

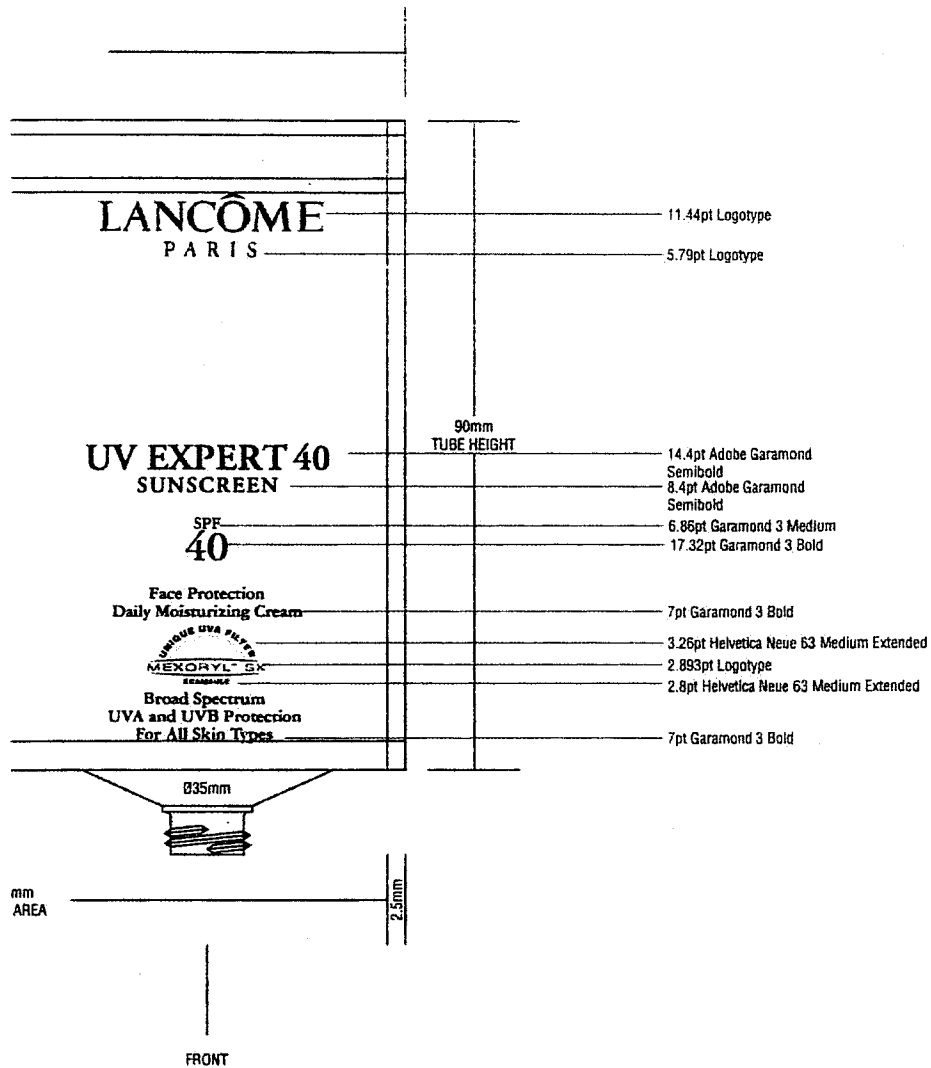
**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-009

