SPF 50 PLUS SUNSCREEN ALL MINERAL ACTIVE INGREDIENTS- titanium dioxide and zinc oxide stick

KIDS SPF 50 PLUS SUNSCREEN ALL MINERAL ACTIVE INGREDIENTS- titanium dioxide and zinc oxide stick

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.

SPF 50+ Sunscreen Stick All Mineral Active Ingredients

Drug Facts

Active ingredients

Titanium Dioxide 7.9%, Zinc Oxide 6.7%

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 evenly 15 minutes before sun exposure
- reapply:
 - after 80 minutes of swimming or sweating
 - immediately after towel drying
 - at least every 2 hours
- this product is meant for targeted protection and small areas of exposed skin

- for full protection use in conjunction with another sunscreen lotion or spray
- 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
- keep outer card for full drug facts

Inactive ingredients

C12-15 alkyl benzoate, caprylic/capric triglyceride, beeswax¹, copernicia cerifera (carnauba) wax¹, neopentyl glycol diethylhexanoate, tribehenin, euphorbia cerifera (candelilla) wax, PPG-3 benzyl ether myristate, hydrogenated dimer dilinoleyl/dimethylcarbonate copolymer, helianthus annuus (sunflower) seed wax, myristyl myristate, stearyl/octadodecyl citrate crosspolymer, simmondsia chinensis (jojoba) seed oil¹, polyglyceryl-10 pentaoleate, jojoba esters, solanum lycopersicum (tomato) seed oil, helianthus annuus (sunflower) seed oil¹, vaccinium macrocarpon (cranberry) seed oil, nigella sativa (black cumin) seed oil¹, rubus idaeus (raspberry) seed oil, polyhydroxystearic acid, caprylyl glycol, ethylhexylglycerin, silica, alumina

1 Certified Organic Ingredient • Unless otherwise specified, product not labeled as organic dist. by KAS direct, LLC Westbury, NY 11590

PRINCIPAL DISPLAY PANEL - 13 g Applicator Blister Pack

babyganics_®
SPF 50 mineral sunscreen
broad spectrum SPF 50
pediatrician
&
dermatologist
tested

water resistant (80 minutes)

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





PRINCIPAL DISPLAY PANEL - 45.5 g Applicator Label

50+

SPF

babyganics

kids

SPF 50+ sunscreen stick all mineral active ingredients

broad spectrum SPF 50+ UVA + UVB protection non-allergenic • water & sweat resistant (80 minutes) tear free • pediatrician & dermatologist tested

formulated with: Titanium Dioxide, Zinc Oxide*

formulated without: PABA phthalates • parabens fragrances • nano-particles

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

Net. Wt. 1.6 OZ (45.5 g)

040-17936-B01



SPF 50+ sunscreen stick all mineral active ingredients

broad spectrum SPF 50+ UVA + UVB protection non-allergenic • water & sweat resistant (80 minutes) tear free • pediatrician & dermatologist tested

formulated with: Titanium

formulated without: PABA phthalates • parabens fragrances • nano-particles

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

Net. Wt. 1.6 OZ (45.5 g)





lift here

The Skin Cancer Foundation recommends this product as an effective broad spectrum sunscreen.



dist. by KAS direct, LLC Westbury, NY 11590 @2018



1 800 378 7803 please recycle we do :)



not tested on animals



pediatrician & dermatologist tested

Drug Facts

Active ingredients

Titarium Dioxide 7.9%, Zinc Oxide 6.7%..

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

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7986-B01

Directions

- · apply liberally and evenly 15 minutes before sun exposure
- . after 80 minutes of swimming or sweating
- immediately after towel drying
- · at least every 2 hours
- . this product is meant for targeted protection and small areas of exposed skin
- for full protection use in conjunction with another sunscreen lotion
- 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 C12-15 akylberzoate, caprylic/capric triglyceride, beeswax+, copernicia cerifera (carnauba) wax+, neopentyl glycol diethylhexanoate, tribehenin, euphorbia cerifera (candelilla) wax, PPG-3 benzyl ether myristate, hydrogenated dimer dilinoleyl/dimethylcarbonate copolymer, helianthus annuus (sunflower) seed wax, myristyl myristate, stearyl/octadodecyl citrate crosspolymer, simmondsia chinensis (jojoba) seed oil†, polyglyceryl-10 pentaoleate, jojoba esters, solanum lycopersicum (tomato) seed oil, helianthus annuus (sunflower) seed oil+, vaccinium macrocarpon (cranberry) seed oil, nigella sativa (black cumin) seed oil+, rubus idaeus (raspberry) seed oil, polyhydroxystearic acid, caprylyl glycol, ethylhexylglycerin, silica, alumina

