

Compilation and Characterization of a Human Skin Sensitization Data Set

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Appropriate evaluation of new approach methodologies (NAMs) requires reference data for assessing a NAM's ability to predict an outcome of interest. Human data would provide the most relevant basis for such comparisons, but they are rarely available due to obvious ethical issues associated with toxicology testing in humans. One exception is data from skin sensitization tests that are routinely conducted using a wide range of materials. For this project, we collected data from 2277 human predictive patch tests conducted under two protocols, the human repeat insult patch test and the human maximization test. Data were collected from more than 1700 publications. We recorded protocol elements and positive or negative outcomes, calculated traditional and non-traditional dose metrics, and developed a scoring system to evaluate each test for reliability. Test information was considered adequate for use if 1) dose metrics were reported or calculable, 2) the primary report, test substance, and test type were identified, and 3) positive responses and the total number of subjects tested were reported. The resulting database, which contains information for 1366 unique substances, was characterized for physicochemical properties, chemical structure categories, and protein binding mechanisms. The complete database is publicly available on the NTP Integrated Chemical Environment website to serve as a resource for the development and evaluation of NAMs for skin sensitization testing. This project was funded with federal funds from the NIEHS, NIH under Contract No. HHSN273201500010C. The views expressed above do not necessarily represent the official positions of any federal agency.