LABELING

PRIMARY FRONT PANEL

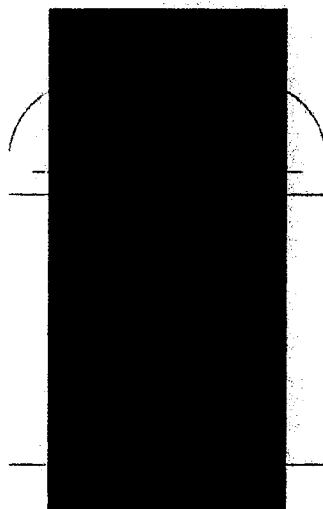


PRIMARY BACK PANEL

		2mm	
		2mm x 6mm	
		EYE MARK	
		2mm	
6pt Helvetica Bold Condensed			Introducing UV Expert 40 from Lancôme.
6pt Helvetica Medium Condensed			Dermatologist-tested, this innovative sunscreen combines Mexoryl™ SX (ecamsule), Parsol® 1789 (avobenzone), Octocrylene and Titanium Dioxide to help provide protection against UVA and UVB rays.
6pt Garamond 3 Medium			ACTIVE INGREDIENTS: AVOBENZONE* 2%, ECAMSULE** 3%, OCTOCRYLENE 10%, TITANIUM DIOXIDE 5%
6pt Helvetica Bold Condensed			USES: Helps prevent sunburn. Higher SPF gives more sunburn protection. Helps provide protection from UVA rays (short and long wavelengths).
6pt Helvetica Medium Condensed			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.
	76mm		DIRECTIONS: Apply evenly 15 minutes before sun exposure. Reapply as needed or after towel drying, swimming, or perspiring. Children under 6 months of age, ask a doctor.
6pt Garamond 3 Medium			*Avobenzone: Parsol® 1789 is a trademark of L'Oréal Parfums.
4pt Helvetica Bold Condensed			**Ecamsule: MEXORYL™ is a trademark of L'Oréal S.A.
10pt Futura Light			1.7 OZ. 50g
6pt Helvetica Medium Condensed			STORE AT 20-25° C (68-77° F).
6pt Helvetica Bold Condensed			DISTRIBUTED BY:
6pt Helvetica Medium Condensed			LANCÔME, LUXURY PRODUCTS LLC
	4mm		NEW YORK, NY 10017
			MADE IN THE U.S.A. 3833-00

BACK

SECONDARY FRONT PANEL



LANCÔME
PARIS

12.156pt "Lancôme" Logotype

6.145pt "Paris" Logotype

UV EXPERT 40
SUNSCREEN

16.2pt Adobe
Garamond Semibold
9.45pt Adobe
Garamond Semibold

SPF
40

8.35pt Garamond 3 Medium
21.1pt Garamond 3 Bold

Face Protection
Daily Moisturizing Cream

8pt Garamond 3 Bold



4.24pt Helvetica Neue 53
Medium Extended

Broad Spectrum
UVA and UVB Protection
For All Skin Types

3.28pt Helvetica Neue 53
Medium Extended

8pt Garamond 3 Bold

1.7 OZ. 50g

12pt Futura Light

SECONDARY BACK PANEL

ALL TEXT: 6pt Helvetica Medium, 7pt leading
 ALL SUBHEADINGS: 6pt Helvetica Bold, 8pt leading
 ALL HEADINGS: 8pt Helvetica Bold Oblique, 14pt lead
 TITLE: 14pt Helvetica Bold Oblique, 14pt leading
 ALL BULLETS: 6pt Helvetica Medium, 7pt leading
 MAX CHARACTERS PER INCH: 25 (NOT MONOSPACED)

2pt stroke

0.5pt stroke

4⁵/₈

Drug Facts

Active Ingredients	Purpose
Avobenzone 2%	Sunscreen
Ecamsule 3%	Sunscreen
Octocrylene 10%	Sunscreen
Titanium dioxide 5%	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 15 minutes before sun exposure
- reapply as needed or after towel drying, swimming or perspiring
- children under 6 months of age: ask a doctor

Inactive Ingredients carboner 940, carboner copolymer Type B, cyclomethicone, dimethicone, edetate disodium, glycerin, hydroxypropyl methylcellulose, isopropyl palmitate, methylparaben, phenoxethanol, polyvinylpyrrolidone/tetrasocone copolymer, propylene glycol, propylparaben, purified water, stearic acid, stearyl macroglycerides, stearyl alcohol, toleamine

Questions?
1-800-983-0617
Monday-Friday (9 a.m. to 5 p.m. EST)

FOR POSITION ONLY!



