# KIDS 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.

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#### Kids 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 San Francisco, CA 94111

#### PRINCIPAL DISPLAY PANEL - 177 mL Tube Label

water resistant

50<sup>+</sup> SPF

babyganics

kids SPF 50+ sunscreen lotion

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

formulated with: Zinc Oxide, Octisalate, Titanium Dioxide\*

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

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

6 FL OZ (177mL)



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- †Certified Organic Ingredient Unless otherwise specified, product not labeled as organic
- \*Learn more about these and all our ingredients and the choices we make at babyganics.com/17004



Broad Spectrum UVA + UVB protection:



Zinc Oxide



Octisalate



Titanium Dioxide





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please recycle we do :)



product not tested on animals



pediatrician & dermatologist tested

reef safe formulated without oxybenzone and octinoxate



#### KIDS SPF 50 PLUS SUNSCREEN

titanium dioxide, octisalate, and zinc oxide lotion

Product information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59062-1100	

Route of Administration TOPICAL

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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: 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		

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)	
ojoba Oil (UNII: 724GKU717M)	
Glyceryl Monostearate (UNII: 230 O U9 XXE4)	
GLYCERIN (UNII: PDC6 A3C0 OX)	
Coconut Oil (UNII: Q9L0O73W7L)	
Tomato Seed Oil (UNII: 7N87T9C06T)	
Gunflower Oil (UNII: 3W1JG795YI)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
Cranberry Seed Oil (UNII: 73KDS3BW5E)	
Nigella Sativa Seed Oil (UNII: CS4U38E731)	
Raspberry Seed Oil (UNII: 9S8867952A)	
PHENO XYETHANO L (UNII: HIE49 2ZZ3T)	
KANTHAN GUM (UNII: TTV12P4NEE)	
Shea Butter (UNII: K49155WL9Y)	
OJOBA OIL, RANDOMIZED (UNII: 7F0 EV20 QYL)	
Stearyl Alcohol (UNII: 2KR8914H1Y)	
Arachidyl Alcohol (UNII: 1QR1QRA9BU)	
Arachidyl Glucoside (UNII: 6JVW35JOOJ)	
Occosanol (UNII: 9G10E216XY)	
POLYHYDRO XYSTEARIC ACID STEARATE (UNII: 8 KQ7I65XZE)	
Gilicon Dioxide (UNII: ETJ7Z6XBU4)	
Aluminum Oxide (UNII: LMI26O6933)	
Trisodium Ethylenediamine Disuccinate (UNII: YA22H34H9Q)	

F	Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
1	NDC:59062-1100-2	59 mL in 1 TUBE; Type 0: Not a Combination Product	07/24/2017		
2	NDC:59062-1100-6	177 mL in 1 TUBE; Type 0: Not a Combination Product	07/24/2017		
3	NDC:59062-1100-1	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		

Revised: 7/2020 KAS Direct LLC dba BabyGanics