

BABYGANICS SPF 50 PLUS SUNSCREEN- zinc oxide, octisalate, and octocrylene 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 SPF 50+ SUNSCREEN SPRAY

Drug Facts

Active ingredients

Zinc Oxide 11.20%, Octocrylene 6.0%, Octisalate 5.0%

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
- do not spray directly into face. Spray on hands then apply to face.
- 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, butyloctyl salicylate, stearyl/octyldodecyl citrate crosspolymer, aloe barbadensis leaf juice, glyceryl stearate, polyglyceryl-6 polyricinoleate, helianthus annuus (sunflower) seed oil, solanum lycopersicum (tomato) seed oil, lecithin, polysorbate 60, vaccinium macrocarpon (cranberry) seed oil, nigella sativa (black cumin) seed oil organic, rubus idaeus (raspberry) seed oil, squalane, xanthan gum, polysorbate 80, phenethyl alcohol, glyceryl caprylate, lithium magnesium sodium silicate, hydroxyethyl acrylate/sodium acryloyldimethyltaurate copolymer, sorbitan isostearate, citric acid

dist. by KAS Direct, LLC.
Westbury, NY 11590

PRINCIPAL DISPLAY PANEL - 177 mL Bottle Label

50+
SPF

tear
free

water
resistant

babyganics

SPF 50+
sunscreen
spray

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

formulated with: Zinc Oxide,
Octocrylene, Octisalate*

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

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

6 FL OZ (177 mL)

040-12078-B02



SPF 50+ sunscreen spray

broad spectrum SPF 50+
UVA + UVB protection



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please recycle, we do :)
product not tested on animals

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†Certified Organic Ingredient - Unless otherwise specified, product not labeled as organic* Learn about these and all our ingredients and the choices we make at babyganics.com 12078



BABYGANICS SPF 50 PLUS SUNSCREEN

zinc oxide, octisalate, and octocrylene spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59062-0120
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
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	50 mg in 1 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	60 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
GLYCERIN (UNII: PDC6A3C0OX)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	
GLYCERYL MONOCAPRYLATE (UNII: TM2TZD4G4A)	
LAPONITE (UNII: D703131383)	
XANTHAN GUM (UNII: TTV12P4NEE)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (10000 MPAS AT 1.5%) (UNII: 86FQE96TZ4)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SQUALANE (UNII: GW89575KF9)	
TOMATO SEED OIL (UNII: 7N87T9C06T)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CRANBERRY SEED OIL (UNII: 73KDS3BW5E)	
RASPBERRY SEED OIL (UNII: 9S8867952A)	
NIGELLA SATIVA SEED OIL (UNII: CS4U38E731)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:59062-0120-1	177 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	07/01/2019	
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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	07/01/2019	

Labeler - KAS Direct LLC dba Babyganics (002764605)

Revised: 1/2021

KAS Direct LLC dba Babyganics