2534704693

UV EXPERT 40

Face Protection Cream

SECONDARY LEFT SIDE PANEL

UV Rays Revealed

Ultraviolet (UV) light is energy from the sun that cannot be seen, but its effects can be observed. Unprotected exposure to UVA and UVB rays can increase the risk of skin cancer. These rays may also cause premature skin aging such as the appearance of wrinkles, age spots and loss of firmness.

UVA rays have the power to penetrate deep into the skin and may cause harm to the elastin and collagen fibers that make skin supple and firm.

UVB rays are the "burning" rays. Overexposure can result in sunburn, but even casual exposure to UVB rays may cause damage to the skin's DNA, which is one of the foremost causes of skin cancer.

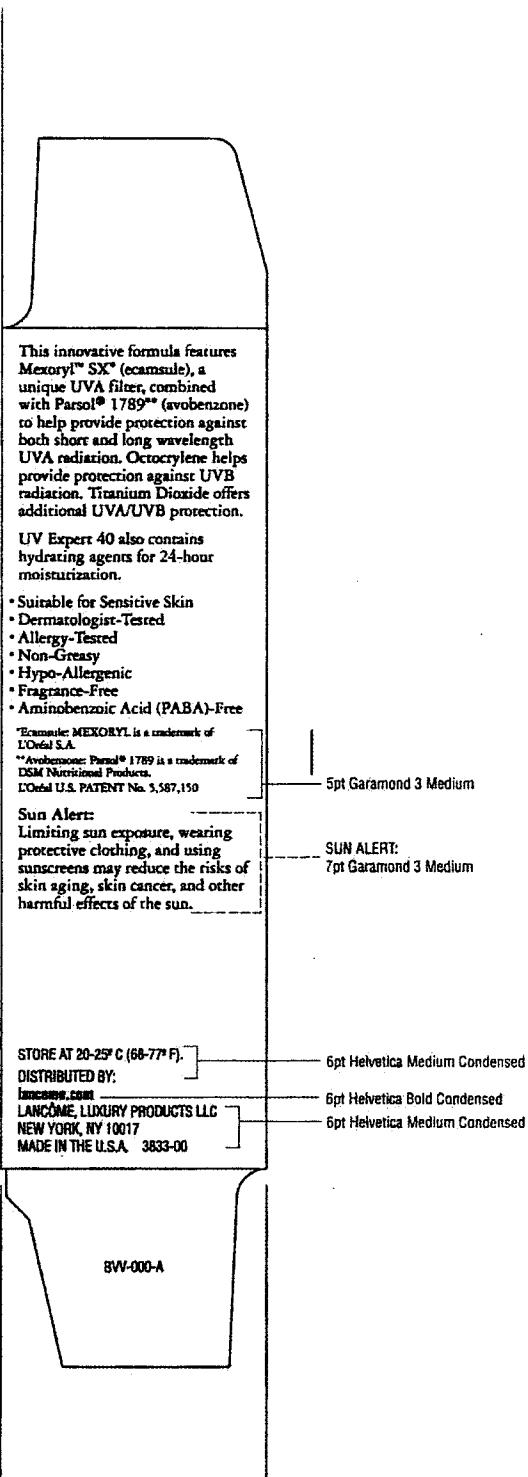
Broad Spectrum UVA and UVB Filtering System

- Octocrylene offers protection by absorbing UVB rays.
- Mexoryl™ SX (ecamsule) offers protection by absorbing short UVA rays.

