

# ESTABLISHMENT OF *IN VIVO* LD50 REFERENCE VALUES FOR CHEMICALS USED IN VALIDATION STUDIES OF *IN VITRO* CYTOTOXICITY ASSAYS

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## SUMMARY

The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and NICEATM convened an international workshop in October 2000 to evaluate the validation status of *in vitro* methods for predicting acute systemic toxicity (<http://iccvam.niehs.nih.gov/>). Workshop participants recommended further evaluation of *in vitro* methods to predict rodent and human acute toxicity. NICEATM and ECVAM subsequently designed a multi-laboratory validation study to evaluate the utility of two *in vitro* cytotoxicity tests using 72 chemicals. A major aspect of the study design was the selection of the rodent LD50 reference value for each chemical. LD50 studies were located through literature searches and secondary references. Studies were reviewed to identify the most appropriate LD50 reference value for each chemical. Criteria used to select reference LD50 values included: 1) similarity of age, gender, and species to that recommended in current acute lethality testing guidelines, and 2) quality of the data, including conduct in accordance with standardized test guidelines and Good Laboratory Practices. Chemical-specific examples of the selection decisions for reference LD50 values will be provided. These reference data will be useful in evaluating the extent that *in vitro* test methods can predict rodent LD50 values. Supported by NIEHS contract N01-ES-85424.

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