EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000001986-61-05/F Helsinki, 04/07/2012

DECISION ON A TESTING PROPOSAL SET OUT IN A REGISTRATION PURSUANT TO ARTICLE 40(3) OF REGULATION (EC) NO 1907/2006

For Mequinol, CAS No 150-76-5 (EC No 205-769-8), registration number: [redacted]

Addressee: [redacted]

The European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

I. Procedure

Pursuant to Article 40(1) of the REACH Regulation, ECHA has examined testing proposals set out in the registration dossier for Mequinol, CAS No 150-76-5 (EC No 205-769-8) submitted by: [redacted] (Registrant), latest submission number [redacted], for more than a 1000 tonnes per year.

In accordance with Articles 10(a)(ix) and 12(1)(e) of the REACH Regulation, the Registrant submitted the following testing proposals as part of the registration dossier to fulfil the information requirements set out in Annex IX and X:

Annex IX, 8.7.2.: Pre-natal developmental toxicity study (OECD Test Guideline 414)

Annex IX, 9.1.5., column 2: Long term toxicity to aquatic invertebrates (Daphnia) (OECD Test Guideline 211)

The examination of the testing proposals was initiated 24 November 2010.

ECHA opened a third party consultation for the testing proposal including testing on vertebrate animals that was held from the 29 April 2011 until 14 June 2011. ECHA did not receive any comments from third parties.

On 13 October 2011 ECHA notified the Registrant of its draft decision and invited him pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision.

The Registrant did not provide any comments on the draft decision.

On 20 January 2012 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, Competent Authorities of the Member States submitted proposals for

amendment to the draft decision.

On 23 February 2012 ECHA notified the Registrant of proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on those proposals for amendment within 30 days of the receipt of the notification.

ECHA reviewed the proposals for amendment received and decided not to amend the draft decision.

On 5 March 2012 ECHA referred the draft decision to the Member State Committee.

On 19 March 2012 following an informal discussion the Member State Committee modified the draft decision.

On 22 March 2012 the Registrant provided comments on the proposals for amendment. The Member State Committee took the comments of the Registrant into account.

The Member State Committee reached unanimous agreement on the draft decision in a written procedure launched on 2 April and closed on 12 April 2012.

This decision does not imply that the information provided by the Registrant in his registration dossier is in compliance with the requirements of the REACH Regulation. The decision does not prevent ECHA to initiate a compliance check on the present dossier at a later stage.

II. Testing required

Pursuant to Articles 40(3)(a) of the REACH Regulation, the Registrant shall carry out the following tests using the indicated test method:

- Pre-natal developmental toxicity study (Annex IX, 8.7.2, method B.31 of Regulation (EC) No 440/2008, OECD test guideline 414) in rat by the oral route;
- Long term toxicity to aquatic invertebrates study (Annex IX, 9.1.5. column 2, method C.20 of Regulation (EC) No 440/2008, OECD 211) in Daphnia.

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA **by 4 July 2013** an update of the registration dossier containing the information required by this decision.

Data from a second pre-natal developmental toxicity study on another species is a standard information requirement according to Annex X, 8.7.2. of the REACH Regulation. The Registrant should firstly take into account the outcome of the pre-natal developmental toxicity on a first species and all other relevant available data to determine if the conditions are met for adaptations according to Annex X, 8.7. column 2, or according to Annex XI. If the Registrant considers that testing is necessary to fulfil this information requirement, he should include in the update of his dossier a testing proposal for a pre-natal developmental toxicity study on a second species.

At any time, the Registrant shall take into account that there may be an obligation to make every effort to agree on sharing of information and costs with other registrants.

III. Statement of reasons

The decision of ECHA is based on the examination of the testing proposals of the Registrant for the registered substance. In accordance with Article 40(3) ECHA has decided to impose the following tests for the reasons set out below.

The performance of these studies is subject to all appropriate column 2 or Annex XI data adaptations.

a) Pre-natal developmental toxicity study (Annex IX, 8.7.2)

Pursuant to Article 40(3)(a) of the REACH Regulation ECHA may take a decision requiring the Registrant to carry out the proposed test and setting a deadline for the submission of the requested information.

A pre-natal developmental toxicity study in one species is required under Annex IX, 8.7.2. Since information on this endpoint is missing and since no acceptable adaptations to omit this information requirement has been received from either the Registrant or third parties, ECHA considers that the Registrant should perform the proposed test.

However, the testing proposal did not indicate the species to be used for the test and the appropriate route of administration.

Pursuant to OECD Guideline 414 and EU test method B31 the standard rodent species to be used for this test is the rat and the usual route of administration is oral.

ECHA sees no reason to deviate from these standard requirements and therefore has decided to accept the proposed test under the condition that the test should be conducted in rat by the oral route.

When considering the need for a testing proposal for a prenatal developmental toxicity study in a second species, the Registrant should take into account the outcome of the pre-natal developmental toxicity study on the first species and all available data to determine if the conditions are met for adaptations according to Annex X, 8.7. column 2, or according to Annex XI; for example if the substance meets the criteria for classification as toxic for reproduction Category 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, or alternatively, if Weight of Evidence assessment of all relevant available data provides scientific justification that the study in a second species is not needed.

b) Long term toxicity to aquatic invertebrates study (Annex IX, 9.1.5)

Pursuant to Article 40(3)(a) of the REACH Regulation ECHA may take a decision requiring the Registrant to carry out the proposed test and setting a deadline for the submission of the requested information.

Pursuant to column 2 of Annex IX, 9.1. of the REACH Regulation the Registrant shall propose long term toxicity testing if the chemical safety assessment indicates the need to investigate further the effects on aquatic organisms. The Registrant considered that long term toxicity testing to aquatic invertebrates (Annex IX, 9.1.5) is necessary in order to increase the knowledge on the ecotoxicological profile of the substance and to refine the PNEC.

Since the Registrant considers the information on this endpoint as necessary, and since no acceptable adaptations to omit this information requirement has been received from the Registrant, ECHA considers that the Registrant should perform the proposal test. The test shall be carried out using the EU test method indicated in section II above.

IV. General requirements for the generation of information and Good Laboratory Practice

ECHA always reminds registrants of the requirements of Article 13(4) of the REACH Regulation that ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (GLP). National authorities monitoring GLP maintain lists of test facilities indicating the relevant areas of expertise of each facility.

According to Article 13(3) of the REACH Regulation, tests that are required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the European Chemicals Agency as being appropriate. Thus, the Registrant shall refer to Commission Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 as adapted to technical progress or to other international test methods recognised as being appropriate and use the applicable test methods to generate the information on the endpoints indicated above.

V. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 51(8) of the REACH Regulation. Such appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on the ECHA's internet page at http://echa.europa.eu/appeals/app_procedure_en.asp. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]

Geert Dancet
Executive Director