

## **SARA-ICE: A Self-contained Model for Predicting a Human-relevant Point-of-departure for Skin Sensitization**

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The Skin Sensitization Risk Assessment – Integrated Chemical Environment (SARA-ICE) defined approach (DA) is a Bayesian statistical model that estimates a human-relevant metric of skin sensitizer potency. This metric, termed ED01, is the dose with a 1% chance of human skin sensitization. SARA-ICE accounts for input data variability and explicitly quantifies uncertainty in estimating the ED01. To highlight SARA-ICE DA application, we conducted several case studies on different chemical classes, such as isothiazolinones and fragrances. These case studies show the SARA-ICE DA's utility in deriving a point-of-departure and providing UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS) hazard and potency categorizations. The model does not require a specific dataset to make predictions, thus allowing for iterative and flexible application of the model based on available data. The SARA-ICE DA is under evaluation by the Organisation for Economic Co-operation and Development for inclusion in Test Guideline 497, Defined Approaches for Skin Sensitisation, with Guideline updates underway. The U.S. Environmental Protection Agency Office of Pollution Prevention and Toxics is also considering using SARA-ICE in risk assessment. Recently, a stand-alone software platform has been developed to allow local installation and making the SARA-ICE DA available to all stakeholders. This presentation will highlight the case studies and evaluation of the model, along with demonstrating the use of the SARA-ICE stand-alone platform for deriving human relevant points-of-departure for skin sensitization risk assessment. This project was funded with federal funds from the NIEHS, NIH under Contract No. HHSN273201500010C.