

SAFE HARBOR NATURAL SUNCARE NATURAL FACE AND NECK 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.

Active ingredients

Titanium Dioxide 7.1%

Zinc Oxide 3.5%

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, coco-glucoside, coconut alcohol, ricinus communis (castor) oil, simmondsia chinensis (jojoba) seed oil, butyrospermum parkii (shea) butter, microcrystalline cellulose, cellulose gum,

arachidyl alcohol, behenyl alcohol, arachidyl
glucoside, phenoxyethanol, ethylhexylglycerin,
xanthan gum, PEG-40 stearate, trimethoxycaprylylsilane,
fragrance, allantoin, tocopheryl acetate
(vitamin E), panthenol (pro-vitamin B5), lecithin, soy
isoflavones, polysorbate 80, hippophae rhamnoides
oil, bisabolol, chamomilla recutita (matricaria)flower
extract, tilia vulgaris _ower extract, Melissa
officinalis leaf extract, aspalathus linearis leaf
extract, sodium lactate, porphyra umbilicalis extract



SAFE HARBOR™
NATURAL SUNCARE

NATURAL

FACE & NECK

natural moisturizing
sunscreen lotion



free from
chemical
UV filters



paraben
free



water
resistant
(80 minutes)

4.2 FL. OZ. (124 mL)

Drug Facts

Active ingredients	Purpose
Titanium Dioxide 7.125%	Sunscreen
Zinc Oxide 3.5%	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, coco-glucoside, coconut alcohol, ricinus communis (castor) oil, simmondsia chinensis (jojoba) seed oil, butyrospermum parkii (shea) butter, microcrystalline cellulose, cellulose gum, arachidyl alcohol, behenyl alcohol, arachidyl glucoside, phenoxyethanol, ethylhexylglycerin, xanthan gum, PEG-40 stearate, trimethylcaprylyl-silane, fragrance, allantoin, tocopheryl acetate (vitamin E), panthenol (pro-vitamin B5), lecithin, soy isoflavones, polysorbate 80, hippophae rhamnoides oil, bisabolol, chamomilla recutita (matricaria) flower extract, lilas vulgaris flower extract, melissa officinalis leaf extract, aspalathus linearis leaf extract, sodium lactate, porphyra umbilicalis extract.



Z775 2E 12

Distributed by: Emilia Personal Care Inc. 555 Sun Valley Drive, Suite M-2 Roswell, GA 30076. Made in Israel. Visit: www.safeharborsuncare.com

SAFE HARBOR NATURAL SUNCARE NATURAL FACE AND NECK BROAD SPECTRUM

titanium dioxide, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42421-076
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	8.8 g in 124 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	4.34 g in 124 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
SESAME OIL (UNII: QX10HYY4QV)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
GLYCERIN (UNII: PDC6A3C0OX)	
COCO GLUCOSIDE (UNII: ICS790225B)	
COCONUT ACID (UNII: 40U37V505D)	
CASTOR OIL (UNII: D5340Y2I9G)	
JOJOBA OIL (UNII: 724GKU717M)	
SHEA BUTTER (UNII: K49155WL9Y)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
ARACHIDYL GLUCOSIDE (UNII: 6JVVW35JOOJ)	
DOCOSANOL (UNII: 9G1OE216XY)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PEG-40 SOY STEROL (UNII: 58L481H732)	
TRIMETHOXYCAPRYLYLSILANE (UNII: FZ07E4LW2M)	
ALLANTOIN (UNII: 344S277G0Z)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
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)	
ASPALATHUS LINEARIS LEAF (UNII: H7UGK1GJCU)	

MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)	
SODIUM LACTATE (UNII: TU7HW0W0QT)	
PORPHYRA UMBILICALIS (UNII: 14AN0J70WO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42421-076-15	124 g in 1 TUBE; Type 0: Not a Combination Product	12/30/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/30/2016	

Labeler - Emilia Personal Care Inc (965445112)

Revised: 1/2017

Emilia Personal Care Inc