EUROPEAN COMMISSION
JOINT RESEARCH CENTRE
Institute for Health and Consumer Protection (Ispra)
I.5 Systems Toxicology Unit
EU Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM)

Ispra, 16 December 2014
IHCP/I05/MW/tav Ares (2014)

To the attention of:

Dr Oliver Engelking
CellSystems®
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Subject: ESAC Peer review on the revised full submission on the EST1000 SIT/epiCS® SIT for skin irritation testing (ref. TM2009-09)

Dear Dr. Engelking,

I would like to inform you that the independent scientific peer review of your validation study dossier based on the OECD Performance Standards for in vitro skin irritation testing has been finalised by the ESAC in December 2014. We attach the opinion for your information.

While the ESAC agreed that the data of the two studies allow concluding that the test method meets the required predictive capacity, the committee was concerned about aspects of study design and data grouping, in particular with regard to within-laboratory reproducibility. While ESAC acknowledged that the data from the second study (after improvement of SOP implementation relating to the washing procedure) supports the notion that the target values for WLR can be attained by well trained and instructed laboratories, ESAC is of the opinion that a bias has been introduced into the data matrix by deleting non-concordant data from the two non-naïve laboratories in the 2012 study and inserting concordant data from retesting without subjecting all chemicals to retesting under identical conditions (relating to the SOP implementation). ESAC holds that this grouping is not in agreement with good scientific practice and it does not allow arriving at values for WLR that would be comparable to the conditions of other PS-based studies.

In order to address this issue, ESAC recommended to test, in addition to the 6 and 7 already tested Reference Chemicals (RCs), also the remaining 14 and 13 RCs in the two non-naïve laboratories in order to arrive at a complete data set for all 20 RCs, generated under identical conditions of SOP implementation.

Once this additional testing data are available, you are encouraged to submit these to EURL ECVAM for an expedited follow-up ESAC peer review that would focus on this outstanding issue. We would like to kindly ask you to report the newly generated data (13 and 14 RCs from the two naïve laboratories) together with the data set from 2013 (i.e. 20 RCS from ACS, 6 and 7 RCs in IIVS and Harlan) using our EURL ECVAM reporting sheet (the excel template will be sent to you this week). Finally, we would like to point out that ESAC strongly suggested that the same laboratories are used for this third phase testing.

Please feel free to contact us (JRC-ECVAM-TEST-SUBMISSIONS@ec.europa.eu) if you require further clarification or for discussing any possible follow-up that you may consider.

Thank you for submitting your test method to EURL ECVAM.

Yours sincerely,

Maurice Whelan,
Head of Unit, on behalf of EURL ECVAM.

ENCL.: ESAC opinion on the validation study of the epiCS® test method based on the EURL ECVAM/OECD Performance Standards for in vitro skin irritation testing using Reconstructed human Epidermis (RhE)