

BABYGANICS SUNSCREEN 30SPF- titanium dioxide 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.

babyganics® Sunscreen Lotion 30SPF

Drug Facts

Active ingredients

Titanium dioxide 3.0%, Zinc oxide 3.0%

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 40 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, cetearyl olivate, cocos nucifera (coconut) oil, sorbitan olivate, caprylic/capric triglyceride, carthamus tinctorius (safflower) seed oil, cetyl alcohol, stearyl/octadodecyl citrate crosspolymer, glycerin, ozokerite, simmondsia chinensis (jojoba) seed oil, butyrospermum parkii (shea) butter, theobroma cacao (cocoa) seed butter, jojoba esters, squalane, glyceryl caprylate, arachidyl alcohol, behenyl alcohol, arachidyl glucoside, sucrose stearate, stearic acid, polyglyceryl-2 caprate, xanthan gum, polyhydroxystearic acid, silica, alumina, trisodium ethylenediamine disuccinate, ethylhexylglycerin, phenoxyethanol

Dist. by:

KAS Direct, LLC.

Hicksville, NY 11801

PRINCIPAL DISPLAY PANEL - 118 mL Tube Label

30

SPF

tear

free

water

resistant

babyganics®

pure mineral

sunscreen

broad spectrum SPF 30

UVA + UVB protection

water resistant

(40 minutes)

non-allergenic

no: chemical sunscreen,

PABA, phthalates, parabens,

fragrances or nano-particles

4 FL OZ (118mL)

Drug Facts

Active ingredients

Titanium dioxide 3.0%, Zinc oxide 3.0%..... Sunscreen

Purpose

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 40 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, cetearyl olivate, cocos nucifera (coconut) oil, sorbitan olivate, caprylic/capric triglyceride, carthamus tinctorius (safflower) seed oil, cetyl alcohol, stearyl/octadodecyl citrate crosspolymer, glycerin, ozokerite, simmondsia chinensis (jojoba) seed oil, butyrospermum parkii (shea) butter, theobroma cacao (cocoa) seed butter, jojoba esters, squalane, glyceryl caprylate, arachidyl alcohol, behenyl alcohol, arachidyl glucoside, sucrose stearate, stearic acid, polyglyceryl-2 caprate, xanthan gum, polyhydroxystearic acid, silica, alumina, trisodium ethylenediamine disuccinate, ethylhexylglycerin, phenoxyethanol



pediatrician +
dermatologist
tested



to learn more,
please visit
babyganics.com



© 2014 dist. by
KAS direct, LLC
Westbury, NY 11590



1 800 378 7803
please recycle
we do :)



made in the USA
never tested
on animals

028-01227-02



babyganics®

pure mineral sunscreen

broad spectrum SPF 30

UVA + UVB protection
water resistant
(40 minutes)
non-allergenic

no: chemical sunscreen,
PABA, phthalates, parabens,
fragrances or nano-particles

4 FL OZ (118mL)

BABYGANICS SUNSCREEN 30SPF

titanium dioxide and zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59062-1227
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name		Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)		TITANIUM DIOXIDE 30 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)		ZINC OXIDE 30 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
COCONUT OIL (UNII: Q9L0O73W7L)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
MONOSTEARYL CITRATE (UNII: YWW937R1QR)	
GLYCERIN (UNII: PDC6A3C0OX)	
CERESIN (UNII: Q1LS2UJO3A)	
JOJOBA OIL (UNII: 724GKU717M)	
SHEA BUTTER (UNII: K49155WL9Y)	
COCOA BUTTER (UNII: 512OYT1CRR)	
DECYL JOJOBATE (UNII: ZL61O8TFZU)	
SQUALANE (UNII: GW89575KF9)	
GLYCERYL MONOCAPRYLATE (UNII: TM2TZD4G4A)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
DOCOSANOL (UNII: 9G1OE216XY)	
ARACHIDYL GLUCOSIDE (UNII: 6JVV35JOOJ)	
SUCROSE STEARATE (UNII: 274KW0O50M)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
XANTHAN GUM (UNII: TTV12P4NEE)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TRISODIUM ETHYLENEDIAMINE DISUCCINATE (UNII: YA22H34H9Q)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59062-1227-1	118 mL in 1 TUBE; Type 0: Not a Combination Product	06/21/2013	

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: 2/2020

KAS Direct LLC dba BabyGanics