

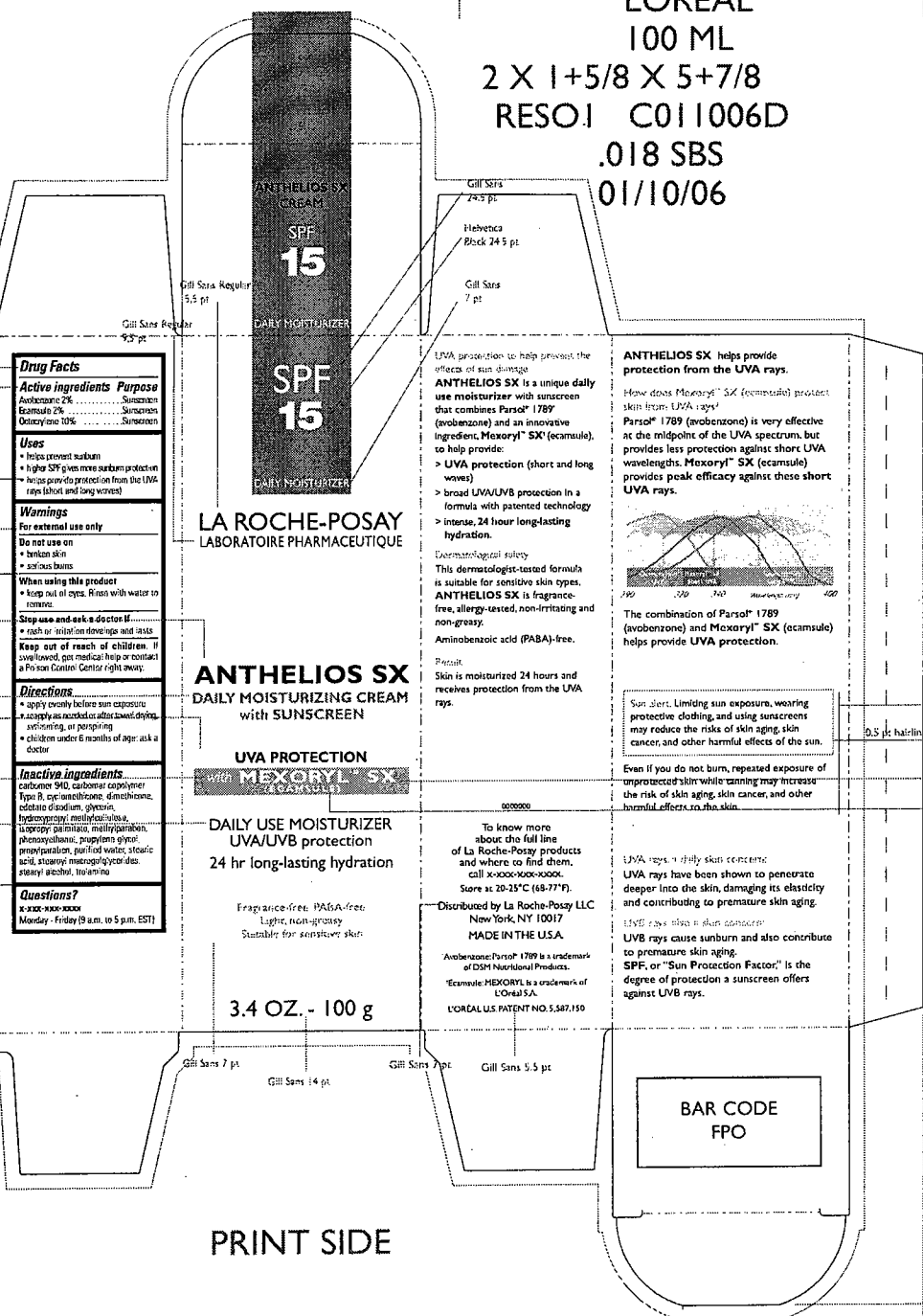
**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-502

