~~CONFIDENTIAL~~

European Chemicals Agency

Decision number: TPE-D-0000001600-87-06/F Helsinki, 28/09/2011

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

For m-phenylenebis(methylamine), CAS 1477-55-0 (EC NUMBER 216-032-5), 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 **m-phenylenebis(methylamine), CAS 1477-55-0 (EC number 216-032-5), Registration Number:** [redacted] 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:

Annex IX, 7.16: Dissociation Constant (OECD Guideline 112 (Dissociation Constants in Water));

Annex IX, 7.17: Viscosity (OECD Test Guideline 114 (Viscosity of Liquids)).

The examination of the testing proposal was initiated on 17 September 2010.

On 4 April 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.

By 4 May 2011 the Registrant did not provide to ECHA comments on the draft decision.

On 17 June 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 submitted a proposal for amendment to the draft decision.

On 20 July 2011 ECHA notified the Registrant of the proposal for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments within 30 days of the receipt of the notification.

ECHA reviewed the proposal for amendment received and decided not to modify the draft decision.

On 1 August 2011 ECHA referred the draft decision to the Member State Committee.

By 19 August 2011 the Registrant did not provide any comments on the proposal for amendment.

A unanimous agreement of the Member State Committee on the draft decision was reached on 2 September 2011 in a written procedure launched on 22 August 2011.

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 while taking full account of the obligation to make every effort to agree on sharing of information and costs with other registrants:

- Dissociation Constant (Annex IX, 7.16., OECD Guideline 112 (Dissociation Constants in Water));
- Viscosity (Annex IX, 7.17., OECD Guideline 114 (Viscosity of Liquids)).

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **28 March 2012** 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 proposal of the Registrant for the registered substance.

According to Article 10(a)(vi) and Annex IX, dissociation constant data must be included in the dossier. The dossier contains a supporting study which refers to a dissociation constant value reported in an OECD SIDS report. This supporting information is alone not sufficient to cover the standard information requirement hence there is a data gap for this endpoint which must be filled by data from a valid test.

According to article 10(a)(vi) and Annex IX, viscosity data must be included in the dossier. As the dossier does not contain any information on the viscosity of the substance there is a data gap for this endpoint which must be filled by data from a valid test.

IV. Avoidance of unnecessary testing by data and cost sharing

The Registrant is hereby designated already now to perform the above mentioned tests in accordance with Article 53(1) of the REACH Regulation in case the same substance is registered by further registrant(s) at a later stage. This is to avoid unnecessary testing and the duplication of tests as a general aim of the REACH Regulation (Article 25). The legal text foresees the sharing of information between registrants.

In case a dossier evaluation decision for another registration of the same substance requests the same information requested from the Registrant of the decision at hand, ECHA will inform the subsequent registrant thereof. The costs of the test should be shared equally and the Registrant should provide each of the other registrant(s) concerned with a copy of the full study report. This is stipulated by Article 53(2) and (3) of the REACH Regulation.

V. 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.

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

VI. 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,

[redacted]

Director of Regulatory Affairs