News Alert:

ECHA/NA/09/29

Helsinki, 19 November 2009

ECHA CALLS FOR INFORMATION TO AVOID UNNECESSARY ANIMAL TESTING

The European Chemicals Agency (ECHA) is calling for information on the health effects of a specific chemical substance by 24 December 2009. This is a public consultation foreseen by the REACH Regulation for testing proposals involving animals. The aim of the call is to give anyone the opportunity to submit relevant data with a view to make sure that animal testing is only conducted as a last resort when the available information is not sufficient to assess the potentially harmful effects of this chemical on human health or the environment

The chemical is a new substance with the name of "Polysulfo {5-hydroxy-1-naphthalen-2-yl-[4-[4-(2-sulfatoethyl-sulfonyl)-phenyl]diazenyl]-1H-pyrazole-3-carboxylic acid}, alkali metal salt". The registrant has, as permitted by the legislation, claimed certain details of the chemical confidential and so they cannot be made public. Based on the available data the registrant has classified the substance as an irritant and skin sensitiser. The testing proposal from the registrant concerns information on genetic toxicity *in vivo*, i.e. an experimental test involving vertebrate laboratory animals.

The testing proposal will be evaluated by ECHA in the coming months, together with any information resulting from this call. On the basis of the evaluation ECHA will propose a decision to accept, amend or to reject the testing proposal.

How do I submit information?

You are invited to submit scientifically valid information, particularly study reports, using the format provided by ECHA. These should address the substance and the toxicological properties covered by the testing proposal.
(http://echa.europa.eu/consultations/test_proposals/test_prop_cons_en.asp)

European Chemicals Agency Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland
Tel.: +358 9 6861 80 | Fax +358 9 6861 8210 | http://echa.europa.eu | press@echa.europa.eu

Further Information

Why this call now?
Manufacturers and importers of chemical substances are required by the REACH Regulation to assess the hazardous properties of substances that they have to register. This is then documented in a registration dossier which is submitted to ECHA. The dossier requires specific information including the results of scientific studies to investigate the effects of the substance on human health or the environment.

If the company considers that further information is needed for the dossier (see below in the Notes to Editors for the detail on the kinds of information concerned) it has to submit a testing proposal to ECHA covering the new tests. Information on testing proposals that would require studies on experimental animals is published on ECHA's website to allow anyone the opportunity to submit relevant data. This will then be taken into account when deciding on the need to carry out the proposed test.

More information on consultations on testing proposals:
http://echa.europa.eu/consultations/test_proposals/test_prop_cons_en.asp

Notes to Editors
This procedure is detailed in the REACH Regulation (Articles 10 (a)(ix) and 40).

Registrants submit testing proposals to ECHA as part of their registrations if they identify a data gap and cannot fulfil the information requirements specified in Annexes IX and X (e.g. reproductive toxicity, chronic fish toxicity). "Downstream users" (companies who make subsequent use of the substances) may also submit testing proposals according to Article 38 (2)(f).

When a testing proposal concerns a study involving vertebrate animals, ECHA publishes the information on the substance and the toxicological or ecotoxicological properties covered by the testing proposal. Anyone is invited to provide any relevant, scientifically valid information and studies on the substance within 45 days.

ECHA drafts a decision, taking into account the information submitted by the registrant and others.

The decision may result in:
- a request to the registrant/downstream user to carry out the study proposed
- a request to the registrant/downstream user to carry out the study proposed with modifications
- a rejection of the testing proposal or
- one of the outcomes mentioned above plus a request for additional studies.

The registrants/downstream users have to submit to ECHA the results of the studies required within the deadline set in the decision. They also have to take them into account in the assessment of the hazards and risks of the substance.

ECHA's decision is taken according to the provisions laid down in Article 50 and 51 of the REACH Regulation. This involves consultation of the registrants that submitted the testing proposal, the Member States' competent authorities and, if necessary ECHA's Member State Committee. ECHA can only adopt a decision if all Member States agree. If an agreement cannot be reached, ECHA refers the draft decision to the European Commission which takes the decision after further consultation with the Member States.
This procedure was established to make sure that the best possible use is made of existing information, and that animal testing is required only when there is a broad consensus that such testing is indeed necessary.

European Chemicals Agency Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland
Tel.: +358 9 6861 80 | Fax +358 9 6861 8210 | http://echa.europa.eu | press@echa.europa.eu