†Certified Organic Ingredient Unless otherwise specified, product not labeled as

organic

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SPF 50 PLUS SUNSCREEN ALL MINERAL ACTIVE INGREDIENTS

titanium dioxide and zinc oxide stick

Product Information	Product Information		
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59062-1200
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	79 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	67 mg in 1 g

Ingredient Name	Strength
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
NEOPENTYL GLYCOL DIETHYLHEXANOATE (UNII: U68ZV6W62C)	
TRIBEHENIN (UNII: 80C9U7TQZ0)	
CANDELILLA WAX (UNII: WL0328HX19)	
PPG-3 BENZYL ETHER MYRISTATE (UNII: 8075L58MKO)	
MYRISTYL MYRISTATE (UNII: 4042ZC00DY)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
Stearyl/Octyldodecyl Citrate Crosspolymer (UNII: PN88NW0KPK)	
JOJOBA OIL (UNII: 724GKU717M)	
Polyglyceryl-10 Pentaoleate (UNII: BH1TF96DJC)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
JOJOBA OIL, RANDOMIZED (UNII: 7F0EV20QYL)	
RASPBERRY SEED OIL (UNII: 9S8867952A)	
CRANBERRY SEED OIL (UNII: 73KDS3BW5E)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
TOMATO SEED OIL (UNII: 7N87T9C06T)	
NIGELLA SATIVA SEED OIL (UNII: CS4U38E731)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Aluminum Oxide (UNII: LMI26O6933)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:59062- 1200-1	1 in 1 BLISTER PACK	06/21/2013		
1		13 g in 1 APPLICATOR; Type 0: Not a Combination Product			
2	NDC:59062- 1200-2	2 in 1 BLISTER PACK	06/21/2013		
2		13 g in 1 APPLICATOR; 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	06/21/2013	

KIDS SPF 50 PLUS SUNSCREEN ALL MINERAL ACTIVE INGREDIENTS

titanium dioxide and zinc oxide stick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59062-2200
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	79 mg in 1 g	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	67 mg in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
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YELLOW WAX (UNII: 2ZA36H0S2V)		
CARNAUBA WAX (UNII: R12CBM0EIZ)		
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)		
NEOPENTYL GLYCOL DIETHYLHEXANOATE (UNII: U68ZV6W62C)		
TRIBEHENIN (UNII: 80C9U7TQZ0)		
CANDELILLA WAX (UNII: WL0328HX19)		
PPG-3 BENZYL ETHER MYRISTATE (UNII: 8075L58MKO)		
MYRISTYL MYRISTATE (UNII: 4042ZC00DY)		
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)		
Stearyl/Octyldodecyl Citrate Crosspolymer (UNII: PN88NW0KPK)		

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Polyglyceryl-10 Pentaoleate (UNII: BH1TF96DJC)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
JOJOBA OIL, RANDOMIZED (UNII: 7F0EV20QYL)	
RASPBERRY SEED OIL (UNII: 9S8867952A)	
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SUNFLOWER OIL (UNII: 3W1JG795YI)	
TOMATO SEED OIL (UNII: 7N87T9C06T)	
NIGELLA SATIVA SEED OIL (UNII: CS4U38E731)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
Silicon Dioxide (UNII: ETJ7Z 6XBU4)	
Aluminum Oxide (UNII: LMI26O6933)	

Packaging				
# Item Code Package Description		Marketing Start Date	Marketing End Date	
1	NDC:59062- 2200-4	45.5 g in 1 APPLICATOR; Type 0: Not a Combination Product	06/21/2013	

Marketing Info	Marketing Information		
Marketing Category Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	06/21/2013	

Labeler - KAS Direct LLC dba BabyGanics (002764605)

Revised: 6/2022 KAS Direct LLC dba BabyGanics