Non-animal approaches to assessing the skin sensitization endpoint under REACH

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Under the REACH Regulation, skin sensitization is an endpoint for which information is already required at the lowest tonnage band of 1-10 tons per year. The requirements for skin sensitisation are described in REACH Annexes VI to XI where the data that shall be submitted for registration purposes is specified. Column I of Annex VII clearly informs on the standard requirements according to which data skin sensitisation should be assessed, comprising the following steps: an assessment of the available human, animal and alternative data, followed, if necessary, by *in vivo* testing. The latter does not need to be conducted if there is information indicating that the substance should be classified for sensitisation or corrosivity, if the substance is a strong acid or base or if the substance is flammable in air at room temperature. In terms of *in vivo* testing, the Murine Local Lymph Node assay (LLNA) is considered to be the first choice. This presentation will describe approaches as currently applied by REACH consortia to the skin sensitization assessment of chemicals. It will discuss the 'tool box' of non-animal and animal methodologies available for chemical registrations under REACH and look at its practical application based on case studies. Focus will be on illustrating how non-animal approaches (e.g., QSAR; read-across; grouping/category assessments; WoE analyses) are used to avoid unnecessary animal testing but examples will also be provided where animal testing is still unavoidable.

Keywords: skin sensitisation; animal testing; QSAR; read-across

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Dr. Thomas Petry is the managing director of ToxMinds BVBA. He is a product safety and regulatory affairs consultant with more than 20 years industry, consulting and research experience in the human safety assessment of chemical exposures occurring at the workplace, through their use or presence in consumer products or via the environment. He is a European registered toxicologist (ERT) as well as a Diplomate of the American Board of Toxicology (DABT) and earned his Ph.D. in toxicology from the Institute of Toxicology of the Swiss Federal Institute of Technology (ETH) of Zurich.