

UVA In Vitro Method – Technical Q&A

Q.1 – Where can I find the Colipa UVA In Vitro Method?

A.1 – It is available on the Colipa website:

<http://www.colipa.eu>

- look at Colipa Recommendation No. 20 In Vitro UVA Test Method

and the Guidelines for Monitoring UV Radiation Sources:

<http://www.colipa.eu>

- look at Colipa Recommendation No. 22 Guidelines for Monitoring UV Radiation Sources

Q. 2 – Can the Colipa UVA In Vitro Method be used instead of the Persistent Pigment Darkening Method (PPD) as applied by the Japanese industry and modified by the French Health Authority (Afssaps) as well as the critical wavelength method?

A. 2 – The *EU Recommendation of 22 September 2006 on the efficacy of sunscreen products and the claims made relating thereto (2006/647/EC)* states that while these testing methods should be used as reference methods, preference should be given to in vitro testing methods delivering equivalent results, as in vivo methods raise ethical concerns.

Therefore Colipa has developed a UVA in vitro method showing good correlation between the measured in vitro PPD and in vivo PPD factors that can be used instead of the in vivo PPD method for the determination of UVAPF.

To ensure consistent application and compliance with the practical details of the UVA in vitro test, the instructions in the Colipa In Vitro Method should be followed very closely.

In the meantime, the use of the existing *in vivo* test method for UVA rating remains perfectly acceptable, and will continue to do so even after the widespread adoption of the cheaper and quicker *in vitro* test.

Minimum levels of sunscreen protection for UVA are set at a third of the SPF and a critical wavelength of 370nm, therefore the critical wavelength method should still be used for the broadness (at least 370nm).

Q.3 – We have difficulties in obtaining good results for SPF testing using the instrument and procedure in the Colipa UVA In Vitro Method. Could this be because our methods of product application are not reproducible?

A.3 – The Colipa in vitro method is for measuring UVA protection of sunscreens. It is NOT an in vitro method for measuring SPF. The *in vivo International SPF Test Method 2006* remains the recommended EU method for measuring SPF.

Q.4 – Can we easily find the type of instrument needed to perform the Colipa UVA In Vitro Method? Must we use the UV source: SUNTEST?

A. 4 – Any UV source fulfilling the technical requirements of UV irradiance 50-140w/m² (5-14mw/cm²), irradiance ratio of UVA to UVB, 8-22, under 40°C can be used. The SUNTEST is simply one example. You should check with the Supplier that the instrument you intend to buy meets the requirements for the Colipa UVA In Vitro Method.

Q.5 – According to the Colipa UVA In Vitro Method: the emission of the solar simulator will be checked (at least) annually for compliance with the given acceptance limits. Should I call an external expert to calibrate? If so, can you suggest the address of an independent expert?

A.5 – The Colipa UVA In Vitro Method indicates that the solar simulator should be checked to ensure that it is compliant with the Method's specifications. This means that irradiance should be between 50 and 140W/m² (5 and 14mW/cm²) and irradiance UVA/UVB should be between 8 and 22. This check should be done by a suitably qualified expert. It should be conducted with a spectroradiometer that has been calibrated against an internationally accepted calibration standard (e.g. institution that is certified by the European co-operation for accreditation EA).

Colipa can provide a list of experts to measure the emission spectrum and irradiance level of your solar simulator.

Q.6 – What steps can I take to keep the temperature stable during the irradiation steps of the Colipa UVA In Vitro Method?

A.6 – You should check whether your solar simulator supplier proposes a cooling system. Using this it is possible to reduce the temperature to below 40°C (close to 33 °C). It is also important to use a black sheet under the plates to avoid reflection of the light. Dividing the exposure in different steps is not recommended.

Q.7 – Are any PMMA plates suitable for the COLIPA in vitro method or is a particular type required? Can you tell me where to buy them?

A.7 – Standard PMMA plates should be used. We recommend using the Schönberg plate because the method was validated using that reference. There are two types of plates:

- 1) for the calibration
- 2) for the actual measurements (roughness ~2 µm)

The plate can be ordered in the size that suits the instrument. A minimum size of 16cm² is recommended.

When ordering plates for the Colipa UVA In Vitro Method, the references to ask for are:

CALIBRATION PLATE (Order number 951) for the calibration plate with UV filter

and SUNTEST for the actual plate for measurements.

The supplier is:

Schönberg Kunststoffe GmbH & Co. KG

Flagentwiet 29/31

22457 Hamburg, Germany

tel. +49 40 55 33 55 33

Fax +49 40 55 97 00 67

E.Mail: taddei@schoenberg-acryl.de

Q.8 – How must we spread the sunscreen on the PMMA plates?

A.8 – Spread using light strokes with a finger tip pre-saturated with the product. First distribute the product over the whole area as quickly as possible (less than 30 seconds) without pressure. Then rub the sample into the rough surface using pressure (20-30 seconds).

Q. 9 – Can I use the same UV dose for all plates for the same product?

A. 9 – No each plate has its own UVAPF₀ which is the basis for the UV dose calculation (UVAPF₀ X 1.2 J/cm²).

Q. 10 – How many samples must we test using the Colipa UVA In Vitro Method?

A. 10 – You should spread each sunscreen sample onto at least 3 PMMA plates as the UVAPF of the product is the mean of the UVAPF₀ applied to at least 3 individual plates. If the coefficient of variance between the 3 plates exceeds 20% then further plates have to be measured until the coefficient of variation requirement is reached.

Q.11 – For the pre-set calculation Excel spreadsheet:

- a) When entering data in the yellow cells on the left hand side of the Excel spreadsheet are the values expressed as Absorbance (Abs)?**
- b) What is the meaning of: "special paste values"?**
- c) Where can I find the result of the first step: Calculation of the SPF In Vitro?**
- d) What number must we introduce into the Excel template when 50+ is labelled? We tried to introduce 50+ but the file accepts only numbers and so it returned an error message.**

A.11 – For the pre-set calculation Excel spreadsheet:

- a) mAF is not monochromatic absorbance factor but monochromatic Attenuation factor. It is equal to $1/T$ where T is the Transmittance of the sunscreen layer.**
 - b) Special paste values mean that we should paste only values of mAF data in order not to change the presentation of the sheet. It is an Excel function.**
 - c) Cell E24 gives an approximation of the SPF in vitro before adjustment to the labelled SPF.**
 - d) 60**
-