

## **650 Limitations in Testing and Risk Assessment for Dermal**

### **Sensitization**

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Two dermal sensitization studies were submitted to the California Dept. of Pesticide Regulation to support the registration of a fruit and vegetable wash product containing the active ingredients Lactic acid and Dodecylbenzene Sulfonic Acid. The first study was performed in Guinea Pigs using a modified Buehler protocol, resulting in positive sensitization scores after challenge (grade 1 erythema in 1/20 animals at 24 hours, increasing to grade 1 in 13/20 and grade 2 in 4/20 at 48 hours). In contrast, negative sensitization potential was indicated in the same study after rechallenge (grade 1 erythema in 2/20 at 24 hours, decreasing to grade 1 in 1/20 at 48 hours). The second study used the Local Lymph Node Assay (LLNA), resulting in stimulation index (SI) values of 1.1, 3.1 and 2.9 for the 25%, 50% and 100% treatment concentrations, respectively (SI values of 3.0 or greater indicate a positive sensitizer). The registrant asserted that two values in the 50% treatment group were possible "outliers" (2922 and 2460 DPM versus a mean of 888 DPM for remaining 3 values), resulting in an SI modification for this group from 3.1 to 1.7. The "dose-response" (i.e., SI values of 1.1, 1.7 and 2.9) as indicated by the LLNA and the results from the Buehler study suggested that the product was a potential sensitizer. Borderline SI values alone present uncertainty in determining whether a subject product is a potential dermal sensitizer. In the workplace, development of sensitivity to allergens and the severity of irritation are thought to be related to exposure levels. Dose-response relationships and no-effect levels from these studies could be used as a basis for risk assessment and to obtain safe exposure concentrations for this and other potential workplace allergens.