

FRE TINTED DEFENSE MOISTURIZER SPF15- octinoxate, titanium dioxide cream
Emilia Cosmetics Ltd

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.

FRE Tinted Defense Moisturizer SPF15

Active ingredients

Octinoxate 4.0%

Titanium Dioxide 2.85%

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 at least every 2 hours. •use water resistant sunscreen if swimming or sweating. •children under 6 months of age: 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, glycerin, potassium cetyl phosphate, argania spinosa kernel oil, cyclopentasiloxane, glyceryl myristate, propanediol, behenyl alcohol, caprylic/capric/triglyceride, microcrystalline cellulose, cellulose gum, sodium lactate, lactic acid, TEA-lactate, serine, urea, sorbitol, sodium chloride, allantoin, ascorbic acid, dimethicone, phenoxyethanol, ethylhexylglycerin, argania spinosa leaf extract, ammonium acryloyldimethyltaurate/VP copolymer,

iron oxides, mica, butylene glycol, pentylene glycol, hydroxyphenyl propamidobenzoic acid, triethanolamine, fragrance, allantoin, trimethoxycaprylylsilane, disodium EDTA, bisabolol, tocopheryl acetate (vitamin E), carnosine, hyaluronic acid, chamomilla recutita (matricaria) flower extract, tilia vulgaris (linden blossom) flower extract, aspalathus linearis (rooibos) leaf extract, melissa officinalis leaf extract.

Approved
June 24, 2018

Liraz Avital

מפרט הדפסה:

PANTONE 7457C 

PANTONE 303C 

PANTONE 101C 

פס צהוב צריך להיות
בלכה סלקטיבית
מודגש במג'נטה בקובץ הבא



FRE TINTED DEFENSE MOISTURIZER SPF15

octinoxate, titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43219-0-10
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1.8 g in 45 mL

TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	1.27 g in 45 mL
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Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
ARGAN OIL (UNII: 4V59G5UW9X)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
GLYCERYL MYRISTATE (UNII: 6992Y81827)	
PROPANEDIOL (UNII: 5965N8W85T)	
DOCOSANOL (UNII: 9G1OE216XY)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
SODIUM LACTATE (UNII: TU7HW0W0QT)	
LACTIC ACID (UNII: 33X04XA5AT)	
TRIETHANOLAMINE LACTATE (UNII: 064C51N81O)	
SERINE (UNII: 452VLY9402)	
UREA (UNII: 8W8T17847W)	
SORBITOL (UNII: 506T60A25R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ALLANTOIN (UNII: 344S277G0Z)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ARGANIA SPINOSA LEAF (UNII: 51XV5WTF7E)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MICA (UNII: V8A1AW0880)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
HYDROXYPHENYL PROPAMIDOBENZOIC ACID (UNII: 25KRT26H77)	
TROLAMINE (UNII: 9O3K93S3TK)	
TRIMETHOXYCAPRYLSILANE (UNII: FZ07E4LW2M)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
LEVOMENOL (UNII: 24WE03BX2T)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
HYALURONIC ACID (UNII: S270N0TRQY)	
MATRICARIA CHAMOMILLA FLOWERING TOP OIL (UNII: SA8AR2W4ER)	
TILIA X EUROPAEA FLOWER (UNII: NHV2K10UDH)	
ASPALATHUS LINEARIS LEAF (UNII: H7UGK1GJCU)	
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:43219-010-45	45 mL in 1 TUBE; Type 0: Not a Combination Product	09/06/2018	04/17/2021
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part352		09/06/2018	04/17/2021

Labeler - Emilia Cosmetics Ltd (600076624)

Revised: 5/2020

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