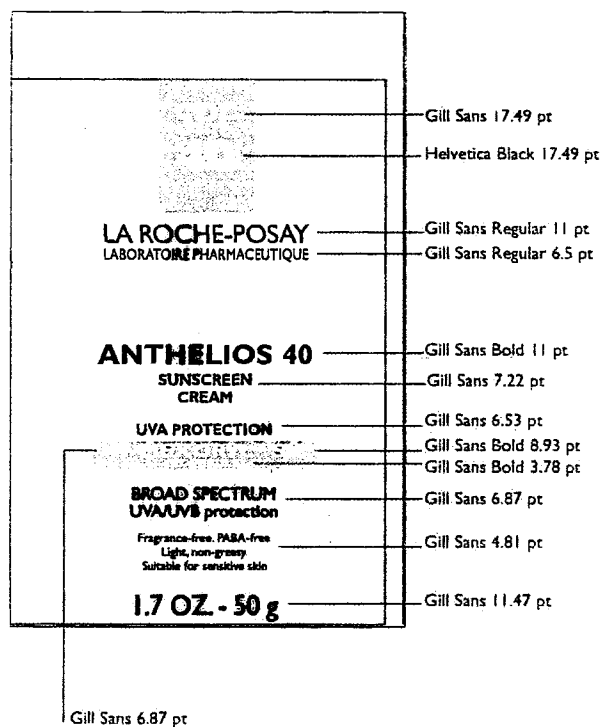


03/07

SECONDARY RIGHT SIDE PANEL



PRIMARY FRONT PANEL



PRIMARY BACK PANEL

Gill Sans 6 pt

Gill Sans 5 pt

UVA protection to help prevent the effects of sun damage
ANTHELIOS 40 is a unique sunscreen that combines
Parasol 1789 (avobenzone) and an innovative ingredient,
MimastylTM 53K (ecamsule), to help provide:
 > UVA protection (short and long wavelengths)
 > broad UVA/UVB protection in a formula with patented
 technology

Active ingredients: Avobenzone 3%, Ecamsule 3%,
 Octocrylene 10%, Titanium dioxide 5%.

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

Questions? 1-800-368-6516

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

*Avobenzone, Parasol 1789 is a trademark of DSH Nutritional Products.
 (Ecamsule) MIMASTYL is a trademark of L'Oréal SA.

Store at 20-25°C (68-77°F).

Distributed by La Roche-Posay U.S.A., New York, NY 10017

Made in the U.S.A.

laroche-posayusa

810035500

SECONDARY FRONT PANEL



SECONDARY BACK PANEL

Title: Univers
CondensedBoldOblique
9 pt/9.5 pt leading
All headings: Univers
CondensedBoldOblique
8 pt/8.5 pt leading

Drug Facts	
Active Ingredients	Purpose
Avobenzone 2%	Sunscreen
Ecamsule 3%	Sunscreen
Octocrylene 10%	Sunscreen
Titanium dioxide 5%	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 15 minutes 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 940, carbomer copolymer Type B, cyclomethicone, dimethicone, edetate disodium, glycerin, hydroxypropyl methylcellulose, isopropyl palmitate, methylparaben, phenoxethanol, polyvinylpyrrolidone/eicosene copolymer, propylene glycol, propylparaben, purified water, stearic acid, stearyl macroglycolates, stearyl alcohol, triethanolamine	
Questions?	
1-800-368-4576 Monday - Friday (9 a.m. to 5 p.m. EST)	

All text: Univers
CondensedLight 6 pt
All bullets: 6 pt
6.5 pt leading

All subheadings:
UniversCondensed Bold
6 pt/6.5 pt leading

0.5 pt hairlines

2.5 pt barlines

Maximum characters
per inch: 32

SECONDARY LEFT SIDE PANEL

ANTHELIOS 40 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.

Octocrylene, Mexoryl™ SX (ecamsule) and Parsol® 1789 (avobenzone) absorb UV rays; titanium dioxide absorbs, reflects, and scatters UV light.

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, the cause of sunburn:

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.

Gill Sans 6 pt

0.5 pt hairlines

SECONDARY RIGHT SIDE PANEL

UVA protection to help prevent the effects of sun damage

ANTHELIOS 40 is a unique 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

Dermatological safety

This dermatologist-tested formula is suitable for sensitive skin types.

