

**PHOTO REGUL CREAM UNIFYING PROTECTIVE FACE CARE SPF 25- homosalate, octisalate, avobenzone cream**  
**Naos USA, Inc.**

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**Drug Facts**

**Active ingredients (w/w)**

Homosalate 9%  
Octisalate 4.5%  
Avobenzone 2.7%

**Purpose**

Sunscreen

**Use**

Helps prevent sunburn.

**Warnings**

**For external use only.**

**Do not use**

on broken skin.

**When using this product**

avoid contact with eyes. If contact occurs, rinse thoroughly with water.

**Stop use and ask a doctor if**

rash occurs.

**Keep out of reach of children.**

If swallowed, call a poison control centre or get medical help right away.

**Directions**

Adults 18 years and older:

- Apply liberally and evenly 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. ; and
- Wear long-sleeve shirts, pants, hats and sunglasses.
- Children under 6 months of age: ask a doctor.

### **Other information**

- Keep the product between 15-30°C (59-86°F). • Protect the product in this container from excessive heat and direct sun.

### **Inactive ingredients**

Aqua/water/eau, Ethylhexyl Methoxycrylene, Glycerin, Propanediol, Silica, Tribehenin Peg-20 Esters, Dimethicone, Dibutyl Adipate, Dipropylene Glycol, Butyloctyl Salicylate, Tocopheryl Acetate, Benzotriazolyl Dodecyl P-cresol, Pentyleneglycol, Fragrance (Parfum), C20-22 Alkyl Phosphate, Creatine, Glyceryl Stearate, Mannitol, Methylpropanediol, Peg-100 Stearate, Soybean Glycerides, C20-22 Alcohols, Glycyrrhethinic Acid, Polysilicone-11, Vp/eicosene Copolymer, Acrylates/c10-30 Alkyl Acrylate Crosspolymer, Sodium Hydroxide, Acetyl Tyrosine, Aspartic Acid, Helianthus Annuus (Sunflower) Seed Oil, Xanthan Gum, Sodium Citrate, Sodium Dextran Sulfate, Palmaria Palmata Extract, Maltodextrin, Hydrolyzed Soy Protein, Oleoyl Tyrosine, Pentaerythrityl Tetra-di-t-butyl Hydroxyhydrocinnamate, Hydrolyzed Wheat Protein, Luffa Cylindrica Seed Oil, Andrographis Paniculata Leaf Extract, Oleic Acid, Propylene Glycol, Butylene Glycol, Aminoethanesulfonic Acid, Phenoxyethanol, Caprylyl Glycol, Copper Gluconate, Carnosine, Disodium Adenosine Triphosphate, Artemia Extract, Medicago Sativa (Alfalfa) Extract, Tocopherol, Laminaria Digitata Extract, Linalool, Hexyl Cinnamal, Hydroxycitronellal, Limonene, Benzyl Benzoate, Geraniol, Citronellol, Isoeugenol, Coumarin, Citral.

