

SUNCARE ESSENTIALS- titanium dioxide, octisalate, and zinc oxide
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.

suncare essentials

SPF 50+ sunscreen lotion

Drug Facts

Active ingredients

Octisalate 5.0%, Titanium Dioxide 3.0%, Zinc Oxide 6.0%

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, butyloctyl salicylate, neopentyl glycol diethylhexanoate, caprylic/capric triglyceride, stearyl/octyldodecyl citrate crosspolymer, polyglyceryl-2 stearate, simmondsia chinensis (jojoba) seed oil¹, hydrogenated dimer dilinoleyl/dimethylcarbonate copolymer, glyceryl stearate, cetyl alcohol, cocos nucifera (coconut) oil¹, glycerin¹, solanum lycopersicum (tomato) seed oil, helianthus annuus (sunflower) seed oil¹, vaccinium macrocarpon (cranberry) seed oil, nigella sativa (black cumin) seed oil¹, rubus idaeus (red raspberry) seed oil, butyrospermum parkii (shea) butter¹, jojoba esters, stearyl alcohol, arachidyl alcohol, arachidyl glucoside, behenyl alcohol, polyhydroxystearic acid, xanthan gum, silica, alumina, ethylhexylglycerin, trisodium ethylenediamine disuccinate, phenoxyethanol

¹ Certified Organic Ingredient

Unless otherwise specified, product not labeled as organic

SPF 50+ sunscreen stick

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 of 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 card for full drug facts

Inactive ingredients

C12-15 alkyl benzoate, caprylic/capric triglyceride, beeswax², copernicia cerifera (carnauba) wax², 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 oil², polyglyceryl-10 pentaoleate, jojoba esters, solanum lycopersicum (tomato) seed oil, helianthus annuus (sunflower) seed oil², vaccinium macrocarpon (cranberry) seed oil, nigella sativa (black cumin) seed oil², rubus idaeus (raspberry) seed oil, polyhydroxystearic acid, caprylyl glycol, ethylhexylglycerin, silica, alumina

² Certified Organic Ingredient

Unless otherwise specified, product not labeled as organic

dist. by KAS direct, LLC
1600 Stewart Avenue
Westbury, NY 11590

PRINCIPAL DISPLAY PANEL - Kit Package

babyganics

suncare essentials
SPF 50+

we've got
you covered
from head
to toe!

SPF 50+ sunscreen lotion
6 FL OZ (177mL)

SPF 50+
sunscreen stick
Net wt 0.47 OZ (13 g)



suncare essentials
SPF 50+

we've got
you covered
from head
to toe!



SPF 50+ sunscreen lotion
6 FL OZ (177 mL)

SPF 50+
sunscreen stick
Net wt 0.47 OZ (13 g)



SUNCARE ESSENTIALS

titanium dioxide, octisalate, and zinc oxide kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59062-5100
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59062-5100-1	1 in 1 PACKAGE	01/01/2017	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	177 mL
Part 2	1 APPLICATOR	13 g

Part 1 of 2

SPF 50 PLUS SUNSCREEN

titanium dioxide, octisalate, and zinc oxide lotion

Product Information

Item Code (Source)	NDC:59062-1000
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	30 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	60 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
Butyloctyl Salicylate (UNII: 2EH13UN8D3)	
Neopentyl Glycol Diethylhexanoate (UNII: U68ZV6W62C)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
Stearyl/Octyldodecyl Citrate Crosspolymer (UNII: PN88NW0KPK)	
Polyglyceryl-2 Stearate (UNII: 253MC0P0YV)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
JOJOBA OIL (UNII: 724GKU717M)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
GLYCERIN (UNII: PDC6A3C0OX)	
COCONUT OIL (UNII: Q9L0O73W7L)	
TOMATO SEED OIL (UNII: 7N87T9C06T)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
CRANBERRY SEED OIL (UNII: 73KDS3BW5E)	
Nigella Sativa Seed Oil (UNII: CS4U38E731)	
RASPBERRY SEED OIL (UNII: 9S8867952A)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SHEA BUTTER (UNII: K49155WL9Y)	
JOJOBA OIL, RANDOMIZED (UNII: 7F0EV20QYL)	
Stearyl Alcohol (UNII: 2KR89I4HIY)	
Arachidyl Alcohol (UNII: 1QR1QRA9BU)	
Arachidyl Glucoside (UNII: 6JVW35JOOJ)	
DOCOSANOL (UNII: 9G1OE216XY)	
POLYHYDROXYSTEARIC ACID STEARATE (UNII: 8KQ7I65XZE)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ALUMINUM OXIDE (UNII: LM26O6933)	
Trisodium Ethylenediamine Disuccinate (UNII: YA22H34H9Q)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59062-1000-6	177 mL in 1 TUBE; 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	07/24/2017	

Part 2 of 2

SPF 50 PLUS SUNSCREEN ALL MINERAL ACTIVE INGREDIENTS

titanium dioxide and zinc oxide stick

Product Information

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

Inactive Ingredients

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: 8OC9U7TQZ0)	
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: 3W1JG795Y)	
TOMATO SEED OIL (UNII: 7N87T9C06T)	
NIGELLA SATIVA SEED OIL (UNII: CS4U38E731)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ALUMINUM OXIDE (UNII: LM26O6933)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59062-1200-1	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	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	01/01/2017	

Labeler - KAS Direct LLC dba BabyGanics (002764605)

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KAS Direct LLC dba BabyGanics