ANTHELIOS 40 is fragrance-free, allergy-tested, non-irritating and non-greasy.

Aminobenzoic acid (PABA)-free.

Result

Skin receives protection from UVA rays.

ANTHELIOS 40 also helps prevent sunburn.

80085500

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.

*Avobenzone: Parsol® 1789 is a trademark of DSM Nutritional Products.

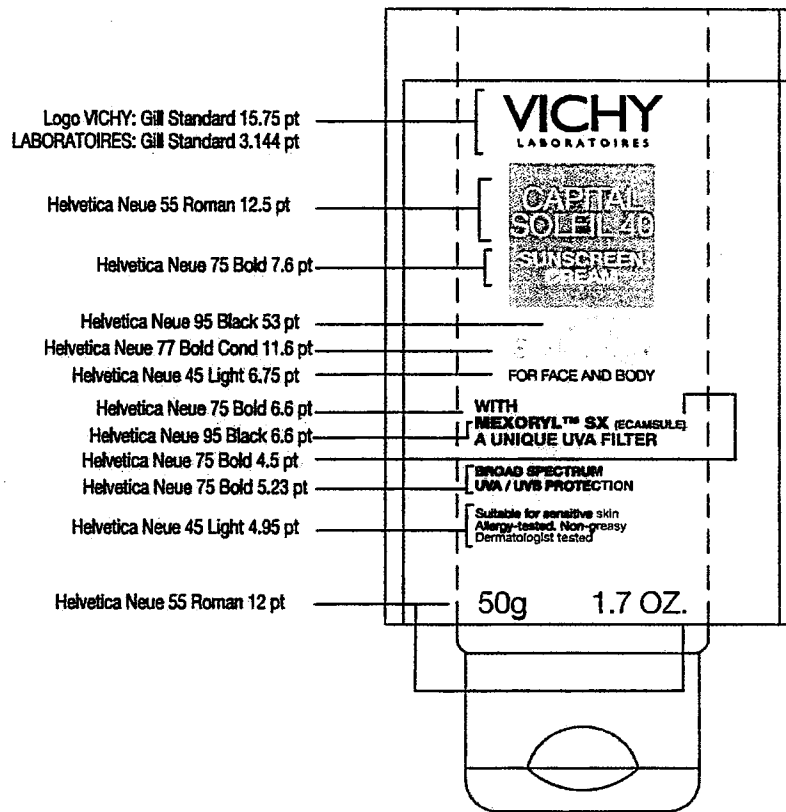
†Ecamsule: MEXORYL is a trademark of L'Oréal S.A.

L'ORÉAL U.S. PATENT NO. 5,587,150

Gill Sans 5 pt

Gill Sans 6 pt

PRIMARY FRONT PANEL



PRIMARY BACK PANEL

Active ingredients: Avobenzone* 2%, Ecamsule** 3%, Octocrylene 10%, Titanium dioxide 5%. 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 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 15 minutes before sun exposure. Reapply as needed or after towel drying, swimming, or perspiring. Children under 6 months of age: ask a doctor. Questions? 1-800-983-0821 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 S.A. L'Oréal US Patent No. 5,587,150 Store at 20-25°C (68-77°F). Distributed by Vichy LLC, New York, NY 10017 Made in U.S.A. www.vichy.com	ALL HEADINGS: Gill Sans Bold Italic 8 pt ALL SUBHEADINGS: Gill Sans Bold 6 pt ALL TEXT: Gill Sans Standard 6 pt Gill Sans Standard 5.5 pt Gill Sans Standard 6.25 pt Gill Sans Standard 7 pt Gill Sans Light 8 pt

SECONDARY FRONT PANEL



SECONDARY BACK PANEL

Drug Facts

Active Ingredients	Purpose
Avo benzene 2%	Sunscreen
Ecamsule 3%	Sunscreen
Octocrylene 10%	Sunscreen
Titanium dioxide 5%	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 15 minutes 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 940, carbomer copolymer Type B, cyclomethicone, dimethicone, edisate disodium, glycerin, hydroxypropyl methylcellulose, isopropyl palmitate, methylparaben, phenoxystanol, polyvinylpyrrolidone/stearyl alcohol copolymer, propylene glycol, propylparaben, purified water, stearic acid, stearyl macroglycolglycerides, stearyl alcohol, triethanolamine

Questions?