### **Questions?**

Call 1-877-443-3762

### **Package Labeling:**

**Drug Facts (continued) /  
Info-médicament (suite)**

**Inactive ingredients /  
Ingrédients inactifs**

Aqua/water/eau, Ethylhexyl Methoxycrylate, Glycerin, Propanediol, Silica, Triphenyl PEG-20 Esters, Dimethicone, Dibutyl Adipate, Dipropylene Glycol, Butyloctyl Salicylate, Tocopheryl Acetate, Benzotriazolyl Dodecyl P-cresol, Pentylen Glycol, Fragrance (Parfum), C20-22 Alkyl Phosphate, Creatine, Glycerol Stearate, Mannitol, Methylpropanediol, Peg-100 Stearate, Soybean Glycerides, C20-22 Alcohols, Glyceryl Stearate, Polysilicone-11, Vp/eicosene Copolymer, Acrylates/c10-30 Alkyl Acrylate Crosspolymer, Sodium Hydroxide, Acetyl Tyrosine, Aspartic Acid, Helianthus Annuus (Sunflower) Seed Oil, Xanthan Gum, Sodium Citrate, Sodium Dextran Sulfate, Palmaria Palmata Extract, Maltodextrin, Hydrolyzed Soy Protein, Oleoyl Tyrosine, Pentaerythrityl Tetra-di-t-butyl Hydroxyhydrocinnamate, Hydrolyzed Wheat Protein, Luffa Cylindrica Seed Oil, Andrographis Paniculata Leaf Extract, Oleic Acid, Propylene Glycol, Butylene Glycol, Aminoethanesulfonic Acid, Phenoxethanol, Caprylyl Glycol, Copper Gluconate, Carnosine, Disodium Adenosine Triphosphate, Artemia Extract, Medicago Sativa (Alfalfa) Extract, Tocopherol, Laminaria Digitata Extract, Linalool, Hexyl Cinnamal, Hydroxycitronellal, Limonene, Benzyl Benzoate, Geraniol, Citronellol, Isoeugenol, Coumarin, Citral.

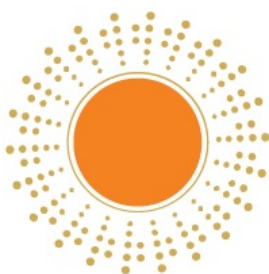
**Questions?**

Call / Composez le 1-877-443-3762

INSTITUT ESTHEDERM est une marque fondée sur l'écobiologie qui est au coeur de la démarche NAOS pour respecter l'écosystème de votre peau et préserver sa santé. Durablement. www.naos.com

INSTITUT ESTHEDERM is a brand built on ecobiology which is at the heart of NAOS approach to respect the skin ecosystem and preserve its health. Lastingly. www.naos.com

INSTITUT  
ESTHEDERM  
PARIS



**PHOTO REGUL  
CREAM / CRÈME**

UNIFYING PROTECTIVE FACE CARE  
SOIN PROTECTEUR VISAGE  
UNIFICATEUR

**SPF 25 / FPS 25**



**PROTECTION UVA-UVB PROTECTION**

Broad Spectrum Sunscreen  
Écran solaire à large spectre

Care first. ✖ NAOS

1.7 fl.oz.

50 mL

DIN : 02516403

**Drug Facts /  
Info-médicament**

**Active ingredients (w/w)/  
Ingrédients actifs (p/p)**

Homosalate 9%  
Octisalate 4.5%  
Avobenzone 2.7% } Sunscreen /  
Écran solaire

**Use / Usage**

Helps prevent sunburn. / Aide à prévenir  
les coups de soleil.

**Warnings / Mises en garde**

For external use only.  
Pour usage externe seulement.

Do not use on broken skin.

Ne pas utiliser sur une peau éraflée.

When using this product avoid contact  
with eyes. If contact occurs, rinse  
thoroughly with water.

Lorsque vous utilisez ce produit, éviter  
tout contact avec les yeux. Le cas échéant,  
bien rincer avec de l'eau.

Stop use and ask a doctor if rash occurs.  
Cessez d'utiliser et consultez un  
médecin si une éruption cutanée se  
développe.

Keep out of reach of children. If  
swallowed, call a poison control centre or  
get medical help right away.

Garder hors de la portée des enfants. En  
cas d'ingestion, appeler immédiatement un  
centre antipoison ou obtenir une  
assistance médicale.

Réf : 05V456303 CA  
Importé et distribué par/  
Imported and distributed by :  
**NAOS CANADA INC.**  
Montréal (QC) H2W 2R2 Canada  
**NAOS USA INC.**  
Wilmington, DE 19808-1609 USA



✖ **NAOS**  
Ecobiology Company - France  
NAOS 13290 Aix-en-Provence  
Made in France



**Drug Facts (continued) /  
Info-médicament (suite)**

**Directions / Mode d'emploi**

Adults 18 years and older:

- Apply liberally and evenly 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.; and • Wear long-sleeve shirts, pants, hats and sunglasses.

