

**SUN ULTIMATE FACE SPF 30- octinoxate, octisalate, homosalate, avobenzone cream  
NAOS**

*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 ULTIMATE CREAM FACE SPF 30**

***Drug Facts***

***Active Ingredients***

Octinoxate 7.0%

Octisalate 5.0%

Homosalate 4.0%

Avobenzone 2.5%

***Purpose***

Sunscreen

***Purpose***

Sunscreen

***Uses***

Help prevent sunburn.

***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 reach of children.***

If swallowed, get medical help or contact a Poison Control Center right away

***Directions***

- Apply liberally, and spread evenly by hand 15 min 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-sleeve shirts, pants, hats and sunglasses.
- Children under 6 months of age: Ask a doctor.

***Other information***

- Keep the product between 15-30°C.
- Protect the product in this container from excessive heat and direct sun.

***Inactive Ingredients***

Aqua/Water, Dicaprylyl Carbonate, Glycerin, Pongamia Glabra Seed Oil, Potassium Cetyl Phosphate, Vp/Eicosene Copolymer, Ethylhexyl Methoxycrylene, Glyceryl Stearate, Peg-100 Stearate, Cetyl Alcohol, Tocopheryl Acetate, C20-22 Alkyl Phosphate, Creatine, Glycyrrhetic Acid, Mannitol, C20-22 Alcohols, Sodium Dextran Sulfate, Phenoxyethanol, Chlorphenesin, Acrylates/C10-30 Alkylacrylate Crosspolymer, Cerium Oxide, Disodium Edta, Hydrolyzed Soy Protein, Sodium Hydroxide, Hydrolyzed Wheat Protein, Propylene Glycol, Butylene Glycol, Alcohol, Caprylyl Glycol, Artemia Extract, Tris(Tetramethylhydroxypiperidinol) Citrate, Carnosine, Bht, Xanthan Gum, Algae Extract, Disodium Adenosine Triphosphate, Tocopherol, Potassium Sorbate.

***Question?***

Call to 1-877-443-3762

***Package Labeling:***

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**Drug Facts (continued) /  
Information sur le  
médicament (suite)**

**Inactive ingredients /  
Ingrédients inactifs**

Water/eau, Dicaprylyl Carbonate, Glycerin,  
Pongamia Glabra Seed Oil, Potassium  
Cetyl Phosphate, Vp/eicosene Copolymer,  
Ethylhexyl Methoxycrylene, Glyceryl  
Stearate, Peg-100 Stearate, Cetyl Alcohol,  
Tocopheryl Acetate, C20-22 Alkyl  
Phosphate, Creatine, Glycyrhretinic Acid,  
Mannitol, C20-22 Alcohols, Sodium  
Dextran Sulfate, Phenoxyethanol,  
Chlorphenesin, Acrylates/ C10-30 Alkyl  
Acrylate Crosspolymer, Cerium Oxide,  
Disodium Edta, Hydrolyzed Soy Protein,  
Sodium Hydroxide, Hydrolyzed Wheat  
Protein, Propylene Glycol, Butylene Glycol,  
Alcohol, Caprylyl Glycol, Artemia Extract,  
Tris(Tetramethylhydroxypiperidinol) Citrate,  
Carnosine, Bht, Xanthan Gum, Laminaria  
Digitata Extract, Disodium Adenosine  
Triphosphate, Tocopherol, Potassium  
Sorbate.

**Questions?**

Call / Composez le 1-877-443-3762

INSTITUT  
ESTHEDERM  
PARIS



SUN ULTIMATE  
CREAM / CRÈME

SPF / FPS 30

Broad Spectrum  
Sunscreen  
Écran solaire  
à large spectre

PROTECTION UVA-UVB PROTECTION

1.7 fl.oz.

50 mL  
DIN : 02445557

**Drug Facts / Information  
sur le médicament**

**Active ingredients / Purpose/  
Ingrédients actifs / Utilité**

Octinoxate 7%	} Sunscreen / Écran solaire
Octisalate 5%	
Homosalate 4%	
Avobenzone 2.5%	

**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 damaged or broken skin.  
**Ne pas utiliser** sur une peau  
endommagée ou éraflée.

**When using this product** keep out of  
eyes. Rinse with water to remove.  
**Lorsque vous utilisez ce produit**, évitez  
tout contact avec les yeux. En cas de  
contact, rincer avec de l'eau.

**Stop use and ask a doctor** if rash occurs.  
**Cessez d'utiliser ce produit et consultez  
un médecin** en cas d'éruption cutanée.

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

**Garder hors de portée des enfants.** En  
cas d'ingestion, consulter un médecin  
immédiatement ou appeler un centre  
antipoison.

