

**SAFE HARBOR NATURAL SUNCARE 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.*

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**Drug Facts**

**Active ingredients**

Titanium Dioxide 7.6%

Zinc Oxide 4.0%

**Purpose**

Sunscreen

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: 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 value 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.

**Other information** protect the product in this container from excessive heat and direct sun

**Inactive ingredients** water, caprylic/capric triglyceride, sesamum indicum (sesame) seed oil, helianthus annuus

(sunflower) seed oil, glycerin, cetearyl alcohol,

cetearyl glucoside, simmondsia chinensis

(jojoba) seed oil, glyceryl stearate,

butyrospermum parkii (shea) butter, potassium cetyl phosphate, phenoxyethanol, ethylhexylglycerin, xanthan gum, PEG-40 stearate, trimethoxycaprylsilane, allantoin, tocopherol acetate (vitamin E), panthenol (pro-vitamin B5), bisabolol, hippophae rhamnoides oil, avena sativa (oat) kernel extract, echinacea purpurea root extract, chamomilla recutita (matricaria) flower extract, tilia vulgaris flower extract, melissa officinalis leaf extract, aspalathus linearis leaf extract

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**SAFE HARBOR™  
NATURAL SUNCARE**

# NATURAL


## BABY & KIDS

natural moisturizing  
sunscreen lotion




# 50


BROAD SPECTRUM  
SPF 50  
SUNSCREEN



free from  
chemical  
UV filters



paraben  
free



water  
resistant  
(80 minutes)

4.2 FL OZ (124 mL)

Distributed by: Emilia Personal Care 5890 Sawmill Rd Suite 230, Dublin, OH 43017, Made in Israel, Visit: www.safeharborsuncare.com

## SAFE HARBOR NATURAL SUNCARE BROAD SPECTRUM

titanium dioxide, zinc oxide lotion

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42421-575
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	9.4 g in 124 g

ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)

ZINC OXIDE

4.96 g in 124 g

**Inactive Ingredients**

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
SESAME OIL (UNII: QX10HYY4QV)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
JOJOBA OIL (UNII: 724GKU717M)	
GLYCERYL 1-STEARATE (UNII: 258491E1RZ)	
SHEA BUTTER (UNII: K49155WL9Y)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PEG-40 STEARATE (UNII: ECU18C66Q7)	
TRIMETHOXYCAPRYLYLSILANE (UNII: FZ07E4LW2M)	
ALLANTOIN (UNII: 344S277G0Z)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PANTHENOL (UNII: WV9CM0O67Z)	
LEVOMENOL (UNII: 24WE03BX2T)	
HIPPOPHAE RHAMNOIDES SEED OIL (UNII: T53SBG6741)	
OAT (UNII: Z6J799EAJK)	
ECHINACEA PURPUREA ROOT (UNII: OS64WTR4KU)	
MATRICARIA RECUTITA ROOT (UNII: BTG5H50X7F)	
TILIA X EUROPAEA FLOWER (UNII: NHV2K10UDH)	
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)	
ASPALATHUS LINEARIS LEAF (UNII: H7UGK1GJCU)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42421-575-15	124 g in 1 TUBE; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/15/2015	

**Labeler** - Emilia Personal Care Inc (965445112)