

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.

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, sodium lactate, porphyra umbilicalis extract

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NATURAL

SHEER MINERAL

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 5690 Sawmill Rd Suite 230, Dublin, OH 43017, Made in Israel, Visit: www.safeharborsuncare.com

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SAFE HARBOR NATURAL SUNCARE BROAD SPECTRUM

titanium dioxide, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42421-875
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: 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
1	NDC:42421-875-15	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)