~~CONFIDENTIAL~~

European Chemicals Agency

Decision number: TPE-D-0000001654-74-04/F Helsinki, 22 September 2011

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

For 101-77-9_4,4'-methylenedianiline, CAS 101-77-9 (EC No 202-974-4), 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'-methylenedianiline, CAS 101-77-9 (EC No 202-974-4),)** submitted by [redacted] (Registrant), latest submission number [redacted], for 1000 tonnes or more 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 9.2.1.4 Sediment simulation testing using OECD Guideline 308 (Aerobic and anaerobic transformation in sediments)
- Annex IX 9.4.2. Effects on soil micro-organisms using OECD Guideline 216 (Soil Microorganisms: Nitrogen Transformation Test)
- Annex X 9.4.4 Long term toxicity testing on invertebrates using OECD 232 (Collembolan Reproduction Test)

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

On 10 June 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.

On 6 July 2011 the Registrant provided to ECHA comments on the draft decision. ECHA reviewed the further information received and amended the draft decision by extending the deadline to 18 months.

On 29 July 2011 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 did not propose amendments to the draft decision and ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

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:

- Sediment simulation testing (Annex IX 9.2.1.4.), EU Method C.24. (Aerobic and anaerobic transformation in aquatic sediment systems)
- Effects on soil microorganisms (Annex IX 9.4.2.), EU Method C.21. (Nitrogen transformation test)
- Long term toxicity testing on invertebrates, (Annex X 9.4.4.) OECD TG 232 (Collembolan Reproduction Test in Soil)

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

III. Statement of reasons

The decision of ECHA is based on the examination of the testing proposals of the Registrant for the registered substance.

Sediment simulation testing (EU Method C.24., Aerobic and anaerobic transformation in aquatic sediment systems)

The Registrant proposed to perform biotic degradation simulation testing in sediment. As the substance shows strong adsorption to soil, the sediment can be seen as a relevant target compartment for the distribution of the substance in the environment. Degradation simulation testing in sediment is an appropriate medium supporting risk assessment of the substance in sediments. The proposed test is part of the information requirements as laid down in Annex IX (9.2.1.4.) of the REACH Regulation. As the information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements it is necessary to generate the data and to perform the test.

Effects on soil microorganisms (EU Method C.21., Nitrogen transformation test)

The Registrant proposed to investigate effects on the nitrogen transformation by soil microorganisms. The proposed test is part of the information requirements as laid down in Annex IX (9.4.2.) of the REACH Regulation. Moreover, a potential effect on the transformation of nitrogen by soil micro-organisms was indicated as a concern in the EU-Risk Assessment Report in 2001 and the test proposed addresses this concern.

As the information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements it is necessary to generate the data and to perform the test.

Long term toxicity testing on invertebrates, (OECD TG 232 Collembolan Reproduction Test in Soil)

The Registrant proposed to perform long term toxicity testing on invertebrates. The proposed test is part of the information requirements as laid down in Annex X (9.4.4.) of the REACH Regulation. It is appropriate to address long-term toxicity of the substance to soil organisms using soil athropods, because information from a short term toxicity test in worms is already available in the dossier. Also, the information gain will be larger if using a different second species.

As the information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements it is necessary to generate the data and to perform the test.

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 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 the technical progress 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.

Done at Helsinki,

Director of Regulatory Affairs