

**2-POWER FABRIC SPF 25- octinoxate cream  
BPS 60**

*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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**2-Power Fabric SPF 25**

***Drug Facts***

***Active ingredient***

Octinoxate 6.7%

***Purpose***

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**

**Flammable until dry.** Do not use near fire, flame, or heat.

**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***

For sunscreen use:

- apply liberally 15 minutes before sun exposure
- reapply at least every 2 hours
- use a water resistant sunscreen if swimming or sweating
- **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
- children under 6 months of age: Ask a doctor

**Other information**

- protect the product in this container from excessive heat and direct sun

**Inactive ingredients**

cyclohexasiloxane, water, dimethicone, vinyl dimethicone/methicone silsesquioxane crosspolymer, propanediol, alcohol denat., butylene glycol, phenyl trimethicone, cetyl PEG/PPG-10/1 dimethicone, synthetic fluorphlogopite, tocopherol, phenoxyethanol, magnesium sulfate, PEG/PPG-18 dimethicone, polyglyceryl-4 isostearate, dimethicone/vinyl dimethicone crosspolymer, limonene, benzyl salicylate, benzyl alcohol, linalool, pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate, isobutane, acrylonitrile/methylmethacrylate/vinylidene chloride copolymer, disodium stearyl glutamate, BHT, butylphenyl methylpropional, aluminum hydroxide, hexyl cinnamal, fragrance; may contain: iron oxides, titanium dioxide

**Questions or comments ?**

CONTACT: GIORGIO ARMANI PARFUMS  
LUXURY PRODUCTS LLC  
10 HUDSON YARDS, NEW YORK, NY 10001

**Package Labeling:**

**power fabric**  
longwear high cover foundation  
55

**power fabric**  
longwear high cover foundation  
octinoxate sunscreen  
broad spectrum SPF 25  
55

**GIORGIO ARMANI**

5 ml 0.16 FLOZ.

**Drug Facts (continued)**  
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  
• children under 6 months of age: Ask a doctor

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

**Drug Facts (continued)**  
**Inactive ingredients**  
cyclohexasiloxane, water, dimethicone, vinyl dimethicone / methicone silsesquioxane crosspolymer, propanediol, alcohol denat., butylene glycol, phenyl trimethicone, cetyl PEG / PPG-10 / 1 dimethicone, synthetic fluorphlogopite, tocopherol, phenoxyethanol, magnesium sulfate, PEG / PPG-18 / 18 dimethicone, polyglyceryl-4 isostearate, dimethicone / vinyl dimethicone crosspolymer, limonene, benzyl salicylate, benzyl alcohol, linalool, pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate, isobutane, acrylonitrile / methyl methacrylate / vinylidene chloride copolymer, disodium stearyl glutamate, BHT, butylphenyl methylpropional, aluminum hydroxide, hexyl cinnamal, fragrance; may contain: iron oxides, titanium dioxide

DERMATOLOGICALLY TESTED.  
NON COMEDOGENIC.  
FREE SAMPLE - NOT FOR SALE  
GIORGIO ARMANI PARFUMS,  
16 PLACE VENDÔME 75001 PARIS,  
LUXURY PRODUCTS LLC, 10 HUDSON  
YARDS, NEW YORK, NY 10001 IMP.  
BY BEST EVER FRAGRANCES,  
MONTREAL, CANADA, H4T 1K3.  
TSA 75000 95384 ST LOUEN CEDEX FR  
MADE IN FRANCE  
QUESTIONS OR COMMENTS?  
CONTACT GIORGIO ARMANI PARFUMS  
LUXURY PRODUCTS LLC, 10 HUDSON  
YARDS, NEW YORK, NY 10001  
FOR MORE INFORMATION ON THIS  
ARMANIBEAUTY.COM

**Drug Facts (continued)**  
protection measures (see *Directions*), decreases the risk of skin cancer and early skin aging caused by the sun

**Warnings**  
For external use only

**Drug Facts (continued)**  
**Directions**  
For sunscreen use:  
• apply liberally 15 minutes before sun exposure  
• reapply at least every 2 hours  
• use a water resistant sunscreen if swimming or sweating  
• 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 **UFT**

**Drug Facts (continued)**  
Flammable until dry. Do not use near fire, flames, or heat.  
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.

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PAP 1

G992011 - FIL: B190915/1

## 2-POWER FABRIC SPF 25

octinoxate cream

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:70581-011 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

### Active Ingredient/Active Moiety

| <b>Ingredient Name</b>                                       | <b>Basis of Strength</b> | <b>Strength</b> |
|--|--------------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE               | 67 mg in 1 mL   |

### Inactive Ingredients

| <b>Ingredient Name</b>   | <b>Strength</b> |
|--|-----------------|
| CYCLOMETHICONE 6 (UNII: XHK3U310BA)  |                 |
| WATER (UNII: 059QF0KO0R)   |                 |
| DIMETHICONE (UNII: 92RU3N3Y1O)   |                 |
| VINYL DIMETHICONE/METHICONE SILSESQUOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)                    |                 |
| PROPANEDIOL (UNII: 5965N8W85T)   |                 |
| ALCOHOL (UNII: 3K9958V90M)   |                 |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA)   |                 |
| PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)   |                 |
| TOCOPHEROL (UNII: R0ZB2556P8)  |                 |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)  |                 |
| MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)                                       |                 |
| POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)  |                 |
| LIMONENE, (+)- (UNII: GFD7C86Q1W)  |                 |
| BENZYL SALICYLATE (UNII: WAO5MKN9TU)   |                 |
| BENZYL ALCOHOL (UNII: LKG8494WBH)  |                 |
| LINALOOL, (+/-)- (UNII: D81QY6I88E)  |                 |
| PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS) |                 |
| ISOBUTANE (UNII: BXR49TP611)   |                 |
| DISODIUM STEAROYL GLUTAMATE (UNII: 45ASM2L11M)   |                 |
| BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)  |                 |
| BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)   |                 |
| ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)  |                 |
| .ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)   |                 |

### Packaging

| # | <b>Item Code</b> | <b>Package Description</b>                        | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|---|------------------|---|-----------------------------|---------------------------|
| 1 | NDC:70581-011-00 | 1 in 1 BOX  | 12/25/2017                  |                           |
| 1 |                  | 5 mL 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                                  | 12/25/2017           |                    |

**Labeler** - BPS 60 (272259304)

Revised: 12/2019

BPS 60