Human Reference Database for Skin Sensitization

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To support the evaluation of non-animal approaches for skin sensitization assessment, we collected data for over 2500 human predictive patch tests (human maximization test and human repeated insult patch test) from more than 1500 publications. Each test was evaluated for reliability. Results from 1900 tests considered to be sufficiently reliable were classified using the Globally Harmonized System of Classification and Labeling of Chemicals (GHS). Human predictive patch test data based on single doses makes identification of thresholds uncertain and these data difficult to use as reference data. To overcome this challenge, classification criteria from the GHS were extended using a decision tree to help resolve ambiguity in the results. If individual chemicals had multiple discordant test results, a weight-of-evidence approach was used to arrive at a single classification for each chemical. This classification approach was applied to the Cosmetics Europe reference list of 128 substances to support the evaluation of defined approaches for skin sensitization proposed for inclusion in a guideline under consideration by the Organisation for Economic Co-operation and Development. The entire human skin sensitization patch test database will be made publicly available in the future to serve as a resource for additional evaluation of alternative skin sensitization methods and development of quantitative structure-activity relationships and other new models. 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.