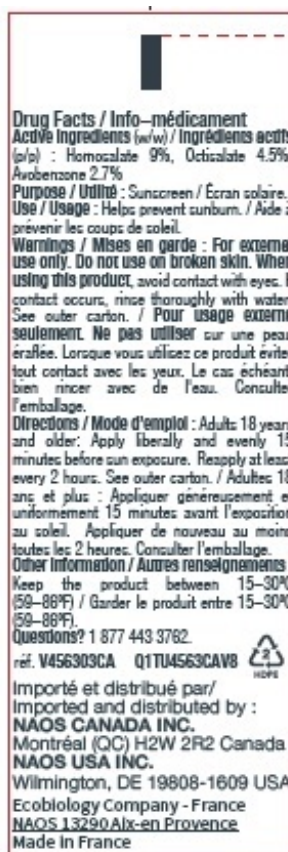
• Children under 6 months of age: ask a doctor. /

Adultes 18 ans et plus :

- Appliquer généreusement et uniformément 15 minutes avant l'exposition au soleil.
- Appliquer de nouveau au moins toutes les 2 heures.
- Utiliser un écran solaire résistant à l'eau lors d'une activité aquatique ou s'il y a transpiration.
- Mesures de protection contre le soleil : Passer du temps au soleil augmente le risque de cancer de la peau et du vieillissement prématuré de la peau. Afin de diminuer ce risque, il convient d'utiliser régulièrement un écran solaire avec un FPS à large spectre d'au moins 15 et d'appliquer d'autres mesures de protection contre le soleil telles que : • Limiter le temps passé au soleil, notamment entre 10h - 14h ; et • Porter des chemises à manches longues, des pantalons, un chapeau et des lunettes de soleil.
- Pour les enfants de moins de 6 mois : demander l'avis d'un médecin.

**Other information / Autres  
renseignements**

- Keep the product between 15-30°C (59-86°F). • Protect the product in this container from excessive heat and direct sun. / • Garder le produit entre 15-30°C (59-86°F). • Tenir loin de la chaleur excessive ou des rayons du soleil.



## PHOTO REGUL CREAM UNIFYING PROTECTIVE FACE CARE SPF 25

homosalate, octisalate, avobenzone cream

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:14324-026 |
| Route of Administration | TOPICAL        |                    |               |

### Active Ingredient/Active Moiety

| Ingredient Name                                                     | Basis of Strength | Strength      |
|---------------------------------------------------------------------|-------------------|---------------|
| <b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) | HOMOSALATE        | 90 mg in 1 mL |
| <b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | OCTISALATE        | 45 mg in 1 mL |
| <b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZONE        | 27 mg in 1 mL |

### Inactive Ingredients

| Ingredient Name                                     | Strength |
|-----------------------------------------------------|----------|
| <b>WATER</b> (UNII: 059QF0KO0R)                     |          |
| <b>ETHYLHEXYL METHOXYCRYLENE</b> (UNII: S3KFG6Q5X8) |          |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                  |          |
| <b>PROPANEDIOL</b> (UNII: 5965N8W85T)               |          |

