Retrospective Analysis of Dermal Triple Pack Data

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Dermal toxicity is driven by the ability of a substance to penetrate the skin. Dermal absorption can be estimated using the “triple pack”, a study design that combines in vivo rat, in vitro rat, and in vitro human data to calculate an estimated human dermal absorption factor (DAF). To assess the feasibility of deriving a DAF using only in vitro data, we conducted a retrospective evaluation of agrochemical formulations to compare the DAF derived from each method. We also compared the DAF derived from the human in vitro study to the DAF generated from the triple pack approach. For most of the formulations evaluated, the in vitro rat method generated a similar or higher DAF value than the in vivo method. Absorption through in vitro human skin was found to be similar to or less than that observed in rat skin for all formulations. For most of the formulations, the human in vitro method provided a similar or higher estimate of dermal absorption than the triple pack approach. For human health risk assessment, in vitro assays using human skin would be preferable. Such tests would be directly relevant to the species of interest (which is humans) and avoid any overestimation of dermal absorption using rat models. However, rat in vitro studies would still have utility if human in vitro data were not available. In vitro rat data provide estimates of dermal absorption that are at least as protective as in vivo rat data, and thus could also be considered adequate for use in establishing dermal absorption factors. Accordingly, the comparisons presented in this poster support potentially using in vitro data alone for DAF derivation for human health risk assessment of pesticides. This project was funded with federal funds from the NIEHS, NIH under Contract No. HHSN273201500010C.