Evaluation report on the reduced Local Lymph Node Assay (rLLNA)

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Summary
ICCVAM has concluded that, when performed in accordance with the latest ICCVAM-recommended LLNA protocol, rLLNA is sufficiently capable of distinguishing between skin sensitizers and non-sensitizers. ICCVAM also recommends that rLLNA be used to screen chemicals and products for allergic contact dermatitis (ACD) hazard potential prior to implementing LLNA. As compared with LLNA, rLLNA reduces the number of animals used per test by as much as 40%. rLLNA has been shown to yield a false negative rate of 1.9% (6/318). In cases where potentially false negative results are concerned with, retesting with LLNA or other approved skin-sensitization test method should be considered. In cases where dose-response information is required, it is necessary to test using LLNA with a suitable dosing regimen.

Based on the above, rLLNA is a suitable means of evaluating the skin-sensitization potential of chemicals and products. In cases where the SI values of rLLNA are between 2 and 3, it is necessary to make a conservative evaluation by referencing other information about the test substance, including reduced response to the maximum dose, protein binding, or skin sensitization of similar compounds. In cases where the SI values of rLLNA are 3 or more, no further testing for skin sensitization is necessary. When evaluating products manufactured from bulk drugs (chemicals) that have been determined to be non-sensitizers using LLNA or GPMT, testing by rLLNA alone is sufficient.