



ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

DIRECTION DE L'ENVIRONNEMENT
ENVIRONMENT DIRECTORATEDivision Environnement, santé et sécurité
Environment, Health and Safety Division

ENV/EHS/PA/ka/2004.5

21 May, 2004

To: Working Group of National Co-ordinators of the Test Guidelines Programme (WNT)

Cc: Task Force on Endocrine Disrupters Testing and Assessment (EDTA)
 EDTA Validation Management Groups (VMG-mammalian, VMG-eco and VMG-non-animal)
 European Commission (DGs Environment, Enterprise, Sanco, Science, JRC, ECVAM)
 BIAC (including ACC, CEFIC, Croplife International, ECETOC, JCIA)
 EEB
 ICAPO
 ILSI Europe/North America
 IPCS
 TUAC
 National Delegations (letter only)

SUBJECT: PROPOSAL FOR A NEW TEST GUIDELINE 435 “IN VITRO MEMBRANE BARRIER TEST METHOD FOR SKIN CORROSION”

Dear Madam/Sir,

It's my pleasure to present to you a new draft Test Guideline 435 “*In Vitro* Membrane Barrier Test Method for Skin Corrosion”, submitted by the US, for your consideration. The test method is based on an approach of using a synthetic test system comprising a macromolecular bio-barrier and a chemical detection system. This new Test Guideline proposal constitutes a third *in vitro* method for skin corrosion in conjunction with the newly adopted TG 430 (TER) and TG 431 (Human skin model)

The UN GHS tiered testing and evaluation strategy for the assessment and classification of skin corrosivity allows for the use of validated and accepted *in vitro* test methods. In this tiered testing strategy, positive results from *in vitro* test methods can be used to classify a substance as corrosive without the need for animal testing, thus reducing and refining the use of animals in testing.

The draft TG 435 may be used to test solids, liquids and emulsions, however, before a chemical can be tested it needs to be subjected to a compatibility test. Since some non-corrosive chemicals and chemical mixtures and some corrosive chemicals and chemical mixes do not qualify for the final testing there are



some limitations for the test method. Chemicals not qualifying will need to be tested using other test methods.

Like in the case with TG 431 (Human skin model), the draft TG 435 is generically written and based upon a commercially available test method, in this case Corrositex®. The commercially available test method has gone through validation and after subsequent peer review by the ICCVAM the test method is considered fully validated. The supportive documents for this validated reference test method, and where to access these documents, are listed in the literature section of draft Guideline 435.

In Test Guideline 431, in addition to fulfilment of the “general and functional model conditions”, a proposed test; “...should be capable of predicting the corrosive potential of the reference chemicals when used in the testing protocol selected...”. The number of reference chemicals in TG 431 that needs to be correctly identified is twelve.

In draft TG 435 a new concept of “performance standards” for proposed, or “me-to”, tests is introduced. These performance criteria, originally developed by the ICCVAM, constitute a considerably more stringent approach to the setting up of proposed tests and should be considered as a new ingredient in OECD Test Guidelines, where appropriate. In general a performance standard should include:

- Minimum procedural standards;
- a minimum list of recommended reference chemicals; and,
- the accuracy and reliability characteristics that should be obtained.

The Secretariat recognises that the draft Test Guideline 435 introduces formal performance standards into OECD Test Guidelines and the Secretariat is generally supportive of the idea of including these performance criteria in specific cases such as draft Test Guideline 435. The performance standard in draft TG 435 clearly outlines the procedural standard and the accuracy and reliability that a proposed test method needs to fulfil, including a list comprising 40 chemicals of different corrosive potential, before it can be considered comparable to that of the validated reference test method. As this approach has implications for new and revised Guidelines in the OECD Test Guidelines Programme, the considered views of Member countries is now sought.

National Co-ordinators are now kindly requested to arrange for national expert reviews of the draft Test Guideline 435 in their Member countries. The Secretariat would appreciate to receive your comments **by no later than 16 August 2004**. National Experts are requested to submit comments to their National Co-ordinator well in advance of the deadline for submission to the Secretariat in order to ensure that their comments are properly included in the National Position.

I would like to remind you of the request (see letter [ENV/EHS/HK/ka/2002.88]) to include in your National Position information about the number of experts/agencies/institutions/ministries who contributed to the National Position. A template that could be used by national experts for the submission of their comments to the National Co-ordinator can be found on the same website where the proposal is posted. The use of the template is not mandatory and is only added to assist in the review.

If you have any questions or concerns, please don't hesitate to contact me directly.

Yours sincerely,



Patric Amcoff

Administrator
Environment, Health and Safety Division