# BABY SPF 60 SUNSCREEN- titanium dioxide - 6.00% zinc oxide - 4.70% stick Walgreens

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.

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#### Walgreens

#### **Drug Facts**

Active ingredients	Purpose	
Titanium Dioxide - 6.00%	Sunscreen	
Zinc Oxide - 4.70%	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 damage 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 the 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 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 month: Ask a doctor

#### **Inactive ingredients**

Aluminum Hydroxide, Beeswax, BHT, Butyloctyl Salicylate, C12-15 Alkyl Benzoate, Cetyl Alcohol, Dimethicone, Euphorbia Cerifera (Candelilla) Wax, Isostearic Acid, Neopentyl Glycol Diethylhexanoate, Ozokerite, Paraffin, Polyethylene, Stearic Acid, Triethoxycaprylylsilane

#### **Other Information**

• protect this product from excessive heat and direct sun

#### **Questions or comments?**

1-866-483-2846



BABY SPF 60 SUNSCREEN							
titanium dioxide - 6.00% zinc oxide - 4.70% stick							
Product Information							
Product T ype	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-3216				
Route of Administration	Route of Administration TOPICAL						
Active Ingredient/Active Moiety							

Zinc Oxide (UNIE SOELO HE4Z) (ZINC CATION - UNIE:135 IS8SF37)       ZINC CATION       4.7 g in 100         Inactive IngredientS         IngredientName       Strength         Auminum Hydroxide (UNIE: 5QB072/UN0)         Strength         Auminum Hydroxide (UNIE: 5QB072/UN0)         Strength         Auminum Hydroxide (UNIE: 5QB072/UN0)         Strength         BUTYLATED HYDROXTYTOLENE (UNIE: 1P9D02/17/IK)         Butyloctyl Salicylate (UNIE: 22A36H052))         Cetyl Alcohol (UNIE: 22A378/U062)         Catyl Alcohol (UNIE: 33575/CN)         Dimethicone (UNIE: 936/3576/CN)         Dimethicone (UNIE: 3378/U062)         CANDELILLA WAX (UNIE: W0328HX19)         Isostearic Acid (UNIE: 3378/U062)         Stearic Acid (UNIE: 3378/U062)         Neopentyl Glycol Diethylhexanoate (UNIE: U682V6W62C)         CERESIN (UNIE: W10232HX19)         Isostearic Acid (UNIE: 3378/U062)         Stearic Acid (UNIE: 42U7265AP)         Triethoxycaprylylsilane (UNIE: LDC33/IP08E)         Parafing Colspan="2">Marketing Start Date         Marketing Info'TLE; Type 0: Not a Combin		Ingredient Name	Basis of Stre	ngth Strength	
Ingredient Name       Strength         Aluminum Hydroxide (UNII: 5QB07L9UN0)       Strength         Aluminum Hydroxide (UNII: 5QB07L9UN0)       Strength         Strength         Aluminum Hydroxide (UNII: 5QB07L9UN0)       Strength         Strength         Strength         ButyLacyte (UNII: 5QB07L9UN0)         Strength         ButyLacyte MyDRoxYTOLUENE (UNII: 199D02171K)         ButyLacyte LetH3UNB3)         ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)         Cetyl Alcohol (UNII: 936JST6JCN)         Dimethicone (UNII: 92RU3N3Y10)         CANDELILLA WAX (UNII: WL0328HX19)         Isostearic Acid (UNII: X33R8 U0062)         Noopentyl Glycol Diethylhexanoate (UNII: U68ZV6W62C)         CERESIN (UNII: WL0328HX19)         Isostearic Acid (UNII: X33R8 U0062)         Strength         Itiet Boot Diethylhexanoate (UNII: U68ZV6W62C)         CERESIN (UNII: WL020JKM4WR7)         Stearic Acid (UNII: 4ELV7265AP)         Triethoxycaprylylsilane (UNII: LDC33IP08E)         Packaging	Titanium Dioxide (UNII:	Titanium Dioxide	6 g in 100 g		
Ingredient NameStrengthAluminum Hydroxide (UNIE: 5QB0T21UN0)YELLOW WAX (UNIE: 2ZA36 H0 S2V)BUTYLATED HYDROXYTOLUENE (UNIE: 1P9 D0 Z171K)Butyloctyl Salicylate (UNIE: 2H13UN8D3)ALKYL (C12-15) BENZOATE (UNIE: A9EJ316 HQ)Cetyl Alcohol (UNIE: 936 J5 T6 JCN)Dimethicone (UNIE: 936 J5 T6 JCN)Dimethicone (UNIE: 937 S76 JCN)Dimethicone (UNIE: 938 J3 SY10)CANDELILLA WAX (UNIE: WL0328 HX19)Isostearic Acid (UNIE: X33R8 U0062)Neopentyl Glycol Diethylhexanoate (UNIE: U68 ZV6 W62 C)CERESIN (UNIE: 1900 E3H2ZE)HiGH DENSTY POLYETHYLENE (UNIE: UG00 KM4WR7)Stearic Acid (UNIE: 4L07Z65AP)Triethoxycaprylylsilane (UNIE: LDC331P08E)Yackaging#Item CodePackage DescriptionMarketing Start DateMarketing End DMarketing Information02/13/2013	Zinc Oxide (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37) ZINC CATION			4.7 g in 100 g	