**Directions / Mode d'emploi**

- Apply liberally and spread evenly by  
hand 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-sleeve shirts, pants, hats and  
sunglasses.
- Children under 6 months of age: ask a  
doctor. /

**Drug Facts (continued) /  
Information sur le  
médicament (suite)**

- Appliquer généreusement, puis étaler  
uniformément avec les mains 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 de  
vieillesse 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 10  
et 14 heures. • 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.

Réf : V 4600 01CA

Importé et distribué par/Imported and  
distributed by :  
**INSTITUT ESTHEDERM CANADA INC.  
LABORATOIRES ESTHEDERM USA INC.**  
Montréal (QC) H2W 2R2 Canada  
Wilmington, DE 19808-1609 USA

Made in France  
**NAOS**  
F-13290 Aix-en Provence



N1ET4600CAV7

INSTITUT  
ESTHEDERM  
PARIS

**SUN ULTIMATE  
CREAM/CRÈME**

**SPF / FPS 30**

Broad Spectrum  
Face Sunscreen  
Écran solaire visage  
à large spectre

PROTECTION UVA-UVB PROTECTION

1.7 fl.oz.

50 mL  
DIN : 02445557

**Drug Facts / Information sur le médicament**

**Active ingredients / Ingrédients actifs :**

Octinoxate 7%, Octisalate 5%, Homosalate 4%,  
Avobenzone 2.5%

**Purpose / Utilité :** Sunscreen / Écran solaire.

**Use / Usage :** Helps prevent sunburn. Aide à  
prévenir les coups de soleil.

**Warning / Mises en garde :** 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. See outer carton. / Pour usage externe  
seulement. Ne pas utiliser sur une peau  
endommagée ou éraflée. Lorsque vous utilisez ce  
produit éviter tout contact avec les yeux. En cas  
de contact, rincer avec de l'eau. Consulter  
l'emballage.

**Directions / Mode d'emploi :** Apply liberally and  
spread evenly by hand 15 min before sun  
exposure. Reapply at least every 2 hours. See  
outer carton.

Appliquer généreusement puis étaler  
uniformément avec les mains 15 min avant  
l'exposition au soleil. Appliquer de nouveau au  
moins toutes les 2 heures. Consulter  
l'emballage.

**Other information / Autre renseignement :** Keep the  
product between 15-30°C (59-86°F) / Garder le  
produit entre 15-30°C.

**Questions?**

Call to / Téléphoner au 1 877 443 3762.

réf. V 4600 01CA

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Imported and distributed by :

INSTITUT ESTHEDERM CANADA INC.

LABORATOIRES ESTHEDERM USA INC.

Montréal (QC) H2W 2R2 Canada

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Made in France

NAQS - F-13290 Aix-en-Provence



**55 MM**

**SUN ULTIMATE FACE SPF 30**

octinoxate, octisalate, homosalate, avobenzone cream

**Product Information**

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:14324-013

**Route of Administration**

TOPICAL

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	70 mg in 1 mL
<b>OCTISALATE</b> (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	50 mg in 1 mL
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	40 mg in 1 mL
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	25 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>TRIS(TETRAMETHYLHYDROXYPIPERIDINOL) CITRATE</b> (UNII: 7NW772I64Y)	
<b>CARNOSINE</b> (UNII: 8HO6PVN24W)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>ADENOSINE TRIPHOSPHATE DISODIUM</b> (UNII: 5L51B4DR1G)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>DICAPRYLYL CARBONATE</b> (UNII: 609A3V1SUA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>KARUM SEED OIL</b> (UNII: 62160PU6FJ)	
<b>POTASSIUM CETYL PHOSPHATE</b> (UNII: 03KCY6P7UT)	
<b>ETHYLHEXYL METHOXYCRYLENE</b> (UNII: S3KFG6Q5X8)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>C20-22 ALKYL PHOSPHATE</b> (UNII: L4VKP0Y7RP)	
<b>CREATINE</b> (UNII: MU72812GK0)	
<b>ENOXOLONE</b> (UNII: P540XA09DR)	
<b>MANNITOL</b> (UNII: 3OWL53L36A)	
<b>C20-22 ALCOHOLS</b> (UNII: O4M0347C6A)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)	
<b>CERIC OXIDE</b> (UNII: 619G5K328Y)	
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	
<b>HYDROLYZED SOY PROTEIN (ENZYMATIC; 2000 MW)</b> (UNII: 1394NXB9L6)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>HYDROLYZED WHEAT PROTEIN (ENZYMATIC; 3000 MW)</b> (UNII: J2S07SB0YL)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14324-013-00	1 in 1 BOX	01/31/2018	10/31/2020
1		50 mL in 1 BOTTLE; 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	01/31/2018	10/31/2020

**Labeler** - NAOS (263520841)

Revised: 5/2020

NAOS