# TOTAL PROTRECTOR 15 - octinoxate, zinc oxide cream MD Formulation

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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#### **Sun Total Protector 15**

Octinoxate - 7.5% Sunscreen Zink Oxide - 4.9% Sunscreen

When using this product do not use in or near the eyes. If product gets into eyes, rlnse thoroughly with water.

Warnings: For external use only.

Stop use and ask a doctor if Irritation or rash appears and lasls.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions: Children under 2 years of age should use sunscreen products with a minimum SPF of 4. Adult and children 6 months and over: apply liberally 15 minutes before sun or water exposure; reapply after swimming or excessive sweating or anytime after towel drying. Children under 6 months ask a doctor.

Other information store at 20.25C (68-770 F)

Sun Alert: The sun causes sun damage. Regular use of sunscreens over the years may reduce the chance of skIn damage, some types of skin cancer, and other harmful effects due to the sun.

Inactive ingredients: Water (Aqua), Glyceryl Stearate, C12-15 Alkyl Benzoate, GlycerIn, Steareth-2, Steareth-100, Tricontanyl PVP, PEG-100 Stearate, Tocopheryl Acetate, Allantoin, Xanthan Gum, Cetyl Hydroxyelhylcellulose, Dimethicone, Disodium EDTA, Diazolidinyl Urea, lodopropynyl Butylcarbamate, Methylparaben. Propylparaben.

Provide skin with daily, year-round protection against sun exposure.

### **Drug Facts**

Active Ingredient Octinoxate - 7.5% Zinc Oxide (Cl 77947) - 4.9%

**Purpose** Sunscreen Sunscreen

Uses to help prevent sunburn and for the temporary protection of sunburn.

Warnings For external use only.

When using this product do not use in or near the eyes. If product gets into eyes, rinse thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and lasts.

Keep out of reach of children
If swallowed, get medical help or contact a
Poison Control Center right away.

See Carton for complete information

NDC 66078-110-25



#### FACE / VISAGE

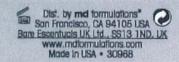


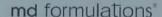
total protector 15 total daily protection

écran haute protection 15 protection quotidienne

75 ml (2.5 fl. oz.)

md formulations°





### PRODUIT DE TRAITEMENT PROFESSIONNEL -

Cette formule non grasse multi-actions apparte à la peau, fout au long de l'année, la protection quotidienne dont elle a besoin la protection quadularine dont ette a desant pour futter contre les rayons du soteil. L'oxyde de zinc micronisé prolége la peau contre les UVA et UVB. La vitamine E et l'ell'antoine apaisent et adouctissent. La Skin Concer Foundation (Fondation pour le cancer de la peau) recommande l'utilisation de ce produit comme écran solaire sûr et efficace.

- · testé sous contrôte dermatologique
- non-comédogène
  hypoollergénique

· sons porfum

Utilisation: Appliquer sur le visage, le cou, la poitrine et les mains, même sous le maquillage. Renouveler l'application avant toute exposition ou soleil, après avoir nagé, transpiré ou s'être épongé à l'aide d'une servielle. Il est recommandé d'utiliser des produits avec écran solaire SPF 4 minimum chez les enfants de

Méfaits du soleil: Le soleil peut être dangereux pour la peau. L'utilisation régulière d'écrans solaires peuf réduire les risques de cancers de la peau et autres effets nocifs provoqués par le soleil

Précautions d'emploi: À usage externe seulement. Éviter tout contact ovec les yeux. En cas d'irritation, rincer abon-damment, interrompre l'utilisation du produit et consulter un médecin. Arrêter toute utilisation en cas d'apparition de signes d'irritation ou de rougeurs. Ne pas ufiliser chez les enfants de moins de 6 mois sons avis médical.

NDC 66078-110-25



md formulations

### SUN

total protector 15 total daily protection all skin types all weather

écran haute protection 15

protection quotidienne tout type de peau tout climat

FACE/VISAGE

 $75 \,\mathrm{ml}_{\flat}(2.5 \,\mathrm{fl.}\,\mathrm{oz.})$ 

## ES PRODUCTO PARA TRATA-

Protejo dioriamente su piel, durante todo el año, de la exposición solar con esta el ano, de la exposición sotar con esta támula no grasa de amplio especiro. El coado de zina micronizado profege la plei de los rayos UVA y UVB, mientros que la villoniña E y la atanticina autiman y suovizon la piel. La Fundación de Lucha contra el Cáncer de Piel recomienda este producto como una segura y efectiva pantalia contra los rayos UV.

- dermatológicamente testeada
   no corriedogénica
   hipoalergénica
   libre de fragancia

protección mínimo de 4.

