

CVS CHILDRENS BABYS SPF50- titanium dioxide, zinc oxide lotion
CVS PHARMACY

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.

CVS CHILDREN'S BABY'S SPF50 LOTION

Active Ingredients

Titanium Dioxide 3.1%

Zinc Oxide 4.0%

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 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, caprylic/capric triglyceride, isohexadecane, butyloctyl salicylate, octyldodecyl citrate crosspolymer, cetyl PEG/PPG-10/1 dimethicone, lauryl PEG-8 dimethicone, C30-38 olefin/isopropyl maleate/MA copolymer, sodium chloride, ethylhexyl methoxycrylene, dimethicone, caprylyl glycol, PEG-8, silica, triethoxycaprylylsilane, glycerin, sodium citrate, tocopheryl acetate, aloe barbadensis leaf juice, propanediol, pentylene glycol, phenethyl alcohol

Label

CVS CHILDREN'S SPF50 LOTION

8.0 fl oz (237 mL)

NDC: 69842-289-05

CVS
Health™



children's

50

LOTION

**BROAD SPECTRUM SPF 50
SUNSCREEN**

UVA/UVB protection

- Water resistant (80 minutes)
- Tear free & hypoallergenic
- Pediatrician tested
- Oxybenzone & octinoxate free



RECOMMENDED
AS AN EFFECTIVE
BROAD SPECTRUM
SUNSCREEN

COMPARE TO BANANA BOAT®
KIDS TEAR FREE LOTION*

8.0 FL OZ (237 mL)

CVS Health™ Children's Lotion SPF 50 is a broad-spectrum, tear- and sting-free sunscreen. Its hypoallergenic, ultra-gentle formula is mild on children's sensitive skin. It's also water resistant, providing protection in and out of the water for up to 80 minutes.

Drug Facts	
Active ingredients	Purpose
Titanium Dioxide 3.1% Zinc Oxide 4.0%	Sunscreen
Uses	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • apply liberally 15 minutes before sun exposure • reapply: <ul style="list-style-type: none"> • 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 of 15 or higher and other sun protection measures including: <ul style="list-style-type: none"> • limit time in the sun, especially from 10 a.m. to 2 p.m. • wear long-sleeve shirts, pants, hats, and sunglasses 	
Other information	
<ul style="list-style-type: none"> • protect this product from excessive heat and direct sun • may stain or damage some fabrics/materials or surfaces 	
Inactive ingredients	
water, caprylic/capric triglyceride, isohexadecane, butylacetyl salicylate, octyldodecyl citrate crosspolymer, cetyl PEG/PPG-10/1 dimethicone, lauryl PEG-8 dimethicone, C30-38 olefin/isopropyl maleate/MA copolymer, sodium citrate, ethylhexyl methoxycrylene, dimethicone, caprylyl glycol, PEG-9, silica, triethoxycaprylylsilane, glycerin, sodium citrate, tocopheryl acetate, alba barbadensis leaf juice, propanediol, pentylene glycol, phenethyl alcohol.	

*This product is not manufactured or distributed by Edgewell Personal Care Brands LLC, owner of the registered trademark Banana Boat®.

#938757

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V-13190



CVS BABY'S SPF50 LOTION

8.0 fl oz (237 mL)

NDC: 69842-289-05

CVS Health™



baby

50

LOTION

BROAD SPECTRUM SPF 50 SUNSCREEN

UVA/UVB protection

- Water resistant (80 minutes)
- Tear free, fragrance free & hypoallergenic
- Pediatrician tested
- Oxybenzone & octinoxate free



COMPARE TO BANANA BOAT® BABY TEAR FREE LOTION*

8.0 FL OZ (237 mL)

CVS Health™ Baby Lotion SPF 50 is a broad-spectrum, tear-free sunscreen. Its hypoallergenic, ultra-gentle formula is ideal for baby's delicate skin. It's also water resistant, providing protection in and out of the water for up to 80 minutes.

Drug Facts	
Active ingredients	Purpose
Titanium Dioxide 3.1% Zinc Oxide 4.0%	Sunscreen
Uses	
<ul style="list-style-type: none"> • helps prevent sunburn • if used as directed with other sun protection measures (see <i>Directions</i>), 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	
<ul style="list-style-type: none"> • apply liberally 15 minutes before sun exposure • reapply: <ul style="list-style-type: none"> • 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 of 15 or higher and other sun protection measures including: <ul style="list-style-type: none"> • limit time in the sun, especially from 10 a.m. - 2 p.m. • wear long-sleeve shirts, pants, hats, and sunglasses 	
Other information	
<ul style="list-style-type: none"> • protect this product from excessive heat and direct sun • may stain or damage some fabrics/materials or surfaces 	
Inactive ingredients	
water, caprylic/capric triglyceride, isohexadecane, butyloctyl salicylate, octyldodecyl citrate copolymer, cetyl PEG/PPG-10/1 dimethicone, lauryl PEG-8 dimethicone, C30-38 olefin/isopropyl maleate/MA copolymer, sodium chloride, ethylhexyl methoxycarbonyl dimethicone, caprylyl glycol, PEG-8, silica, triethoxycaprylylsilane, glycerin, sodium citrate, tocopheryl acetate, silyl barbadensis leaf juice, propanediol, pentylene glycol, phenethyl alcohol	

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CVS CHILDRENS BABYS SPF50

titanium dioxide, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-289
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	31 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	40 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PROPANEDIOL (UNII: 5965N8W85T)	
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	
OCTYLDODECYL CITRATE CROSSPOLYMER (UNII: X323T6QO4M)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HFI6D95)	
WATER (UNII: 059QF0KO0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5) (UNII: 035JKJ76MT)	
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ETHYLHEXYL METHOXYCRYLENE (UNII: S3KFG6Q5X8)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-289-05	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/31/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/31/2018	

Labeler - CVS PHARMACY (062312574)