WALGREENS BABY SPF50- titanium dioxide and zinc oxide lotion Walgreen Company

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.

WAG Sun Baby Lotion SPF50 3oz

1491-23(V) Rev 01

Walgreen Baby SPF 50 Lotion

Active Ingredients

Titanium Oxide 3.30%, Zinc Oxide 4.2%

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
- **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
- children under 6 months: Ask a doctor

Inactive Ingredients

Deionized Water, Caprylic/Capric Triglycerides, Tridecyl Neopentanoate, Sorbitol, Cetyl PEG/PPG 10/1 Dimethicone, Butly Octyl Salicylate, Glycerin, Octyldodecyl Citrate Copolymer, C28-52 Olefin/Undecylenic Acid Copolymer, PEG 8, Dimethicone, Aloe Barbadensis Leaf Juice, Ethylhexyl Methoxycrylene, Tocopherol Acetate, Lauryl PEG-8 Dimethicone, Caprylyl Glycol, Sodium Chloride, Phenoxyethanol, Sodium Citrate

Other Information

- for use on skin only. Avoid contact with fabric
- protect this product from excessive heat and direct sun

Questions or comments?

www.walgreens.com or call toll free 1-800-XX-XXXX

PRINCIPAL DISPLAY PANEL

Walgreens
50
Baby
Broad spectrum SPF 50
Sunscreen UVA/UVB
HYPOALLERGENIC
OXYBENZONE FREE
TEAR FREE
3 FL OZ (88 ML)

Drug Facts

Active Ingredient

Titanium Dioxide (3.1%), Zinc Oxide (4%)

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. Finse with water to remove.

Stop use and ask a doctor if rash occurs

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away. May stain some fabrics

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
- Sun Protection Measures
- Spending time in the sun increases your risk of skin cancer and early skin aging.
 To decrease this risk, regularly use 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-sleeved shirts, pants, hats and sunglasses
- . Children under 6 months of age: ask a doctor

Inactive Ingredients:

Water, Caprylic/Capric Triglycerides, Tridecyl Neopentanoate, Butly Octyl Salicylate, Octyldodecyl Citrate Copolymer, Cetyl PEG/PPG 10/1 Dimethicone, C28-52 Olefin/Undecylenic Acid Copolymer, PEG-8, Dimethicone, Glycerin, Aloe Barbadensis Leaf Juice, Ethylhexyl Methoxycrylene, Tocopheryl Acetate, Lauryl PEG-8 Dimethicone, Caprylyl Glycol, Sodium Chloride, Phenoxyethanol, Sodium Citrate

Other Information

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

Questions or Comments? 1-800-925-4733

Walgreens Pharmacist Recommended Walgreens Pharmacist Survey

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PKTB-41301-WG01 ORG0817-F



Walgreens

50 Baby

NEW

BROAD SPECTRUM SPF 50 SUNSCREEN UVA/UVB



HYPOALLERGENIC

OXYBENZONE FREE

TEAR FREE

• Water resistant (80 minutes)

3 FL OZ (88 mL)

WALGREENS BABY SPF50

titanium dioxide and zinc oxide lotion

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0363-9926

Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) (TITANIUM DIO XIDE - UNII:15FIX9 V2JP)	TITANIUM DIO XIDE	3.1 mg in 100 mL	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	4 mg in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)		
TRIDECYL NEO PENTANO ATE (UNII: 3Z8 H1DA7J5)		
SORBITOL (UNII: 506T60A25R)		
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 3) (UNII: G300307ZXP)		
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)		
GLYCERIN (UNII: PDC6A3C0OX)		
POLYOXYL 8 STEARATE (UNII: 2P9L47VI5E)		
DIMETHICO NE (UNII: 92RU3N3Y1O)		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
ETHYLHEXYL METHO XYCRYLENE (UNII: S3KFG6Q5X8)		
ALPHA-TO COPHEROL ACETATE (UNII: 9E8X80D2L0)		
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)		
CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)		
SODIUM CHLORIDE (UNII: 451W47IQ8X)		
PHENO XYETHANO L (UNII: HIE49 2ZZ3T)		
SODIUM CITRATE (UNII: 1Q73Q2JULR)		

l	Packaging					
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
l	1 NDC:0363-9926-20	89 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/25/2017			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC MONOGRAPH NOT FINAL	part352	08/25/2017			

Labeler - Walgreen Company (008965063)

Registrant - Walgreen Company (008965063)

Revised: 8/2017 Walgreen Company