

SAFE HARBOR - NATURAL - SENSITIVE SPF50 BROAD SPECTRUM- titanium dioxide, zinc oxide lotion

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 10.4%

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, trimethoxycaprylylsilane, phenyl trimethicone, phenoxyethanol, ethylhexylglycerin, sodium chloride, hydrogenated castor oil, microcrystalline wax, tocopheryl acetate (vitamin E), allantoin, panthenol (pro-vitamin B5), lecithin, soy isoflavones, polysorbate 80, hippophae rhamnoides oil, bisabolol, camomilla recutita (matricaria) flower extract, tilia vulgaris (linden blossom) flower extract, melissa officinalis (lemon balm) leaf extract, aspalanthus linearis (rooibos) leaf extract, sodium lactate, porphyra umbilicalis extract

Package/Label Principal Display Panel**Safe Harbor™ Natural Suncare**

Free from chemical UV filters

50 Mineral SPF Broad Spectrum Sunscreen

Sensitive Lotion**With Natural Anti-Aging Complex**

Moisturizing sunscreen lotion

Anti-aging treatment

rich in age-defying antioxidants

4 Fl. Oz (118.3 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

ZD926 2E T1

NEW



SAFE HARBOR™
NATURAL SUNCARE

Free from chemical
UV filters

50 MINERAL SPF
BROADSPECTRUM
SUNSCREEN

**SENSITIVE
LOTION**

WITH NATURAL
ANTI-AGING COMPLEX

Moisturizing
sunscreen lotion

Anti-aging treatment
rich in age-defying
antioxidants

4 FL.OZ. (118.3 mL)

- Silky smooth & quickly absorbed
- Blends in clear
- Reduces visible signs of UV aging including wrinkles & age spots
- Helps prevent stripping of the skin's natural nutrients

Drug Facts

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Zinc Oxide 4.0%	Sunscreen

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UVA	WITH CERTIFIED
UVB	ORGANIC INGREDIENTS
WATER RESISTANT	ALLERGY TESTED

ZD926 2E T1

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

Label

SAFE HARBOR - NATURAL - SENSITIVE SPF50 BROAD SPECTRUM

titanium dioxide, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42421-926
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	10.4 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)	
TRIMETHOXYCAPRYLYLSILANE (UNII: FZ07E4LW2M)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALLANTOIN (UNII: 344S277G0Z)	
PANTHENOL (UNII: WV9CM0O67Z)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
SOY ISOFLAVONES (UNII: 71B37NR06D)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
HIPPOPHAE RHAMNOIDES FRUIT OIL (UNII: TA4JCF9S1J)	
LEVOMENOL (UNII: 24WE03BX2T)	
CHAMOMILE (UNII: FGL3685T2X)	
TILIA X EUROPAEA FLOWER (UNII: NHV2K1OUDH)	
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)	
ASPALATHUS LINEARIS LEAF (UNII: H7UGK1GJCU)	
SODIUM LACTATE (UNII: TU7HW0W0QT)	
PORPHYRA UMBILICALIS (UNII: 14AN0J70WO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:42421-926-11	118.3 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.