|                                                                                                     |  |
|-----------------------------------------------------------------------------------------------------|--|
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)                                                           |  |
| <b>TRIBEHENIN PEG-20 ESTERS</b> (UNII: 84K9EH29Y9)                                                  |  |
| <b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)                                                               |  |
| <b>DIBUTYL ADIPATE</b> (UNII: F4K100DXP3)                                                           |  |
| <b>DIPROPYLENE GLYCOL</b> (UNII: E107L85C40)                                                        |  |
| <b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)                                                     |  |
| <b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)                                                |  |
| <b>BENZOTRIAZOLYL DODECYL P-CRESOL</b> (UNII: 298PX4M11X)                                           |  |
| <b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)                                                          |  |
| <b>C20-22 ALKYL PHOSPHATE</b> (UNII: L4VKP0Y7RP)                                                    |  |
| <b>CREATINE</b> (UNII: MU72812GK0)                                                                  |  |
| <b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)                                                     |  |
| <b>MANNITOL</b> (UNII: 3OWL53L36A)                                                                  |  |
| <b>METHYLPROPANEDIOL</b> (UNII: N8F53B3R4R)                                                         |  |
| <b>PEG-100 STEARATE</b> (UNII: YD01N1999R)                                                          |  |
| <b>C20-22 ALCOHOLS</b> (UNII: O4M0347C6A)                                                           |  |
| <b>ENOXOLONE</b> (UNII: P540XA09DR)                                                                 |  |
| <b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5)                |  |
| <b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)                                                          |  |
| <b>ACETYL L-TYROSINE</b> (UNII: DA8G610ZO5)                                                         |  |
| <b>ASPARTIC ACID</b> (UNII: 30KYC7MIAI)                                                             |  |
| <b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)                                                             |  |
| <b>XANTHAN GUM</b> (UNII: TTV12P4NEE)                                                               |  |
| <b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)                                          |  |
| <b>PALMARIA PALMATA</b> (UNII: 7832HOY4ZQ)                                                          |  |
| <b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)                                                              |  |
| <b>OLEOYL TYROSINE</b> (UNII: 131P1BQX1U)                                                           |  |
| <b>PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE)</b> (UNII: 255PIF62MS) |  |
| <b>LUFFA AEGYPTIACA SEED OIL</b> (UNII: 1A281RJ859)                                                 |  |
| <b>ANDROGRAPHIS PANICULATA TOP</b> (UNII: I49U6EUL9X)                                               |  |
| <b>OLEIC ACID</b> (UNII: 2UMI9U37CP)                                                                |  |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)                                                          |  |
| <b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)                                                           |  |
| <b>HYPOTAURINE</b> (UNII: 5L08GE4332)                                                               |  |
| <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)                                                            |  |
| <b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)                                                           |  |
| <b>COPPER GLUCONATE</b> (UNII: RV823G6G67)                                                          |  |
| <b>CARNOSINE</b> (UNII: 8HO6PVN24W)                                                                 |  |
| <b>MEDICAGO SATIVA WHOLE</b> (UNII: DJO934BRBD)                                                     |  |
| <b>TOCOPHEROL</b> (UNII: R0ZB2556P8)                                                                |  |
| <b>LAMINARIA DIGITATA</b> (UNII: 15E7C67EE8)                                                        |  |
| <b>LINALOOL, (+/-)-</b> (UNII: D81QY6I88E)                                                          |  |
| <b>.ALPHA.-HEXYLCINNAMALDEHYDE</b> (UNII: 7X6O37OK2I)                                               |  |
| <b>HYDROXYCITRONELLAL</b> (UNII: 8SQ0VA4YUR)                                                        |  |
| <b>LIMONENE, (+)-</b> (UNII: GFD7C86Q1W)                                                            |  |
| <b>BENZYL BENZOATE</b> (UNII: N863NB338G)                                                           |  |
| <b>GERANIOL</b> (UNII: L837108USY)                                                                  |  |
| <b>.BETA.-CITRONELLOL, (R)-</b> (UNII: P01OUT964K)                                                  |  |
| <b>ISOEUGENOL</b> (UNII: 5M0MWWY797U)                                                               |  |
| <b>COUMARIN</b> (UNII: A4VZ22K1WT)                                                                  |  |

**CITRAL** (UNII: T7EU0O9VPP)

### Packaging

| # | Item Code        | Package Description                                | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:14324-026-00 | 1 in 1 CARTON                                      | 04/01/2022           | 09/30/2024         |
| 1 |                  | 50 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 Drug | M020                                     | 04/01/2022           | 09/30/2024         |

**Labeler -** Naos USA, Inc. (080727572)

Revised: 11/2023

Naos USA, Inc.