

**LA ROCHE POSAY LABORATOIRE DERMATOLOGIQUE ANTHELIOS SX DAILY  
MOISTURIZING SUNSCREEN BROAD SPECTRUM SPF 15- avobenzene,  
ecamsule and octocrylene cream  
L'Oreal USA Products Inc**

-----

**Drug Facts**

**Active ingredients**

Avobenzene 2%

Ecamsule 2%

Octocrylene 10%

**Purpose**

Sunscreen

**Uses**

- helps prevent sunburn
- higher SPF gives more sunburn protection
- helps provide protection from UVA rays (short and long wavelengths)

**Warnings**

**For external use only**

**Do not use on**

- broken skin
- serious burns

**When using this product**

keep out of eyes. Rinse with water to remove.

**Stop use and ask a doctor if**

rash or irritation develops and lasts

**Keep out of reach of children.**

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

### **Directions**

- apply evenly before sun exposure
- reapply as needed or after towel drying, swimming, or perspiring
- children under 6 months of age: ask a doctor

### **Inactive ingredients**

carbomer homopolymer Type C, carbomer copolymer Type B, cyclomethicone, dimethicone, edetate disodium, glycerin, hydroxypropyl methylcellulose, isopropyl palmitate, methylparaben, phenoxyethanol, propylene glycol, propylparaben, purified water, stearic acid, stearyl macroglycerides, stearyl alcohol, trolamine

### **Questions?**

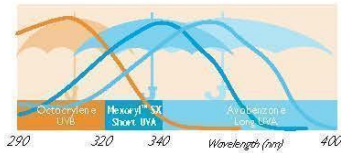
**1-800-308-4516**

Monday - Friday (9 a.m. to 5 p.m. EST)

**ANTHELIOS SX** helps provide protection from UVA rays.

How does Mexoryl™ SX (ecamsule) protect skin from UVA rays?

Parso® 1789 (avobenzone) is very effective at the midpoint of the UVA spectrum, but provides less protection against short UVA wavelengths. Mexoryl™ SX (ecamsule) provides peak efficacy against these short UVA rays.



The combination of Parso® 1789 (avobenzone) and Mexoryl™ SX (ecamsule) helps provide UVA protection.

**Sun alert:** Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.

Even if you do not burn, repeated exposure of unprotected skin while tanning may increase the risk of skin aging, skin cancer, and other harmful effects to the skin.

**UVA rays, a daily skin concern:**

UVA rays have been shown to penetrate deeper into the skin, damaging its elasticity and contributing to premature skin aging.

**UVB rays, also a skin concern:**

UVB rays cause sunburn and also contribute to premature skin aging. SPF, or "Sun Protection Factor," is the degree of protection a sunscreen offers against UVB rays.

**Drug Facts**

Active ingredients	Purpose
Avobenzone 2%	Sunscreen
Ecamsule 2%	Sunscreen
Octocrylene 10%	Sunscreen

**Uses**

- helps prevent sunburn
- higher SPF gives more sunburn protection
- helps provide protection from UVA rays (short and long wavelengths)

**Warnings**

For external use only

**Do not use on**

- broken skin
- serious burns

**When using this product**

- keep out of eyes. Rinse with water to remove.

**Stop use and ask a doctor if**

- rash or irritation develops and lasts

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

**Directions**

- apply evenly before sun exposure
- reapply as needed or after towel drying, swimming, or perspiring
- children under 6 months of age: ask a doctor

**Inactive ingredients**

carbomer homopolymer Type C, carbomer copolymer Type B, cyclomethicone, dimethicone, edetate disodium, glycerin, hydroxypropyl methylcellulose, isopropyl palmitate, methylparaben, phenoxyethanol, propylene glycol, propylparaben, purified water, stearic acid, stearyl macroglycolglycerides, stearyl alcohol, triamine

**Questions?**

1-800-308-4516  
Monday - Friday (9 a.m. to 5 p.m. EST)

SPF 15

DAILY MOISTURIZER

LA ROCHE-POSAY  
LABORATOIRE DERMATOLOGIQUE

BROAD SPECTRUM  
SPF15

**ANTHELIOS SX**  
DAILY MOISTURIZING CREAM  
with SUNSCREEN

UVA PROTECTION

with **MEXORYL™ SX**  
(ECAMSULE)

DAILY USE MOISTURIZER.  
UVA/UVB protection  
24 hr long-lasting hydration

Fragrance-free. PABA-free  
Light, non-greasy  
Suitable for sensitive skin

3.4 OZ. - 100 g

UVA protection to help prevent the effects of sun damage

**ANTHELIOS SX** is a unique daily use moisturizer with sunscreen that combines Parso® 1789\* (avobenzone) and an innovative ingredient, **Mexoryl™ SX†** (ecamsule), to help provide:

- > UVA protection (short and long wavelengths)
- > broad UVA/UVB protection in a formula with patented technology
- > intense, 24 hour long-lasting hydration.

**Dermatological safety**

This dermatologist-tested formula is suitable for sensitive skin types. **ANTHELIOS SX** is fragrance-free, allergy-tested, non-irritating and non-greasy.

Aminobenzoic acid (PABA)-free.

**Result**

Skin is moisturized 24 hours and receives protection from UVA rays.

To know more about the full line of La Roche-Posay products and where to find them, call 1-800-308-4516

Store at 20-25°C (68-77°F)

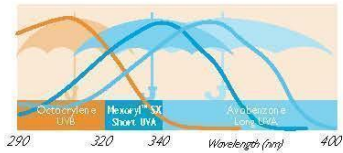
Distributed by La Roche-Posay LLC  
New York, NY 10017  
MADE IN THE U.S.A.

