ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000002019-79-05/F Helsinki, 13 June 2012

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

For 4,4'-sulphonyldiphenol, CAS No 80-09-1 (EC No 201-250-5), 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 **4,4'-sulphonyldiphenol, CAS No 80-09-1 (EC No 201-250-5)**, submitted by [redacted] (Registrant), latest submission number [redacted], for more than 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 Annexes IX:

Annex IX, 8.6.2: Sub-chronic toxicity study (90-day), oral route;
Annex IX, 8.7.2: Pre-natal developmental toxicity study.

The examination of the testing proposals was initiated on 14 October 2010.

ECHA opened a third party consultation for the testing proposals including testing on vertebrate animals that was held from 15 April 2011 until 30 May 2011. ECHA did not receive any comments from third parties.

On 28 October 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.

On 28 November 2011 the Registrant provided comments on the draft decision. ECHA has taken into account the information received and decided to amend the draft decision by extending the deadline from the original 18 months to 24 months.

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.

Subsequently, Competent Authorities of the Member States submitted proposals for amendment to the draft decision. ECHA reviewed the proposals for amendment received and decided not to modify 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 within 30 days of the receipt of the notification.

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

By 26 March 2012 the Registrant did not provide any comments on the proposals for amendment.

The Member State Committee modified the draft decision and 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 Article 40(3)(a) of the REACH Regulation, the Registrant shall carry out the following tests using the indicated test method:

- Sub-chronic toxicity study (90-day) (Annex IX, 8.6.2, method B.26 of Regulation (EC) No 440/2008, OECD test guideline 408) in rat by the oral route;
- 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.

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **13 June 2014** 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.

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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

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. In accordance with that provision ECHA decided to accept all the tests proposed by the Registrant for the reasons set out below.

The decision of ECHA is based on the examination of the testing proposals of the Registrant for the registered substance. A sub-chronic toxicity study (90-day) is required under Annex IX 8.6.2 and a pre-natal developmental toxicity study in one species under Annex IX, 8.7.2, and on a second species under Annexes IX and X, 8.7.2.

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

Since information on these endpoints is missing or inadequate in the registration dossier, and since no acceptable adaptations to omit these information requirements have been received from either the Registrant or third parties, ECHA decided to accept the proposed tests. The tests shall be carried out using the EU test methods indicated in section II above.

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.

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 reads:

> "*Ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice provided for in Directive 2004/10/EC or other international standards recognised as being equivalent by the Commission or the Agency and with the provisions of Directive 86/609/EEC, if applicable.*"

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

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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.

National authorities monitoring good laboratory practice (GLP) maintain lists of test facilities indicating the relevant areas of expertise of each facility.

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.

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Jukka MALM
Director of Regulatory Affairs