1-800-783-8821

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

TITLE: Gill Sans Bold Italic 14 pt. Leading: 14 pt

ALL BULLETS: Gill Sans Standard 6 pt.

ALL HEADINGS: Gill Sans Bold Italic 8 pt. Leading: 14 pt

ALL SUBHEADINGS: Gill Sans Bold 6 pt. Leading: 8 pt

ALL HORIZONTALS: 0.3 pt

ALL VERTICALS: 0.8 pt

Maximum characters per inch: 39 (NOT MONOSPACED)

ALL TEXT: Gill Sans Standard 6 pt. Leading: 6 pt

SECONDARY LEFT SIDE PANEL

**CAPITAL SOLEIL SUNSCREEN CREAM
WITH MEXORYL™ SX (ECAMSULE)
BROAD SPECTRUM UVA/UVB
PROTECTION**

Unprotected exposure to the sun can lead to UV-induced skin damage. UVA and UVB rays may increase the risk of skin cancer. UVA rays can diminish the skin's natural protective mechanism. The cumulative effects of exposure to UVA can cause an alteration to the skin structure leading to wrinkles, loss of firmness and the appearance of age spots. UVB rays may also contribute to premature skin aging. There are two types of UVA rays, long and short UVA rays. Some sunscreen products do not provide protection against UVA rays.

CAPITAL SOLEIL 40's innovative formula combines a unique UVA filter, Mexoryl™ SX® (ecamsule), with Parsol® 1789™ (avobenzone), to create a new concept in sun protection. **CAPITAL SOLEIL 40** with Mexoryl™ SX® protects against both long and short UVA rays, while also providing UVB protection against sunburn.

**Broad Spectrum
UVA/UVB protection; SPF 40**
CAPITAL SOLEIL 40 with Mexoryl™ SX® helps provide protection from UVA and UVB rays.

**GENTLE FORMULA
SUITABLE FOR SENSITIVE SKIN**

- For face and body
 - Suitable for sensitive skin
 - Aminobenzoic acid (PABA)-free
 - Non-greasy
 - Fragrance-free
 - Dermatologist tested
- Store at 20-25°C (68-77°F).

Gill Sans Standard 7 pt

SECONDARY RIGHT SIDE PANEL

ULTRAVIOLET RAYS UVA AND UVB

**UV rays may contribute to premature skin aging
UVB rays cause sunburn
UVA and UVB rays may increase the risk of skin cancer**

UVA rays have been shown to penetrate deeper into the skin, damaging the elasticity of the tissue which may accelerate the aging of the skin. The two types of UVA rays, UVA short and UVA long, penetrate the skin at different levels. UVB rays may also contribute to premature skin aging. UVA and UVB rays may lead to the increased risk of developing skin cancer.

What does SPF mean?

SPF, or "Sun Protection Factor", is the degree of protection a sunscreen offers against UVB rays which cause sunburn.

Repeated exposure of unprotected skin to the sun may increase the risk of skin cancer, even if you don't burn.

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.

* **Estimate:** MEXORYL is a trademark of L'Oréal S.A.

** **Avobenzone:** Parsol 1789 is a trademark of DSM Nutritional Products.
L'Oréal U.S. Patent No. 5,587,150

Distributed by Vichy LLC,
New York, NY 10017
Made in U.S.A.
R&F. 00 00 00
www.vichy.com

Gill Sans Standard 5.75 pt