

SPF 50 PLUS SUNSCREEN- titanium dioxide, octisalate, and zinc oxide lotion

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 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

dist. by KAS direct, LLC

Westbury, NY 11590

PRINCIPAL DISPLAY PANEL - 177 mL Tube Label

50⁺

SPF

tear

free

water

resistant

babyanics

SPF 50+

sunscreen

lotion

broad spectrum SPF 50+

UVA + UVB protection

water resistant (80 minutes)

non-allergenic • pediatrician

& dermatologist tested

formulated with: Zinc Oxide,

Octisalate, Titanium Dioxide*

formulated without: PABA

phthalates • parabens

fragrances • nano-particles

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

6 FL OZ (177mL)

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*Learn more about these and all our ingredients and the choices we make at babyganics.com/12108

Broad Spectrum UVA + UVB protection:

Zinc Oxide

Octisalate

Titanium Dioxide



dist. by KAS direct, LLC
Westbury, NY 11590
©2018
1 800 378 7803
please recycle
we do it!
product
not tested
on animals
pediatrician &
dermatologist
tested

028-12108-801



SPF 50+ sunscreen lotion

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

formulated with: Zinc Oxide,
Octisalate, Titanium Dioxide*

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

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

6 FL OZ (177 mL)

SPF 50 PLUS SUNSCREEN

titanium dioxide, octisalate, and zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59062-1000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9 V2JP) (Titanium Dioxide - UNII:15FIX9 V2JP)	Titanium Dio xide	30 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	50 mg in 1 mL

ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	60 mg in 1 mL
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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: 6JVVW35JOOJ)	
Docosanol (UNII: 9G1OE216XY)	
POLYHYDROXYSTEARIC ACID STEARATE (UNII: 8KQ7I65XZE)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Aluminum Oxide (UNII: LMI26O6933)	
Trisodium Ethylenediamine Disuccinate (UNII: YA22H34H9Q)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59062-1000-2	59 mL in 1 TUBE; Type 0: Not a Combination Product	07/24/2017	
2	NDC:59062-1000-6	177 mL in 1 TUBE; Type 0: Not a Combination Product	07/24/2017	
3	NDC:59062-1000-8	236 mL in 1 TUBE; Type 0: Not a Combination Product	07/24/2017	
4	NDC:59062-1000-1	354 mL in 1 TUBE; Type 0: Not a Combination Product	07/24/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	07/24/2017	

