KIDS SPF 50PLUS SUNSCREEN CONTINUOUS- zinc oxide 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.

kids SPF 50⁺ sunscreen continuous spray

Drug Facts

Active ingredients

Octisalate 5.0%, Zinc oxide 15.0%

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.
- keep away from face to avoid breathing it
- do not puncture or incinerate. Contents under pressure.
- do not store at temperatures above 120° F

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

- spray liberally and spread evenly by hand 15 minutes before sun exposure
- hold can 4-6 inches away from the skin to apply
- do not spray directly into face. Spray into hands then apply to face.
- do not apply in windy conditions
- use in a well-ventilated area
- 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-sleeve shirts, pants, hats, and sunglasses

Other information

- protect this product from excessive heat and direct sun
- may stain or damage some fabrics, materials or surfaces

Inactive ingredients

water, butyloctyl salicylate, C30-38 olefin/isopropyl maleate/MA copolymer, bentonite, caprylic/capric triglyceride, glycerin, olive oil polyglyceryl-6 esters, sodium stearoyl lactylate, cetearyl alcohol, solanum lycopersicum (tomato) seed oil, helianthus annuus (sunflower) seed oil ¹, vaccinium macrocarpon (cranberry) seed oil, nigella sativa (black cumin) seed oil ¹, rubus idaeus (red raspberry) seed oil, phenethyl alcohol, glyceryl caprylate, xanthan gum, tocopherol

1 Certified Organic Ingredient. Unless otherwise specified product not labeled as organic

dist. by KAS direct, LLC San Francisco, CA 94111

PRINCIPAL DISPLAY PANEL - 170 g Can Label

new!

50⁺

SPF

babyganics

kids

SPF 50+ sunscreen continuous spray

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

formulated with: Zinc Oxide, Octisalate*

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

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

NET WT 6 OZ (170 g)





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029-17554-B02

KIDS SPF 50PLUS SUNSCREEN CONTINUOUS

zinc oxide and octisalate spray

Product Information

HUMAN OTC DRUG NDC:59062-0175 Product Type Item Code (Source)

Route of Administration TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	150 mg in 1 g		
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	50 mg in 1 g		

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
BENTO NITE (UNII: A3N5ZCN45C)		
Glycerin (UNII: PDC6A3C0OX)		
XANTHAN GUM (UNII: TTV12P4NEE)		
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)		
GLYCERYL MO NO CAPRYLATE (UNII: TM2TZD4G4A)		
BUTYLO CTYL SALICYLATE (UNII: 2EH13UN8D3)		
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)		
ISOPROPYL MALEATE (UNII: M86R5J916V)		
MALEIC ANHYDRIDE (UNII: V5877ZJZ25)		
SODIUM STEAROYL LACTYLATE (UNII: IN99IT31LN)		
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)		
TOCOPHEROL (UNII: R0ZB2556P8)		
OLIVE OIL POLYGLYCERYL-6 ESTERS (UNII: 4KDO9 AFM9 I)		
C30-38 OLEFIN (UNII: 04DAD0KDZ0)		
NIGELLA SATIVA SEED OIL (UNII: CS4U38E731)		
RASPBERRY SEED OIL (UNII: 9S8867952A)		
CRANBERRY SEED OIL (UNII: 73KDS3BW5E)		
SUNFLOWER OIL (UNII: 3W1JG795YI)		
TOMATO SEED OIL (UNII: 7N87T9C06T)		

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:59062-0175-6	170 g in 1 CAN; Type 0: Not a Combination Product	12/15/20 18			
2	NDC:59062-0175-2	2 in 1 CELLO PACK	12/15/2018			
2		170 g in 1 CAN; Type 0: Not a Combination Product				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	12/15/20 18		

Labeler - KAS Direct LLC dba BabyGanics (002764605)

Revised: 7/2020