### **Call for Test Samples for the ALT-SPF Consortium Test**

We are seeking partners who can donate sunscreen test samples for a large ‘ring study’ that aims to compare *in vivo* SPF values from several alternative SPF methodologies to those from the International Standard ISO24444 – partners could be either within or outside the Consortium. Ideally, donated samples should be currently- / recently-marketed products.

#### Why take part?

There is certainly an altruistic / philanthropic aspect to donating test samples – you will be contributing to a study of singular importance in the development of a next generation of alternative SPF test methods!

Donation also comes with the advantage that partners have the right to receive the measured *in vivo* SPF data (total 40 human subjects) for donated samples (after conclusion of the study),providing a reasonably precise estimate of product performance. We would remind you, however, that these SPF data should not be used to establish a claim for products intended for the USA market.

#### How much of each sunscreen sample is required?

Ideally, donated sunscreen samples should be in bulk form (approximately **10 kg** is required for our study).

#### What types of sunscreens are needed?

We need a variety of emulsion-type formulae, ethanolic sprays and 100%-mineral (inorganic) sunscreens. For detailed specifications, please see the Appendix below “Specification of Samples”.

#### What documentation should be provided?

Test methods include in both *in vitro* and *in vivo* approaches. Because of the human exposure involved in the latter, the Consortium would, therefore, needs a statement of ‘indemnification’ from your experts, asserting that all necessary regulatory, safety and quality aspects have been met, for all samples submitted. If your product donation is accepted into the study, we would provide you with suggested wording to this effect. We will also need an expiration date for all samples (sufficient to cover the period of the study – more details to follow).

#### How can I suggest samples for testing?

Please (a) **fill out the table** below for an overview if you donate more than one sample and (b) send back to us **a sample submission form** for all samples (submissions can be made electronically to Herman Bertrand, ALT-SPF Project Office (email, bertrand@arttic.eu) until 11 January, 2021.

Should more samples be proposed than are needed, we will select samples for the study on a random basis. Either way, you will be notified about your sample(s) proposal. In the case that your submission is successful, you will be notified with further instructions regarding where to send the sample(s), etc. We anticipate that physical samples will need be needed to be shipped to a packing operation in March next year 2022.

#### How will samples be selected for the study? How is it coded?

A dedicated sub-team of the Consortium will review all submission forms for suitability and fit against study requirements. Our statisticians will then randomly draw participating samples from the total pool (and you will be notified whether or not your sample has been chosen). From that point on, chosen samples will be blinded and coded (the identity is known only to a required minimum of Consortium experts, like project management, statisticians and sample filler). This product blind will not be broken until the Consortium work is concluded (including any ensuing publication).

For submission, you will need to sign a short donation form as mentioned above. Please be aware that, after signing, you are committed to donation!

#### What happens to samples after the experimental phase of the consortium is concluded / publication of results?

The samples, still coded, will remain with the Consortium and can be used for further research by Consortium members. However, any such research is the sole responsibility of the investigator and will not in any way compromise or harm the reputation of the donor or the Consortium. The coding of the samples, meaning the encoding of the original name, will still remain also in that phase.

#### Sample Specification

1. **Medium-viscosity emulsions SPF6, 15, 30 and 50/50+** (*total samples required: 16*)

	1. Viscosity according to specifications detailed separately
	2. A maximum of 8% particulate UV filters (inorganic or organic)
2. **High- and low-viscosity emulsions (SPF30)** (*total samples required: 8*)
	1. Viscosity according to specifications detailed separately
	2. A maximum of 8% particulate UV Filters (inorganic or organic)
3. **Single-phase sunscreens (SPF50/50+)** (*total samples required: 4*)

These products should be within the ‘aerosol’ category or be single-phase pump sprays

* 1. No pigments
	2. Low viscosity
	3. Ethanol-only sprays
	4. Bulk only should be supplied (no propellant necessary)
1. **100% mineral SPF50/50+** (total samples required: 4)
	1. Minimum 15% inorganic UV filters in any liquid formulation
	2. No iron oxide present.

#### Sample Specification

Please see below guidelines for measuring and defining three groups of viscosity:

**Viscosity measurement conditions:** Viscometer Brookfield  RV, Heliopath, Spindle TD, 4 RPM, 25oC

**Approximate ranges of viscosity for ‘high’, ‘medium’ and ‘low’ viscosity emulsions:**

|  |  |
| --- | --- |
|  | cPs |
| Viscosity | Lower limit | Upper limit |
| High | 60000 | > 60000 |
| Medium | 30000 | Lower than 45000 |
| Low | 1 | Lower than 15000 |
|  |

#### Protocol for Viscosity Measurement:

1. Transfer the product from its original packaging to the vessels that will be used for viscosity measurement (preferably a 250mL beaker). Do not dispense the product through the package orifice, rather, cut open the entire crimped end of the tube.  Do not stir or agitate the sample more than necessary.
2. Equilibrate the sample in a water bath at 25oC for 1-2 hours before the viscosity measurement.
3. Place the equilibrated sample under the viscometer so that the crossbar of the spindle is above the sample and set so that there will be at least 1 cm clearance between the spindle and the bottom of the container, during measurement.
4. Turn on the equipment and measure viscosity over downward movement of the spindle, at three different separate levels with the sample: top, middle, and bottom. The sample viscosity shall be the average of these three measurements.

#### Submission Information I

Overview table of samples to be donated.

(Please fill in name of samples to be provided, green boxes only are required in the consortium work)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ***In vivo* SPF Claim** | **6** | **15** | **30** | **50/50+** |
| Low-viscosity emulsion |  |  |  |  |
| Medium-viscosity emulsion |  |  |  |  |
| High-viscosity emulsion |  |  |  |  |
| Ethanolic Spray(single-phase) |  |  |  |  |
| 100% mineral |  |  |  |  |

#### Submission information II

Submission table for each individual formula – for submission to the ALT-SPF project manager and Consortium scientific sub-group (please provide a separate form for each sample donated; please delete the explanatory text in the right-hand column)

|  |  |
| --- | --- |
| *Product Name (to be given by Sponsor)* |  |
| *Contact person details* |  |
| *Proposed sample details?* | *e.g., Emulsion, high viscosity, SPF 30* |
| *SPF value substantiated in vivo?* | *Yes/No, please provide supportive rational for SPF level* |
| *Formulation type?* | *W/O or O/W or One Phase* |
| *Countries in which UV filters included in the sample would not be compliant with local regulatory requirements?* |  |
| *Less than 8 % particulate UV filters (inorganic or organic) in total* | *Yes/ No* |
| *More than 15 % inorganic UV filters* | *Yes/No* |
| *Water-soluble UV filters present* | *Yes/No* |
| *Viscosity range (Brookfield, according to the above procedure)* | *Low, medium or high viscosity.*  |
| *Willingness to provide an indemnification certificate for human testing (ISO24444:2019 or HDRS)* | *Yes/No* |