APPROVED LABELING

LOREAL
 100 ML
 2 X 1+5/8 X 5+7/8
 RESO:1 C011006D
 .018 SBS
 01/10/06



Drug Facts

Active ingredients Purpose

Avobenzone 2% Sunscreen
 Benzoin 2% Sunscreen
 Octocrylene 10% Sunscreen

Uses

- helps prevent sunburn
- higher SPF gives more sunburn protection
- helps provide protection from the UVB rays (short and long waves)

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, perspiring, or perspiring
- children under 6 months of age: ask a doctor

Inactive ingredients

cellulose 940, carbomer copolymer, Type B, cycloheximide, dimethicone, edetate disodium, glycerin, hydroxypropyl methylcellulose, isopropyl palmitate, methylparaben, phenoxyethanol, propylene glycol, propylparaben, purified water, stearic acid, stearyl myristoyl glycolides, stearyl alcohol, titanium

Questions?

1-800-XXX-XXXX
 Monday - Friday (9 a.m. to 5 p.m. EST)

ANTHELIOS SX helps provide protection from the UVA rays.

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

Parso® 1789 (avobenzonone) 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 (avobenzonone) 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 in daily skin concerns: UVA rays have been shown to penetrate deeper into the skin, damaging its elasticity and contributing to premature skin aging.

LVB rays also in skin concerns: 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.

To know more about the full line of La Roche-Posay products and where to find them, call 1-800-XXX-XXXX. Store at 20-25°C (68-77°F).

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

Avobenzone, Parso® 1789 is a trademark of DSM Nutritional Products.
 Ecamsule, MEXORYL is a trademark of L'Oréal SA.
 L'ORAL U.S. PATENT NO. 5,587,150

VERSION UVA SIMPLE

POSAY 18222 TER
 ANTHELIOS^{SX} SPF 15 - PFA 15 USA
 VERSION BOX ORANGE
 ETUI 100 ML VENTE

19/07/06 CA TEXTES
 20/07/06 CA TEXTES DOS ETUI
 20/07/06 CA DOS ETUI

PRINT SIDE

BAR CODE
 FPO



Gill Sans 18 pt

Helvetica Black 18 pt

Gill Sans 4.63 pt

LA ROCHE-POSAY
LABORATOIRE PHARMACEUTIQUE

Gill Sans Regular 10.67 pt

Gill Sans Regular 6.52 pt

Gill Sans Bold 14 pt

ANTHELIOS SX DAILY MOISTURIZING CREAM with SUNSCREEN

Gill Sans Bold 8.2 pt

Gill Sans Bold 8.31 pt

Gill Sans Italic 8.75 pt

Gill Sans Bold 11.38 pt

Gill Sans Bold 4.48 pt

Gill Sans 8.75 pt

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

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

Gill Sans 6.13 pt

Gill Sans 11.2 pt

3.4 OZ. - 100 g

Gill Sans 6.5 pt

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

Active ingredients: Avobenzone 2%, Ecamsule 2%, Octocrylene 10%.

Uses:

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

Warnings: For external use only. Do not use on broken skin or 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.

Questions? 1-800-800-XXXX

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

* Avobenzone/Parsol 1789 is a trademark of DSM Nutritional Products

† Ecamsule/MEXORYL is a trademark of L'Oréal USA.

Store at 20-25°C (68-77°F).

Distributed by La Roche-Posay LLC, New York, NY 10017

MADE IN THE U.S.A.

laroche-posay.com



Gill Sans 6 pt

Gill Sans 5 pt

VERSION UVA SIMPLE

POSAY 18222 TER

ANTHELIOS SX SPF 15 - PFA 15 USA
TUBE 100 ML VENTE

19/07/06 CA TEXTES

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Susan Walker
7/21/2006 04:09:45 PM
Signed for Dr Julie Beitz

Charles Ganley
7/21/2006 04:14:58 PM