

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Toxicology Program (NTP); NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM); Availability of Revised Analyses and Proposed Reference Substances for In Vitro Test Methods for Identifying Ocular Corrosives and Severe Irritants**

AGENCY: National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

ACTION: Availability of analyses and proposed reference substances and request for comments.

SUMMARY: NICEATM announces the availability of revised analyses for four *in vitro* test methods proposed for detecting ocular corrosives and severe irritants [the Bovine Corneal Opacity and Permeability (BCOP) assay, the Hen's Egg Test—Chorion Allantoic Membrane (HET—CAM), the Isolated Rabbit Eye (IRE) assay, and the Isolated Chicken Eye (ICE) assay]. A revised list of proposed reference substances for validation studies on *in vitro* test methods for identifying ocular corrosives and severe irritants is also available. The revised analyses and list of proposed reference substances are provided in an addendum that is applicable to each of four draft Background Review Documents (BRDs) that were released to the public on November 3, 2004. The NICEATM invites public comment on the information provided in this addendum. Copies of the draft BRDs and addendum may be obtained on the ICCVAM/ NICEATM Web site (<http://iccvam.niehs.nih.gov> see "Reports & Background Documents"), or by contacting NICEATM at the address given below.

DATES: Written comments and additional information should be received by August 25, 2005.

ADDRESSES: Comments and additional information should be sent by mail, fax, or e-mail to Dr. Raymond Tice, at NICEATM, NIEHS, P. O. Box 12233, MD EC-17, Research Triangle Park, NC 27709, (phone) 919-541-4482, (fax) 919-541-0947, (e-mail) niceatmcomments@niehs.nih.gov.

Courier address: NICEATM, 79 T.W. Alexander Drive, Building 4401, Room 3113, Research Triangle Park, NC 27709

SUPPLEMENTARY INFORMATION:**Background**

On November 3, 2004, NICEATM released draft BRDs that provided

information about the current validation status of four *in vitro* test methods for detecting ocular corrosives and severe irritants (**Federal Register**, Vol. 69, No. 212, pp. 64081–64082, November 3, 2004, available at <http://iccvam.niehs.nih.gov/> see "Reports & Background Documents"). The test methods are the BCOP assay, the HET-CAM assay, the IRE assay, and the ICE assay. NICEATM in conjunction with ICCVAM convened an expert panel meeting on January 11–12, 2005, to independently assess the validation status of the four *in vitro* test methods. The expert panel report is available electronically at <http://iccvam.niehs.nih.gov/methods/eyeirrit.htm>. Public comments at the meeting indicated that additional data could be made available that had not been provided in response to earlier requests for data announced in the **Federal Register** in March and November 2004 (Vol. 69, No. 212, pp. 64081–64082, November 3, 2004; Vol. 69, No. 57, pp. 13859–13861, March 24, 2004). The expert panel recommended that NICEATM conduct a reanalysis of the accuracy and reliability of each test method that would include these data. In response to this recommendation, NICEATM published a notice in the **Federal Register** (Vol. 70, No. 38, pp. 9661–9662, February 28, 2005) requesting additional *in vitro* data on these four *in vitro* ocular irritancy test methods, corresponding *in vivo* rabbit eye test method data, as well as any human ocular exposure/injury data (either from ethical human studies or accidental exposure). In response to this request, NICEATM received additional *in vitro* and *in vivo* data that were used for the revised analyses and considered in revising the list of proposed reference substances.

The revised analyses and list of proposed reference substances are provided in an addendum that is applicable to each of four draft BRDs that were released to the public on November 3, 2004 (available at <http://iccvam.niehs.nih.gov/> see "Reports & Background Documents"). Following the public comment period, NICEATM in coordination with ICCVAM plans to reconvene the expert panel during a public teleconference to comment on the proposed reference substances and finalize their conclusions regarding the current validation status of the four methods for detecting ocular corrosives and severe irritants. The date and time for this teleconference will be announced in a future **Federal Register** announcement.

Request for Comments

NICEATM invites the submission of written comments on the revised analyses and the proposed list of reference substances. When submitting written comments please include appropriate contact information (name, affiliation, mailing address, phone, fax, email and sponsoring organization, if applicable). All written comments received by the deadline listed above will be posted on the ICCVAM/ NICEATM website and made available to the expert panel and ICCVAM.

Background Information on ICCVAM and NICEATM

ICCVAM is an interagency committee composed of representatives from 15 Federal regulatory and research agencies that use or generate toxicological information. ICCVAM conducts technical evaluations of new, revised, and alternative methods with regulatory applicability, and promotes the scientific validation and regulatory acceptance of toxicological test methods that more accurately assess the safety and hazards of chemicals and products and that refine, reduce, and replace animal use. The ICCVAM Authorization Act of 2000 (Pub. L. 106-545, available at <http://iccvam.niehs.nih.gov/about/PL106545.htm>) establishes ICCVAM as a permanent interagency committee of the NIEHS under the NICEATM. NICEATM administers the ICCVAM and provides scientific and operational support for 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://www.iccvam.niehs.nih.gov>.

Dated: July 13, 2005.

David A. Schwartz,

Director, National Institute of Environmental Health Sciences and National Toxicology Program.

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