

Availability of the Recommended Performance Standards

The recommended performance standards are available electronically in PDF format on the ICCVAM/NICEATM Web site at <http://iccvam.niehs.nih.gov> or in printed form by contacting Dr. William Stokes, NICEATM Director, NIEHS, P.O. Box 12233, MD EC-17, Research Triangle Park, NC, 27709, (phone) 919-541-3398, (fax) 919-541-0947, (e-mail) iccvam@niehs.nih.gov.

SUPPLEMENTARY INFORMATION: ICCVAM previously reviewed and recommended four in vitro test methods for assessing the dermal corrosivity potential of chemicals: Corrositex[®], EPISKIN[™], EpiDerm[™] (EPI-200), and the rat skin transcutaneous electrical resistance (TER) Assay (NIEHS 1999 and NIEHS 2002). Because three of these methods were proprietary, ICCVAM was asked by the U.S. Environmental Protection Agency (EPA) to develop and recommend performance standards that could be used to evaluate the acceptability of similar test methods that are based on similar scientific principles and that measure or predict the same biological or toxic effect.

ICCVAM in collaboration with the NICEATM announced the availability and sought public comment on proposed performance standards for these three types of test methods in July 2003 (**Federal Register**, Vol. 68, No. 126, pp. 39104-39105). Comments on the proposed standards were also obtained from the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) in August 2003 (NTP 2003) and the EPA Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel in October 2003 (EPA 2003). Following consideration of public and advisory committee comments, ICCVAM revised and approved recommended performance standards for the three types of in vitro corrosivity test methods.

This document will be forwarded, along with the final ICCVAM recommendations on the four test methods mentioned above, to Federal agencies for their consideration in accordance with the ICCVAM Authorization Act of 2000 (Pub. L. 106-545).

Background Information on ICCVAM and NICEATM

ICCVAM is an interagency committee composed of representatives from fifteen Federal regulatory and research agencies that use, generate, or disseminate toxicological information. ICCVAM promotes the development,

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Public Health Service****National Toxicology Program (NTP); National Institute of Environmental Health Sciences (NIEHS); National Institutes of Health; Notice of Availability of Recommended Performance Standards for In Vitro Test Methods for Skin Corrosion**

SUMMARY: The NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) announces the availability of recommended performance standards for in vitro test methods for skin corrosion. The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) developed the performance standards to communicate the basis by which a validated and accepted proprietary (*i.e.*, copyrighted, trademarked, or registered) or non-proprietary test method has been determined to have sufficient accuracy and reliability for a specific testing purpose. Performance standards should assist other test developers in the validation of test methods that are similar in structure and function and facilitate acceptance of test methods that adhere to applicable performance standards.

validation, regulatory acceptance, and national and international harmonization of toxicological test methods that more accurately assess the safety or hazards of chemicals and products and test methods that refine, reduce and replace animal use. The ICCVAM Authorization Act of 2000 (available at <http://iccvam.niehs.nih.gov/about/PL106545.htm>) established ICCVAM as a permanent interagency committee of the NIEHS under the NICEATM. NICEATM administers the ICCVAM and provides scientific support for ICCVAM and ICCVAM-related activities. NICEATM and ICCVAM work collaboratively to evaluate new and improved test methods applicable to the needs of Federal agencies. Additional information about ICCVAM and NICEATM can be found at the following Web site: <http://iccvam.niehs.nih.gov>.

References

NIEHS. 1999. Corrositex®: An In Vitro Test Method for Assessing Dermal Corrosivity Potential of Chemicals. NIH Publication No. 99-4495. Available at <http://iccvam.niehs.nih.gov/methods/corrode.htm>.

NIEHS. 2002. ICCVAM Evaluation of EPISKIN™, EpiDerm™ (EPI-200), and the Rat Skin Transcutaneous Electrical Resistance (TER) Assay: In Vitro Test Methods for Assessing Dermal Corrosivity Potential of Chemicals. NIH Publication No. 02-4502. Available at <http://iccvam.niehs.nih.gov/methods/epiderm.htm>.

NTP. 2003. Summary Minutes of the August 12-13, 2003 Scientific Advisory Committee on Alternative Toxicological Methods (SACATM). Available at http://iccvam.niehs.nih.gov/about/sacatm/minutes/min_120803.pdf.

EPA. 2003. Minutes of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel Meeting "Ensuring Data Quality for In Vitro Tests Used as Alternatives to Animal Studies for Regulatory Purposes: A Consultation (October 28-29, 2003 in Arlington, VA). Available at <http://www.epa.gov/oscpmont/sap/2003/october/revisedmeetingminutes.pdf>.

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