Modo de uso: Aplique sobie rostro, cuello, pecho y manos, y bajo el maquillaje. Reaplique antes de exponerse al sol, después de nadar, traspirar o de secorse con una toalla. Los niños menares de 2 años deben usar productos con pantallas solares con un factor de

Advertencia: El sol daña la piel. El empleo regular de pantallas solares puede reducir la probabilidad de daños a la piel, de algunos tipos de concer de piel y de otros efectos perjudiciales del sol

Precaución: Sólo para uso externo. Evite que penetre en los ojos. Si se produce irritoción, enjuague bien el producto, suspenda su uso y consulte un médico. Suspenda si aparecen sintomas de irritación o urticaria. Emplee en niños menores de 6 meses sólo con recomendación médica.

### PROFESSIONAL TREATMENT PRODUCT

Provide skin with dolly, year-round protection ogainst sun exposure. Micronized zinc code protects skin from UVA and UVB rays while. vilamin E and allantoin soften and soothe.

#### **Drug Facts**

Active Ingredient Purp Octinoxate - 7.5% Sunsci Znc Oxde (CI 77947) - 4.9 % Sunsci

Uses to help prevent sunburn and for the temporary protection of sunburn

Warnings For external use only.

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Other information store at 20,25° C CMPH INFORMATION Store at 20.25° C (88-75° F) an Alert. The sun causes sun damage. Regular use of sunscreens over the years may reduce the chance of skin damage, some types of skin cancer, and other harmful effects due to the sun.

Omer harmati anders date to the sun.

Inactive ingredients: Water
(Aqua), Glyceryl Stearate, C12-15 Alkyl
Bricarde, Glycerin, Steareth-2, Steareth-100,
Intcontanty PVP, FEG-100 Stearate,
Tocopheryl Acetate, Allantiatin, Xanthan
Gurn, Celyl Hydicoxyethytoellulose,
Dimethicone, Disodium ED1A, Diszolidinyl
Urea, Todopraynyl Bullylarabamate,
Methylparaben, Propylparaben

Dist. by md formulations<sup>®</sup> San Francisco, CA 94105 US Bare Escentuals UK Ltd., SS13 1ND, UK www.mdformulations.com Made in USA + 30968

#### TOTAL PROTRECTOR 15

octinoxate, zinc oxide cream

#### **Product Information**

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:66078-110

Route of Administration

TOPICAL

| Active Ingredient/Active Moiety                              |                   |                |  |
|--|-------------------|----------------|--|
| Ingredient Name  | Basis of Strength | Strength       |  |
| Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51) | Octinoxate        | 7.5 g in 100 g |  |
| Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z) | Zinc Oxide        | 4.9 g in 100 g |  |

| Inactive Ingredients                                       |          |
|--|----------|
| Ingredient Name  | Strength |
| Water (UNII: 059QF0KO0R)                                   |          |
| Glycerin (UNII: PDC6A3C0OX)                                |          |
| ALLANTO IN (UNII: 344S277G0Z)                              |          |
| EDETATE DISO DIUM (UNII: 7FLD9 1C8 6 K)                    |          |
| XANTHAN GUM (UNII: TTV12P4NEE)                             |          |
| CETYL HYDROXYETHYLCELLULOSE (350000 MW) (UNII: T7SWE4S2TT) |          |
| DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)                       |          |
| IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)             |          |
| GLYCERYL STEARATE SE (UNII: FCZ5MH785I)                    |          |
| STEARETH-2 (UNII: V56DFE46J5)                              |          |
| PEG-100 STEARATE (UNII: YD01N1999R)                        |          |
| STEARETH-100 (UNII: 4OH5W9UM87)                            |          |
| TRIACONTANYL PVP (WP-660) (UNII: NOSS3Q238D)               |          |
| .ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)               |          |
| PROPYLPARABEN (UNII: Z8IX2SC1OH)                           |          |

| P | Packaging        |                     |                      |                    |
|---|------------------|---------------------|----------------------|--------------------|
| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:66078-110-25 | 42 in 1 CASE        |                      |                    |
| 1 |                  | 1 in 1 CARTON       |                      |                    |
| 1 |                  | 78 g in 1 TUBE      |                      |                    |

| Marketing Information   |  |                      |                    |
|-------------------------|--|----------------------|--------------------|
| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part352                                  | 07/08/2007           |                    |
|                         |  |                      |                    |

# Labeler - MD Formulation (087008363)

## **Registrant -** Ei Inc (105803274)

| Establishment |         |        |                     |
|---------------|---------|--------|---------------------|
| Name          | Address | ID/FEI | Business Operations |

Revised: 7/2012 MD Formulation