

BLES İLAÇ VE MEDİKAL

Belgium

**SPF in vitro, critical wavelength and UVA-PF in vitro (ratio UVA/SPF)
of one sample**

Technical Report No. PC-08-089A1

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SPF in vitro, critical wavelength and UVA-PF in vitro

Sample	Sample 1 High sun care cream SPF 40+ Lot 81153 (600kg production)
Aim of the study	Assessment of the in vitro SPF (<i>according to Ciba method n°16</i>) Assessment of the critical wavelength (<i>according to Ciba method n°19</i>) Assessment of the UVA-PF in vitro (<i>according to Ciba method n° 28 based on Colipa guideline 2007 "in vitro determination of UVA protection provided by sunscreen products"</i>)
Instrumentation	Labsphere UV Transmittance Analyzer, UV1000S Atlas Sun test CPS+
Reference	Glycerin

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SPF & critical wavelength

Substrate	Roughened Plexiglas (PMMA), Helioscience, France, HD6 Lot 5262
Number of samples	4 (9 measurements per plate)
Applied amount	1,2 mg/cm ²

UVA-PF in vitro

Substrate	Roughened Plexiglas (PMMA), Schönberg, Germany Lot 20080210-PL0014 (Platte Nr. 21)
Number of samples	3 (5 measurements per plate)
Applied amount	0,75 mg/cm ²

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Summary

- According to our evaluation, Sample 1 High suncare cream SPF 40+ Lot 81153 (600kg production), fulfills the EC requirements of $\text{UVA-PF}_{\text{in vitro}} / \text{SPF}_{\text{claimed}} > 1/3$ measured based on Colipa guideline 2007. The sample shows a perfect photostability, no modification of the UVA protection will occur even under longer sun exposure.
- The in-vitro SPF for Sample 1 High suncare cream SPF 40+ Lot 81153 (600kg production) was measured with >40 .

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Results

SPF in vitro & critical wavelength:

<i>Sample</i>	<i>In vitro SPF</i>	<i>Critical Wavelength (nm)</i>
Sample 1 High suncare cream SPF 40+ Lot 81153 (600kg production)	>40	> 370

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UVA-PF in vitro

Based on the UVA-PF in vitro measurement, the criterion $\text{UVA-PF}_{\text{in vitro}} / \text{SPF}_{\text{claimed}}$ can be evaluated.

Sample 1 High suncare cream SPF 40+ Lot 81153 (600kg production)

SPF claimed 40

UVA Dose 19,11 J/cm²

Sample	UVA-PF in vitro ⁽¹⁾	UVA-PF/SPF ⁽¹⁾	UVA-PF in vitro ⁽²⁾	UVA-PF/SPF ⁽²⁾
Sample 1 High suncare cream SPF 40+ Lot 81153 (600kg production)	15,9	> 1/3	16,5	> 1/3

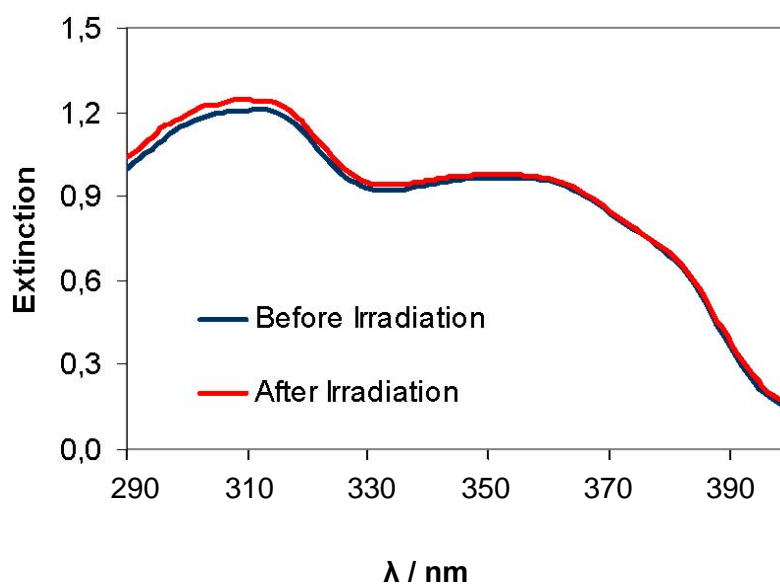
⁽¹⁾ UVA-PF in vitro measured without any pre-irradiation step

⁽²⁾ UVA-PF in vitro measured after the pre-irradiation step given by the Colipa guideline 2007

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Absorption spectra

Sample 1 High suncare cream SPF 40+ Lot 81153 (600kg production)



APPENDIX
Data - coefficient of adjustment

	<i>Plate 1</i>	<i>Plate 2</i>	<i>Plate 3</i>
Sample 1 High suncare cream SPF 40+ Lot 81153 (600kg production)	1,373	1,445	1,369