

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 Proposed Minimum Performance Standards (MPS) for Three Types of *In Vitro* Methods for Assessing the Dermal Corrosivity Hazard Potential of Chemicals; Request for Comments****Summary**

The NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) announces the availability of and invites public comment on proposed MPS for three types of *in Vitro* methods for assessing the dermal corrosivity hazard potential of chemicals. The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) Dermal Corrosivity and Irritation Working Group (DCIWG) developed these proposed MPS. The ICCVAM developed the proposed MPS to communicate criteria which could be used to determine if similar test methods have comparable accuracy and reliability.

Availability of the Proposed MPS

Copies of the MPS 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.

Request for Comments

NICEATM invites the submission of written comments on the proposed MPS. When submitting written comments, please refer to this **Federal Register** notice and provide applicable contact information (name, affiliation, mailing address, phone, fax, e-mail and sponsoring organization). Written comments should be sent by mail, fax, or e-mail to NICEATM (contact information provided above) by noon on August 15, 2003. All written comments received by this date will be posted on the ICCVAM/NICEATM web site and will be considered by the DCIWG and ICCVAM during development of the final ICCVAM MPS for these assays. Final ICCVAM MPS will be published as addendums to previously published ICCVAM reports on these test methods

and will be forwarded to Federal agencies for their consideration. Availability of the final MPS will be announced via a **Federal Register** notice. Copies of the MPS will be made available electronically in PDF format on the ICCVAM/NICEATM web site or can be obtained in printed form by contacting NICEATM (contact information provided above).

Supplemental Information about the Proposed MPS

ICCVAM previously evaluated and recommended four validated test methods for assessing the dermal corrosivity hazard potential of chemicals: Corrositex®, EPISKIN™, EpiDerm™ (EPI-200), and the rat skin transcutaneous electrical resistance (TER) Assay (NIEHS 1999 and NIEHS 2002). Subsequently, the U.S. Environmental Protection Agency (EPA) requested that ICCVAM establish MPS for the three proprietary dermal corrosivity test methods (Corrositex®, EPISKIN™, EpiDerm™) and the non-proprietary rat skin TER test method. In response, the ICCVAM DCIWG drafted proposed MPS based on the validated reference test methods for these three types of *in vitro* dermal corrosivity assays: membrane barrier test methods, human skin model system test methods, and skin TER test methods.

The purpose of the MPS is to communicate the basis on which a validated and accepted proprietary (*e.g.*, copyrighted, trademarked, registered) or non-proprietary test method has been determined to have sufficient accuracy and reliability for a specific testing purpose. Accuracy refers to the ability of the test method to correctly predict or measure the biological effect of interest (also referred to as relevance) while reliability refers to the extent of intra- and inter-laboratory reproducibility. MPS also provide the criteria that should be met by other proposed test methods that are based on similar scientific principles and that measure or predict the same biological or toxic effect.

The three elements of MPS are:

- Minimum procedural standards that identify essential structural, functional, and procedural components of the validated reference test method (*e.g.*, procedural details, proper controls, morphologic structure and integrity of the test system, biological identity of key components, and expected biological responsiveness). Adherence to the minimum procedural standards will help to assure that the proposed test method is based on the same concepts as the referenced test method.

- A list of recommended reference chemicals that can be used to assess the accuracy and reliability characteristics of the proposed test method. The list includes substances that are representative of the chemical and product classes for which the validated test method is considered applicable, as well as substances that are representative of the range of responses (*e.g.*, negative, weak to strong positive) that the validated test method is capable of measuring or predicting.

- The accuracy and reliability that should be achieved by the proposed test method when evaluated using the minimum list of reference chemicals.

Background Information on ICCVAM and NICEATM

The NIEHS established the ICCVAM in 1997 to coordinate the interagency technical review of new, revised, and alternative test methods of interagency interest, and to coordinate cross-agency issues relating to the validation, acceptance, and national/international harmonization of toxicological testing methods. ICCVAM was established as a permanent interagency committee of the NIEHS under the NICEATM on December 19, 2000, by the ICCVAM Authorization Act of 2000 (Pub. L. 106-545, available at <http://iccvam.niehs.nih.gov/about/PL106545.pdf>). The Committee is composed of representatives from fifteen Federal regulatory and research agencies that use or generate toxicological information. Its purpose is to promote the scientific validation and regulatory acceptance of toxicological test methods that will improve the agencies' ability to accurately assess the safety or hazards of chemicals and various types of products, while refining, reducing, and replacing animal use wherever possible. NICEATM provides operational and 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](http://iccvam.niehs.nih.gov/methods/epiderm.htm).

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