SPF50 PLUS MINERAL SUNSCREEN- zinc oxide and titanium dioxide spray KAS Direct LLC dba BabyGanics

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 useon damaged or broken skin

When using this productkeep out of eyes. Rinse with water to remove.

Stop use and ask a doctor ifrash 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, cocoglucoside, cetearyl alcohol, cetearyl glucoside, cetearyl olivate, sorbitan olivate, ethylhexylglycerin, simmondsia chinensis (jojoba) seed oil ¹, sodium hydroxide, chlorphenesin, xanthan gum, tocopherol, glycerin ¹, sodium phytate, helianthus annuus (sunflower) seed oil ¹, solanum lycopersicum (tomato) seed oil, vaccinium macrocarpon (cranberry) seed oil, nigella sativa (black cumin) seed oil ¹, 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



dermatologist tested non-allergenic • tearfree

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



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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			

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: 1670DAL4SZ)	
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	
	NDC:59062- 2210-6	170 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	02/01/2022		
	NDC:59062- 2210-8	236 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	02/01/2022		

Marketing In	keting Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC Monograph Drug	M020	02/01/2022			

Labeler - KAS Direct LLC dba BabyGanics (002764605)

Revised: 10/2024 KAS Direct LLC dba BabyGanics