

**SAFE HARBOR - NATURAL SUNSCREEN - BABY AND KIDS SPF50 BROAD SPECTRUM
SUNSCREEN- titanium dioxide, zinc oxide cream**

Emilia Personal Care Inc.

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.

Safe Harbor Natural Suncare

Active ingredient

Titanium Dioxide 11.4%

Zinc Oxide 4.0%

Purpose

Sunscreen

Uses

- helps prevent sunburn
- If used as directed with other sun protections 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 at least every 2 hours
- Use water resistant sunscreen if swimming or sweating
- Children under 6 months: ask a doctor
- **Sun Protection Measures:** Spending time in the sun increases your risk of sun 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 10a.m. - 2p.m.

- wear long-sleeved shirts, pants, hats, and sunglasses

Other information

- protect the product in this container from excessive heat and direct sun

Inactive ingredients

water, cyclopentasiloxane, C12-15 alkyl benzoate, caprylic/capric triglyceride, glycerin, cetyl PEG/PPG-10/1 dimethicone, cetyl dimethicone, phenyl trimethicone, phenoxyethanol, ethylhexylglycerin, trimethoxycaprylylsilane, sodium chloride, hydrogenated castor oil, microcrystalline wax, tocopheryl acetate (vitamin E), allantoin, panthenol (pro-vitamin B5), hippophae rhamnoides oil, simmondsia chinensis (jojoba) seed oil, bisabolol, avena sativa (oat) extract, echinacea purpurea root extract, camomilla recutita (matricaria) flower extract, tilia vulgaris (linden blossom) flower extract, melissa officinalis leaf extract, aspalanthus linearis (rooibos) leaf extract

Package/Label Principal Display Panel

Safe Harbor™ Natural Suncare

Free from chemical UV filters

50 Mineral SPF Broad Spectrum Sunscreen

Baby & Kids

With Natural Moisturizing Complex

100% naturally sourced sunscreen actives

Gentle formula

Easy to apply

3 Fl. Oz (88.7 mL)

Distributed by: Emilia Personal Care.

Manufactured in Israel.

For more information visit: www.safeharborsuncare.com

UVA, UVB

With Certified Organic Ingredients

Water Resistant

Allergy Tested

ZD821 2E T1

NEW



SAFE HARBOR™ NATURAL SUNCARE

Free from chemical
UV filters

50

MINERAL SPF
BROADSPECTRUM
SUNSCREEN

BABY & KIDS

WITH NATURAL
MOISTURIZING COMPLEX

100% naturally sourced
sunscreen actives

Gentle formula

Easy to apply



3 FL.OZ. (88.7 mL)

- Quickly Absorbed • Blends in clear
- Light & gentle enough for growing skin
- Enriched with Chamomile
- Leaves skin feeling nourished

Drug Facts

Active ingredients

Active ingredients	Purpose
Titanium Dioxide, 11.4%	Sunscreen
Zinc Oxide, 4.0%	Sunscreen

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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.

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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:

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simmondsia chinensis (jojoba) seed oil, bisabolol, avena sativa (oat) extract, echinacea purpurea root extract, camomilla recutita (matricaria) flower extract, linal vulgaris (linden blossom) flower extract, melissa officinalis leaf extract, aspalathus linearis (rooibos) leaf extract.



UVA	WITH CERTIFIED
UVB	ORGANIC INGREDIENTS
WATER	ALLERGY
RESISTANT	TESTED

ZD621 3E 11

Distributed by: Emilia Personal Care. Manufactured in Israel. For more information visit: www.safeharborsuncare.com

Label

SAFE HARBOR - NATURAL SUNSCREEN - BABY AND KIDS SPF50 BROAD SPECTRUM SUNSCREEN

titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42421-821
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	11.4 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	4 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
TRICAPRYLIN (UNII: 6P92858988)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
CETYL DIMETHICONE 150 (UNII: 5L694Y0T22)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
TRIMETHOXYCAPRYLYLSILANE (UNII: FZ07E4LW2M)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALLANTOIN (UNII: 344S277G0Z)	
PANTHENOL (UNII: WV9CM0O67Z)	
HIPPOPHAE RHAMNOIDES FRUIT OIL (UNII: TA4JCF9S1J)	
JOJOBA OIL (UNII: 724GKU717M)	
LEVOMENOL (UNII: 24WE03BX2T)	
OAT KERNEL OIL (UNII: 3UVP41R77R)	
ECHINACEA PURPUREA ROOT (UNII: OS64WTR4KU)	
MATRICARIA CHAMOMILLA FLOWERING TOP OIL (UNII: SA8AR2W4ER)	
TILIA X EUROPAEA FLOWER (UNII: NHV2K1OUDH)	
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)	
ASPALATHUS LINEARIS LEAF (UNII: H7UGK1GJCU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42421-821-11	88.7 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/05/2014	

Labeler - Emilia Personal Care Inc. (965445112)

Revised: 11/2013

Emilia Personal Care Inc.