

SPF 50 MINERAL SUNSCREEN BABYGANICS- titanium dioxide and zinc oxide lotion

SPF 50 MINERAL SUNSCREEN BKIDS- titanium dioxide and zinc oxide lotion

KAS Direct LLC dba BabyGanics

SPF 50 Mineral Sunscreen

Drug Facts

Active ingredients

Titanium dioxide 3%, Zinc oxide 12%

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, ethylhexyl palmitate, butyloctyl salicylate, caprylic/capric triglyceride, trimethylpentanediol/adipic acid/glycerin crosspolymer, cetearyl olivate, glycerin, sorbitan olivate, tocopheryl acetate, phenoxyethanol, cetearyl alcohol, cetearyl glucoside, propanediol, alumina, xanthan gum, jojoba esters, 1,2-hexanediol, bisabolol, helianthus annuus (sunflower) seed oil¹, solanum lycopersicum (tomato) seed oil, lecithin, polyhydroxystearic acid, caprylhydroxamic acid, citric acid, isopropyl myristate, isostearic acid, polyglyceryl-3 polyricinoleate, vaccinium macrocarpon (cranberry) seed oil, nigella sativa (black cumin) seed oil¹, rubus idaeus (red raspberry) seed oil

1 Certified Organic Ingredient • Unless otherwise specified, product not labeled as organic • *Learn about these and all our ingredients and the choices we make at babyorganics.com/products

dist. by KAS Direct, LLC
san francisco, ca 94111

PRINCIPAL DISPLAY PANEL - 59 mL Tube Label - 59062-1001

non
allergenic

tear
free

babyorganics®

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 the back panel.

2 FL OZ (59 mL)



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reef safe
made without oxybenzone & octinoxate

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PRINCIPAL DISPLAY PANEL - 59 mL Tube Label - 59062-1101

tear free
kids by babyganics®
easy rub-in
SPF 50 mineral sunscreen
dermatologist tested
broad spectrum SPF 50 water & sweat resistant (80 minutes)
made without oxybenzone, octinoxate, parabens, fragrance
Discover which of our ingredients are

certified organic on the back panel.

2 FL OZ (59 mL)



easy rub-in

SPF 50
mineral
sunscreen

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broad spectrum SPF 50
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SPF 50 MINERAL SUNSCREEN BABYGANICS

titanium dioxide and zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59062-1001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	31.6 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	120 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
Ethylhexyl Palmitate (UNII: 2865993309)	
Butyloctyl Salicylate (UNII: 2EH13UN8D3)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
TRIMETHYLPENTANEDIOL/ADIPIC ACID/GLYCERIN CROSSPOLYMER (25000 MPA.S) (UNII: 587WKM3S9Q)	
Cetearyl Olivat e (UNII: 58B69Q84JO)	
GLYCERIN (UNII: PDC6A3C0OX)	
Sorbitan Olivat e (UNII: MDL271E3GR)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
Cetearyl Glucoside (UNII: 09FUA47KNA)	
Propanediol (UNII: 5965N8W85T)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
XANTHAN GUM (UNII: TTV12P4NEE)	
JOJOBA OIL, RANDOMIZED (UNII: 7F0EV20QYL)	
1,2-Hexanediol (UNII: TR046Y3K1G)	
.ALPHA.-BISABOLOL, (+/-)- (UNII: 36HQN158VC)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
TOMATO SEED OIL (UNII: 7N87T9C06T)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
Caprylhydroxamic Acid (UNII: UPY805K99W)	
Isopropyl Myristate (UNII: ORE8K4LNJS)	
Isostearic Acid (UNII: X33R8U0062)	
POLYGLYCERYL-3 PENTARICINOLEATE (UNII: 7Q0OK5DOT4)	
CRANBERRY SEED OIL (UNII: 73KDS3BW5E)	
Nigella Sativa Seed Oil (UNII: CS4U38E731)	
RASPBERRY SEED OIL (UNII: 9S8867952A)	
SOYBEAN LECITHIN (UNII: 1DI56QDM62)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59062-1001-2	59 mL in 1 TUBE; Type 0: Not a Combination Product	03/01/2021	12/31/2025
2	NDC:59062-1001-6	177 mL in 1 TUBE; Type 0: Not a Combination Product	03/01/2021	12/31/2025
3	NDC:59062-1001-8	226 mL in 1 TUBE; Type 0: Not a Combination Product	03/01/2021	12/31/2025

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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SPF 50 MINERAL SUNSCREEN BKIDS

titanium dioxide and zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59062-1101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	31.6 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	120 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
Ethylhexyl Palmitate (UNII: 2865993309)	
Butyloctyl Salicylate (UNII: 2EH13UN8D3)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
TRIMETHYLPENTANEDIOL/ADIPIC ACID/GLYCERIN CROSSPOLYMER (25000 MPA.S) (UNII: 587WKM3S9Q)	
Cetearyl Olivat e (UNII: 58B69Q84JO)	
GLYCERIN (UNII: PDC6A3C0OX)	
Sorbitan Olivat e (UNII: MDL271E3GR)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
Cetearyl Glucoside (UNII: 09FUA47KNA)	
Propanediol (UNII: 5965N8W85T)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
XANTHAN GUM (UNII: TTV12P4NEE)	
JOJOBA OIL, RANDOMIZED (UNII: 7F0EV20QYL)	
1,2-Hexanediol (UNII: TR046Y3K1G)	
.ALPHA.-BISABOLOL, (+/-)- (UNII: 36HQN158VC)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
TOMATO SEED OIL (UNII: 7N87T9C06T)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
Caprylhydroxamic Acid (UNII: UPY805K99W)	
Isopropyl Myristate (UNII: 0RE8K4LNJS)	
Isostearic Acid (UNII: X33R8U0062)	
POLYGLYCERYL-3 PENTARICINOLEATE (UNII: 7Q0OK5DOT4)	
CRANBERRY SEED OIL (UNII: 73KDS3BW5E)	
Nigella Sativa Seed Oil (UNII: CS4U38E731)	
RASPBERRY SEED OIL (UNII: 9S8867952A)	

SOYBEAN LECITHIN (UNII: 1DI56QDM62)

CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)

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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59062-1101-2	59 mL in 1 TUBE; Type 0: Not a Combination Product	03/01/2021	12/31/2025
2	NDC:59062-1101-6	177 mL in 1 TUBE; Type 0: Not a Combination Product	03/01/2021	12/31/2025

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph drug	M020	03/01/2021	12/31/2025

Labeler - KAS Direct LLC dba BabyGanics (002764605)

Establishment

Name	Address	ID/FEI	Business Operations
Autumn Harp		064187883	MANUFACTURE(59062-1001, 59062-1101)

Revised: 12/2024

KAS Direct LLC dba BabyGanics