

SPF50 PLUS MINERAL SUNSCREEN- zinc 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.

SPF50+ Mineral Sunscreen Spray

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.

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 and spread evenly by hand 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, 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, coco-glucoside, cetearyl alcohol, cetearyl glucoside, cetearyl olivate, sorbitan olivate, ethylhexylglycerin, simmondsia chinensis (jojoba) seed oil¹, sodium hydroxide, chlorphenesin, xanthan gum, tocopherol, glycerin¹, sodium phytate, helianthus annuus (sunflower) seed oil¹, solanum lycopersicum (tomato) seed oil, vaccinium macrocarpon (cranberry) seed oil, nigella sativa (black cumin) seed oil¹, rubus idaeus (raspberry) seed oil, citric acid

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 - 236 mL Bottle Label

non
allergenic

tear
free

babyganics®

SPF 50
mineral
sunscreen

pediatrician tested

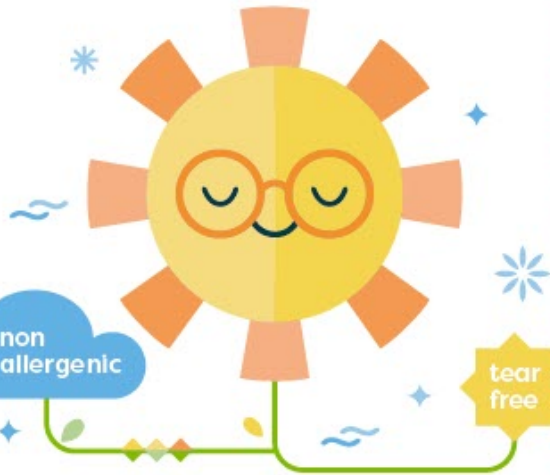
broad spectrum SPF 50
water resistant (80 minutes)

made without oxybenzone, octinoxate,
parabens, fragrance, nano-particles

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

8 FL OZ (236 mL)

1147142



babyganics®

SPF 50
**mineral
sunscreen**

pediatrician tested

broad spectrum SPF 50
water resistant (80 minutes)

 made without oxybenzone, octinoxate, parabens, fragrance, nano-particles

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

8 FL OZ (236 mL)

1147142

dermatologist tested
non-allergenic • tear free

Drug Facts

Active ingredients	Purpose
Titanium dioxide 3.5%, Zinc oxide 7.25%	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 and spread evenly by hand 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, 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, coco-glucoside, cetearyl alcohol, cetearyl glucoside, cetearyl olivate, sorbitan olivate, ethylhexylglycerin, simmondsia chinensis (jojoba) seed oil[†], sodium hydroxide, chlorphenesin, xanthan gum, tocopherol, glycerin[†], sodium phytate, helianthus annuus (sunflower) seed oil[†], solanum lycopersicum (tomato) seed oil, vaccinium macrocarpon (cranberry) seed oil, nigella sativa (black cumin) seed oil[†], rubus idaeus (raspberry) seed oil, citric acid

[†]Certified Organic Ingredient • Unless otherwise specified, product not labeled as organic.

Learn about all our ingredients and the choices we make at babyganics.com/products

©2021 Dist. by KAS Direct, LLC
1525 Howe St., Racine, WI 53403
1 800 378 7803



 made without oxybenzone & octinoxate

 please recycle bottle (less pump)



SPF50 PLUS MINERAL SUNSCREEN

zinc oxide and titanium dioxide spray

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:59062-2210

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	7.25 g in 100 mL
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	3.5 g in 100 mL

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 Olivat (UNII: 58B69Q84JO)	
Sorbitan Olivat (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: 38ZFO1X2U7)	
NIGELLA SATIVA SEED OIL (UNII: CS4U38E731)	
RUBUS IDAEUS SEED (UNII: M3CL7US2ZG)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59062-2210-6	170 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	02/01/2022	
2	NDC:59062-2210-8	236 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	02/01/2022	

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(59062-2210)

Revised: 3/2022

KAS Direct LLC dba BabyGanics