Overview on OECD Defined Approach (DA) for Skin Sensitization Classification

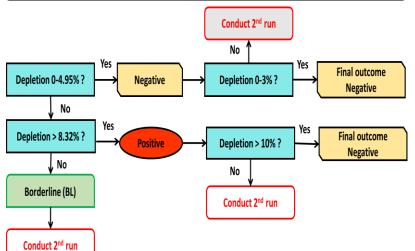
Mahesh Rachamalla¹, Rishabh Hirawat²

¹Department of Biology, University of Saskatchewan, 112 Science Place, Saskatoon, SK, S7N 5E2, Canada ²Department of Regulatory Toxicology, National Institute of Pharmaceutical Education and Research, Balanagar, Hyderabad

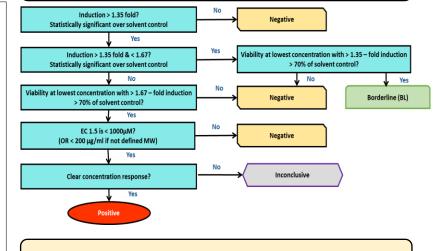
Introduction

- 1. Skin sensitization is an immunologically mediated cutaneous reaction to a substance. The responses may be characterized by pruritis, erythema, edema, papules, vesicles, bullae or a combination of these.
- 2. According to OECD, Guinea Pig Maximization Test, Buehler Test & Local Lymph Node Assay (LLNA) are the animal test available.
- 3. Over the last decade, phenomenal development has been made in development of non-animal tests to assess contact hypersensitivity.
- 4. In order to overcome the animal testing approaches various in chemico and in vitro tests have been developed but it has been concluded that standalone these tests cannot give substantial results.
- 5. Results from multiple information sources has been used together in Defined Approach (DA) to achieve an equivalent or better predictive capacity than that of the animal tests to predict skin sensitization.

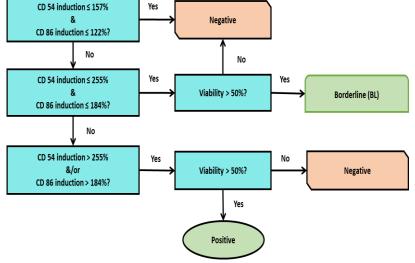
Logic behind DPRA prediction model



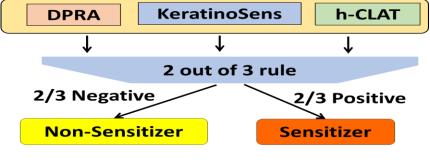
Logic behind KeratinoSens prediction model



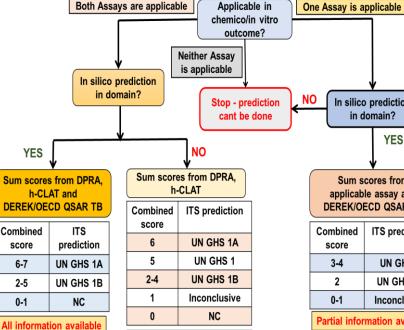
Logic behind h-CLAT prediction model



2 out of 3 approach



Summary of Defined approach (DA)



Partial information available

Both Assays are applicable

Sum scores from applicable assay and DEREK/OECD QSAR TB

In silico prediction

in domain?

YES

Combined score	ITS predictio
3-4	UN GHS 1
2	UN GHS 1B
0-1	Inconclusive
Partial information availab	