Decision number: CCH-D-0000001731-80-05/F Helsinki, 10 February 2012

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006

For BCW 400572 500995 [redacted] Condensation products of m-phenylenebis(methylamine) with condensation products of 4-methyl-m-phenylene diisocyanate with alcohols, C10-14 (even numbered), CAS No [redacted] (EC No 428-710-1), registration No [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 41(1) of the REACH Regulation the ECHA has performed a compliance check of the registration dossier for BCW 400572 500995 [redacted] Condensation products of m-phenylenebis(methylamine) with condensation products of 4-methyl-m-phenylene diisocyanate with alcohols, C10-14 (even numbered), CAS No. [redacted] (EC No 428-710-1), submitted by [redacted] (Registrant), latest submission number [redacted], for 10-100 tonnes per year.

The compliance check was initiated on 29 March 2011.

On 28 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. The Registrant did not provide any comments on the draft decision.

On 2 September 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, one Competent Authority 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 5 October 2011 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 within 30 days of the receipt of the notification. The Registrant did not provide any comments on the proposals for amendment.

On 17 October 2011, the draft decision was referred to the Member State Committee.

A unanimous agreement of the Member State Committee on the draft decision was reached on 18 November 2011 in a written procedure launched on 7 November 2011.

This compliance check decision does not prevent ECHA to initiate further compliance checks on the present dossier at a later stage.

II. Information required

1) Pursuant to Articles 41(1)(a), 41(3), 10(a)(vii), 3(28) and 12(1)(c) as well as Section 1.1.4. of Annex I to the REACH Regulation, the Registrant shall provide robust study summaries for the following studies:
   - In vitro gene mutation study in bacteria (Annex VII, 8.4.1);
   - In vitro cytogenicity study in mammalian cells (chromosome aberration test) (Annex VIII, 8.4.2.);
   - In vitro gene mutation study in mammalian cells (Annex VIII, 8.4.3);
   - Short term repeated dose toxicity study (28 days) oral (Annex VIII, 8.6.1);
   - Screening test for reproductive/developmental toxicity (Annex VIII, 8.7.1).

2) Pursuant to Articles 41(1)(c), 14 and Annex I of the REACH Regulation the Registrant shall submit in the chemical safety report:
   - A derived no effect level (DNEL) for the inhalation route for each relevant population as part of the human health hazard assessment.

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated IUCLID dossier to ECHA by **10 August 2012**.

III. Statement of reasons

Based on the examination of the technical dossier, ECHA concludes that the information therein, submitted by the Registrant for registration of the above mentioned substance for the purpose of registration within the applicable tonnage band of 10 to 100 tonnes per year in accordance with Article 6 of the REACH Regulation, does not comply with the requirements of Articles 3, 10, 12, 13 and 14 and with Annexes I, VII and VIII thereof. Consequently, the Registrant is requested to submit the information mentioned above that is needed to bring the registration into compliance with the relevant information requirements.

1) Insufficient level of information provided in robust study summaries

According to Articles 10(a)(vii) and Sections 1.1.4 and 3.1.5 of Annex I to the REACH Regulation, a technical dossier shall include robust study summaries of all key data used in the human health and environmental hazard assessment. Article 3(28) defines a robust study summary as a "detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report." The level of information of the robust study summaries reported by the Registrant for some studies is not sufficient to make an independent assessment of the studies.

The registration dossier contains results from three mutagenicity studies. The Registrant concluded that the overall results from these studies were negative and considered the registered substance as non-mutagenic in these tests. In the absence of detailed individual test results, the interpretation of the study results made by the Registrant cannot be adequately assessed by ECHA. For instance, information on the frequency of reversions and mutations, the mean number of revertant colonies per plate and standard deviation, the

mean number of cells with chromosome aberration and the type of chromosome aberrations observed would be needed to conduct a full assessment of the data provided.

The registration dossier includes data from a 28-day repeated dose toxicity. The observation of macroscopic and microscopic findings in organs and tissues was reported. The Registrant indicates that these findings did not distinguish between treated animals and control animals and concludes that no adverse effects have been observed up to the highest test dose used. In the absence of a further description of the findings, their incidence and severity, the interpretation of the study results made by the Registrant cannot be adequately assessed by ECHA.

The registration dossier includes data from a developmental/reproductive toxicity screening study. The observation of gross pathological findings, of sporadic macroscopic findings and of histopathological findings in the reproductive organs of test animals was reported. An increase in the absolute and relative weight of the testes and the epididymides was observed in the high dose group when compared to the control group. The Registrant considered these findings as spontaneous, non-treatment related and concludes that no adverse effects have been observed up to the highest test dose used. In the absence of a further description of the findings, their incidence and severity the interpretation of the study results made by the Registrant cannot be adequately assessed by ECHA.

Therefore, the Registrant is required to provide robust study summaries for all studies listed above in the IUCLID format. Further guidance can be found in the *Information requirements Manual 1 Requirements for Robust Study Summary* published on the ECHA website at: http://echa.europa.eu/doc/publications/practical_guides/pg_report_robust_study_summaries.pdf

2) Missing information related to Chemical Safety Report - Derived no effect level (DNEL)

Annex I to the REACH Regulation sets out the general provisions for assessing substances and preparing chemical safety reports (CSR). Annex I, section 1.4 of the REACH Regulation, requires the Registrant to establish DNELs for the registered substance reflecting the likely routes of exposure, duration and frequency of exposure. The CSR under section 5.11.2 does not contain DNELs for the inhalation route. The Registrant has proposed a justification for not deriving $DNEL_{inhalation}$ for any of the relevant population based on the low vapour pressure and on the physical state of the registered substance. Reference is also made to the Annex VIII, 8.5.2 column 2 adaptations for waiving testing via inhalation route. However, as mentioned under section 2.2 in the CSR, the substance is used in process categories involving industrial and non-industrial spraying. The Registrant has not demonstrated that users will not be exposed to aerosols, particles or droplets of inhalable size in that context. Besides, no respiratory protective equipment is recommended in section 13 of the IUCLID dossier. In the absence of this information, the justification for not deriving DNELs for the inhalation route for each relevant population cannot be accepted. Even though testing via the inhalation route is not necessary the Registrant shall derive the appropriate DNELs for the inhalation route using the oral repeated dose NOAEL as a starting point.

The Registrant is accordingly requested to establish the appropriate DNELs and to update the CSR for this endpoint.

IV. 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 an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on 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