1885107

\*Avobenzone, Parso® 1789 is a trademark of DSM Nutritional Products.  
†Ecamsule, MEXORYL is a trademark of L'Oréal S.A.

L'ORÉAL U.S. PATENT NO. 5,587,150

**ANTHELIOS SX** helps provide protection from UVA rays. How does Mexoryl™ SX (ecamsule) protect skin from UVA rays? Parsol® 1789 (avobenzone) is very effective at the midpoint of the UVA spectrum, but provides less protection against short UVA wavelengths. Mexoryl™ SX (ecamsule) provides peak efficacy against these short UVA rays.



The combination of Parsol® 1789 (avobenzone) and Mexoryl™ SX (ecamsule) helps provide UVA protection.

**Sun alert:** Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.

Even if you do not burn, repeated exposure of unprotected skin while tanning may increase the risk of skin aging, skin cancer, and other harmful effects to the skin.

**UVA rays, a daily skin concern:**

UVA rays have been shown to penetrate deeper into the skin, damaging its elasticity and contributing to premature skin aging.

**UVB rays, also a skin concern:**

UVB rays cause sunburn and also contribute to premature skin aging. SPF, or "Sun Protection Factor," is the degree of protection a sunscreen offers against UVB rays.

**Drug Facts**

Active ingredients	Purpose
Avobenzone 2%	Sunscreen
Ecamsule 2%	Sunscreen
Octocrylene 10%	Sunscreen

**Uses**

- helps prevent sunburn
- higher SPF gives more sunburn protection
- helps provide protection from UVA rays (short and long wavelengths)

**Warnings**

For external use only

**Do not use on**

- broken skin
- serious burns

**When using this product**

- keep out of eyes. Rinse with water to remove.

**Stop use and ask a doctor if**

- rash or irritation develops and lasts

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

**Directions**

- apply evenly before sun exposure
- reapply as needed or after towel drying, swimming, or perspiring
- children under 6 months of age: ask a doctor

**Inactive ingredients**

carbomer homopolymer Type C, carbomer copolymer Type B, cyclomethicone, dimethicone, edetate disodium, glycerin, hydroxypropyl methylcellulose, isopropyl palmitate, methylparaben, phenoxyethanol, propylene glycol, propylparaben, purified water, stearic acid, stearyl macroglyglycerides, stearyl alcohol, triethylamine

**Questions?**

1-800-308-4516  
Monday - Friday (9 a.m. to 5 p.m. EST)

SPF 15

DAILY MOISTURIZER

LA ROCHE-POSAY  
LABORATOIRE DERMATOLOGIQUE

BROAD SPECTRUM  
SPF15

**ANTHELIOS SX**  
DAILY MOISTURIZING CREAM  
with SUNSCREEN

UVA PROTECTION

with **MEXORYL™ SX**  
(ECAMSULE)

DAILY USE MOISTURIZER.  
UVA/UVB protection  
24 hr long-lasting hydration

Fragrance-free. PABA-free  
Light, non-greasy  
Suitable for sensitive skin

3.4 OZ. - 100 g

UVA protection to help prevent the effects of sun damage

**ANTHELIOS SX** is a unique daily use moisturizer with sunscreen that combines Parsol® 1789\* (avobenzone) and an innovative ingredient, **Mexoryl™ SX†** (ecamsule), to help provide:

- > UVA protection (short and long wavelengths)
- > broad UVA/UVB protection in a formula with patented technology
- > intense, 24 hour long-lasting hydration.

**Dermatological safety**

This dermatologist-tested formula is suitable for sensitive skin types. **ANTHELIOS SX** is fragrance-free, allergy-tested, non-irritating and non-greasy.

Aminobenzoic acid (PABA)-free.

**Result**

Skin is moisturized 24 hours and receives protection from UVA rays.

To know more about the full line

of La Roche-Posay products and where to find them, call 1-800-308-4516

Store at 20-25°C (68-77°F)

Distributed by La Roche-Posay LLC  
New York, NY 10017  
MADE IN THE U.S.A.

1885107

\*Avobenzone, Parsol® 1789 is a trademark of DSM Nutritional Products.  
†Ecamsule, MEXORYL is a trademark of L'Oréal S.A.

L'ORÉAL U.S. PATENT NO. 5,587,150

**LA ROCHE POSAY LABORATOIRE DERMATOLOGIQUE ANTHELIOS SX DAILY MOISTURIZING SUNSCREEN BROAD SPECTRUM SPF 15**

avobenzone, ecamsule and octocrylene cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49967-017
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	20 mg in 1 g
<b>ECAMSULE</b> (UNII: M94R1PM439) (ECAMSULE - UNII:M94R1PM439)	ECAMSULE	20 mg in 1 g
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	100 mg in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>CARBOMER HOMOPOLYMER TYPE C</b> (UNII: 4Q93RCW27E)	
<b>CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL OR ALLYL SUCROSE CROSSLINKED)</b> (UNII: K6MOM3T5YL)	
<b>CYCLOMETHICONE</b> (UNII: NMQ347994Z)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>ISOPROPYL PALMITATE</b> (UNII: 8CRQ2TH63M)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>PEG-32 HYDROGENATED PALM GLYCERIDES</b> (UNII: G6EP177239)	
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-017-01	1 in 1 CARTON	07/29/2014	11/23/2024
1		100 g in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021502	07/29/2014	11/23/2024

**Labeler** - L'Oreal USA Products Inc (002136794)

### Establishment

Name	Address	ID/FEI	Business Operations
DPT Laboratories, Ltd.		832224526	manufacture(49967-017)

### Establishment

Name	Address	ID/FEI	Business Operations
DPT Laboratories, Ltd.		832224690	analysis(49967-017)