Ingredient NameStrengthAluminum Hydroxide (UNIE: 5QB0T21UN0)YELLOW WAX (UNIE: 2ZA36 H0 S2V)BUTYLATED HYDROXYTOLUENE (UNIE: 1P9 D0 Z171K)Butyloctyl Salicylate (UNIE: 2H13UN8D3)ALKYL (C12-15) BENZOATE (UNIE: A9EJ316 HQ)Cetyl Alcohol (UNIE: 936 J5 T6 JCN)Dimethicone (UNIE: 936 J5 T6 JCN)Dimethicone (UNIE: 937 S76 JCN)Dimethicone (UNIE: 938 J3 SY10)CANDELILLA WAX (UNIE: WL0328 HX19)Isostearic Acid (UNIE: X33R8 U0062)Neopentyl Glycol Diethylhexanoate (UNIE: U68 ZV6 W62 C)CERESIN (UNIE: 1900 E3H2ZE)HiGH DENSTY POLYETHYLENE (UNIE: UG00 KM4WR7)Stearic Acid (UNIE: 4L07Z65AP)Triethoxycaprylylsilane (UNIE: LDC331P08E)Yackaging#Item CodePackage DescriptionMarketing Start DateMarketing End DMarketing Information02/13/2013					
Aluminum Hydroxide (UNII: 5QB0721UN0)       9         YELLOW WAX (UNII: 2ZA36 H0 S2V)       9         BUTYLATED HYDROXTTOLUENE (UNII: 1P9D0Z171K)       9         Butyloctyl Salicylate (UNII: 2EH13UN8D3)       1         ALKYY (C12-15) BENZOATE (UNII: A9EJ3J61HQ)       1         Cetyl Alcohol (UNII: 935J576JN)       1         Dimethicone (UNII: 92RU3N3Y10)       1         CANDELILLA WAX (UNII: KL0328HX19)       1         Bostearic Acid (UNII: X388U0062)       1         Neopentpl Glycol Diethylhexanoate (UNII: U682V6%62C)       1         CERESIN (UNII: 910023H2ZE)       1         HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)       1         Stearic Acid (UNII: 4LV7Z65AP)       1         Triethoxycaprylylsiare (UNII: 1DC33IP08E)       1         Y       Item Code       Package Description         Marketing Start Date       02/13/2013	Inactive Ingredients	S			
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BUTYLATED HYDRO XYTO LUENE (UNII: 199002171K)       900         Butyloctyl Salicylate (UNII: 2EHI3UN8D3)	Aluminum Hydroxide (U	NII: 5QB0T2IUN0)			
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NDELILLA WAX (UNI: WL0328 HX19)       in the state of the state in the state state in the state in the state in the state	Cetyl Alcohol (UNII: 936)	IST6JCN)			
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Paraffin (UNII: 1900E3H2ZE)       i	Neopentyl Glycol Diethy	lhexanoate (UNII: U68ZV6W62C)			
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Stearic Acid (UNII: 4ELV7265AP)   Triethoxycaprylylsilane (UNII: LDC331P08E)     Packaging   I tem Code   Package Description   Marketing Start Date   Marketing Start Date   Warketing Information Number or Monograph Citation   Marketing Start Date     Marketing Start Date     Marketing Start Date     Marketing Category     Application Number or Monograph Citation     Marketing Start Date	Paraffin (UNII: 1900E3H2	ZE)			
Triethoxycaprylylsilane (UNII: LDC331P08E)     Varketing Start Date   Item Code   Package Description   Marketing Start Date   Marketing End D   NDC:0363-3216-01   14.2 g in 1 BOTTLE; Type 0: Not a Combination Product   02/13/2013   Varketing Information Start Date   Marketing End D   Application Number or Monograph Citation   Marketing Start Date   Marketing End D Marketing Start Date   Marketing End D	HIGH DENSITY POLYET	HYLENE (UNII: UG00KM4WR7)			
Packaging       Marketing Start Date       Marketing End D         #       Item Code       Package Description       Marketing Start Date       Marketing End D         1       NDC:0363-3216-01       14.2 g in 1 BOTTLE; Type 0: Not a Combination Product       02/13/2013       02/13/2013         Harketing Information Product         Marketing Category       Application Number or Monograph Citation       Marketing Start Date       Marketing End D	Stearic Acid (UNII: 4ELV)	7Z65AP)			
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OTC monograph not final part352 02/13/2013	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Dat	
	OTC monograph not final	part352	02/13/2013		

## Labeler - Walgreens (008965063)

Registrant - Product Quest Mfg (927768135)

### Establishment

Name	Address	ID/FEI	Business Operations
Product Quest Mfg		927768135	manufacture(0363-3216), label(0363-3216)

Revised: 2/2018