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
Cetearyl Glucoside (UNII: 09FUA47KNA)	
Cetearyl Olivate (UNII: 58B69Q84JO)	
Sorbitan Olivate (UNII: MDL271E3GR)	
Ethylhexylglycerin (UNII: 147D247K3P)	

JOJOBA OIL (UNII: 724GKU717M)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Chlorphenesin (UNII: I670DAL4SZ)	
Xanthan Gum (UNII: TTV12P4NEE)	
Tocopherol (UNII: R0ZB2556P8)	
Glycerin (UNII: PDC6A3C0OX)	
PHYTATE SODIUM (UNII: 88496G1ERL)	
SUNFLOWER SEED (UNII: R9N3379M4Z)	
TOMATO SEED OIL (UNII: 7N87T9C06T)	
CRANBERRY SEED (UNII: 38Z FO1X2U7)	
NIGELLA SATIVA SEED OIL (UNII: CS4U38E731)	
RUBUS IDAEUS SEED (UNII: M3CL7US2ZG)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:59062- 2400-6	170 g in 1 CAN; Type 0: Not a Combination Product	02/01/2022		
2	NDC:59062- 2400-2	2 in 1 BLISTER PACK	06/01/2022		
2	NDC:59062- 2400-6	170 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
OTC MONOGRAPH NOT FINAL	part352	02/01/2022	

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

Establishment				
Name	Address	ID/FEI	Business Operations	
Fruit of the Earth, Inc.		080086802	MANUFACTURE(59062-2400)	

Revised: 6/2022 KAS Direct LLC dba BabyGanics