

BABYGANICS SUNSCREEN 30 SPF- zinc oxide, octinoxate, and octisalate spray
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 Spray 30 SPF

Drug Facts

Active ingredients

Octinoxate 5.0%, Octisalate 4.0%, Zinc oxide 11.2%

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, caprylic/capric triglyceride, glycerin, vp/hexadecene copolymer, aloe barbadensis leaf juice, glyceryl stearate, hexaglyceryl polyricinoleate, polysorbate 80, phenethyl alcohol, glyceryl caprylate, sodium magnesium silicate, xanthan gum, hydroxyethyl acrylate/sodium acryloyldimethyltaurate copolymer, squalane, citric acid, lecithin, polysorbate 60, sorbitan isostearate.

Dist. by:

KAS Direct, LLC.

Hicksville, NY 11801

PRINCIPAL DISPLAY PANEL - 177 mL Bottle Label

30

SPF

tear

free

water

resistant

babyanics®

mineral-based

sunscreen spray

broad spectrum SPF 30

UVA + UVB protection

water resistant (80 minutes)

non-allergenic

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

6 FL OZ (177mL)

040-12290-01

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pediatrician + dermatologist tested

to learn more, please visit babyganics.com

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1800 378 7803 please recycle we do :)

made in the USA never tested on animals

BABYGANICS SUNSCREEN 30 SPF			
zinc oxide, octinoxate, and octisalate spray			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59062-1229
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	112 mg in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	50 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	40 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
GLYCERIN (UNII: PDC6A3C0OX)	
HEXADECYL POVIDONE (UNII: AG75W62QYU)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
POLYGLYCERYL-6 DIOLEATE (UNII: 062SZD3F3X)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	
GLYCERYL MONOCAPRYLATE (UNII: TM2TZD4G4A)	
SODIUM MAGNESIUM FLUORO SILICATE (UNII: U1QJ22MC8E)	
XANTHAN GUM (UNII: TTV12P4NEE)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPAS AT 1.5%) (UNII: 86FQE96TZ4)	
SQUALANE (UNII: GW89575KF9)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59062-1229-1	177 mL in 1 BOTTLE, DISPENSING; 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)