EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000002674-71-03/F Helsinki, 24 April 2013

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

For 4,4'-methylenebis[2-chloroaniline], CAS No 101-14-4 (EC No 202-918-9), 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 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration for 4,4'-methylenebis[2-chloroaniline], CAS No 101-14-4 (EC No 202-918-9) submitted by [redacted] (Registrant).

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 100 to 1000 tonnes per year. This decision does not take into account any updates submitted after 18 January 2013, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation.

This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

The compliance check was initiated on 9 July 2012.

On 9 October 2012 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision. That draft decision was based on submission number [redacted].

On 1 November 2012 ECHA received comments from the Registrant.

The ECHA Secretariat considered the Registrant's comments. The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

On 18 January 2013 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 did not propose amendments to the draft decision and ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

1) Pursuant to Articles 41(1)(a) and (b), 41(3), 10(a)(vi), 12(1)(a), 13 and Annex VII of the REACH Regulation the Registrant shall submit the following information using the test method as indicated on:

   a. Granulometry (Annex VII, 7.14.; test method: such as OECD 110);

2) Pursuant to Articles 41(1)(a)(c), 10 (b), 14 and Annex I of the REACH Regulation the Registrant shall submit in the chemical safety report:

   a. Environmental exposure assessment (Annex I, section 5)
   b. Environmental risk assessment (Annex I, section 6)

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 **24 October 2013**.

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 100 to 1000 tonnes per year in accordance with Article 6 and 11(2) of the REACH Regulation, does not comply with the requirements of Articles 10, 12 and 13 and with Annexes I, VII, VIII, IX and XI 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) Missing information related to endpoints

Pursuant to Articles 10(a)(vi), 12(1)(a) and (b) of the REACH Regulation, a registration for a substance produced in quantities of 100 – 1000 tonnes per year shall contain as a minimum the information specified in Annex IX of the REACH Regulation.

The technical dossier contained an adaptation to the standard information requirement for the endpoint on:

- Granulometry (Annex VII, 7.14.).

The presented adaptation is based on an incorrect interpretation of the information requirements for this endpoint for granular substances. The Registrant is waving the information in this endpoint and justifies the data waving by stating "In accordance with column 2 of REACH Annex VII, the granulometry test (required in section 7.14) does not need to be conducted as the substance is marketed or used in a granular-type form and not as a powder".

ECHA understands that the Registrant reads column 2 of REACH Annex VII in a way that the granulometry test would not be required if the substance is marketed or used in a granular type form. However, ECHA notes that this is not the correct reading of the Annex VII column 2 adaptation. Indeed, Column 2 of REACH Annex VII, section 7.14 provides that *"The study does not need to be conducted if the substance is marketed or used in a non solid or granular form"*. However as specified in ECHA Guidance on information

requirements R7a (May 2008), Section R.7.1.14.1 on granulometry "*The study does not need to be conducted if the substance is marketed or used in a non solid or non granular form*" [emphasis added]. Accordingly, ECHA believes that Column 2 has to be interpreted as referring to substances used or marketed in a non solid and non granular form.

Therefore, the adaptation cannot be accepted, and the Registrant is accordingly requested to submit the information for granulometry performed with the registered substance.

During the commenting phase, the Registrant requested an extension of the deadline of 6 months given to update their registration dossier, and they provided written confirmation that the test could not be completed by the test laboratory before May 2013. ECHA clarifies that the deadline in a draft decision only becomes legally effective and binding for the Registrant when the decision becomes final, and not during the draft decision stages. Thus, for this case the 6 month deadline will not become effective before May 2013.

Therefore, ECHA decided not to modify the current deadline of 6 months.

2) Missing information related to Chemical Safety Report (CSR)

Pursuant to Article 10(b) of the REACH Regulation the registration shall include a chemical safety report when required under Article 14, in the format specified in Annex I to the REACH Regulation. Annex I sets out the general provisions for assessing substances and preparing the CSR.

Annex I, section 0.6.1 of the REACH Regulation indicates that a CSR shall firstly include the following steps: human health hazard assessment, human health hazard assessment of physicochemical properties, environmental hazard assessment, and PBT and vPvB assessment.

Annex I, point 0.6.2 of the REACH Regulation indicates that in the cases referred to in point 0.6.3, the CSR shall also include the exposure assessment and risk characterisation.

The registered substance is classified as Acute Tox. 4, Carcinogenic B1, Aquatic Acute 1 and Aquatic Chronic 1 according to the Harmonized classification listed in EU Regulation 1272/2008 Annex VI, thus falling under points 0.6.3 and 0.6.2. Therefore, the exposure assessment as described in section 5 of Annex I and the risk assessment as described in Section 6 of Annex I of the REACH regulation are necessary.

a) Exposure to the environment

Annex I, section 5 of the REACH Regulation requires the Registrant to generate exposure scenarios and exposure estimations for the registered substance. The exposure assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses and shall cover any exposures that may relate to the identified hazards.

ECHA notes that the Registrant is self classifying the substance as Muta. 2 and he has also indicated in the technical dossier that environmental exposure from solid waste is a significant route. The Registrant has provided, in Section 13 of the IUCLID dossier, a document describing the limited risk of exposure to the environment. In the CSR provided by the Registrant the exposure scenarios or exposure estimations for the environment are missing.

Therefore, the Registrant is requested to generate exposure scenarios and exposure estimations for the environment and update the CSR accordingly.

b) Risk assessment for the environment

Annex I, section 6 of the REACH Regulation requires the Registrant to characterise the risk for each exposure scenario. The risk characterisation shall consider the human population (exposed as workers, consumer or indirectly via the environment and if relevant a combination thereof) and the environmental spheres for which exposure to the substance is known or reasonable foreseeable, under the assumption that the risk management measures described under exposure scenario in the Section 5 have been implemented. In addition, the overall environmental risk caused by the substance shall be reviewed by integrating the results for the overall releases, emissions and losses from all sources to all environmental compartments.

The Registrant has justified not characterising the risk for the environmental compartment by a generic statement *"There is no emission to air or the aquatic compartment. Therefore, the risk to the environment from MOCA in the scenarios described is considered to be controlled."*

ECHA notes that the risk has not been characterised for the exposure scenarios and exposure estimations requested.

Therefore, since in the provided CSR there is no risk assessment for the environment the Registrant is accordingly requested to generate it pursuant to section 6 of Annex I to the REACH Regulation, in line with the exposure scenarios and exposure estimations also requested, and update the CSR accordingly.

During the commenting phase, the Registrant indicated that the only sources of exposure to the environment are from the solid waste phase and that resulting from article waste, and that their exposure and risk assessment would cover for these two exposure scenarios. ECHA would like to note that all exposure scenarios have to be included in the exposure and risk assessment for all the uses the Registrant identified and indicated in the IUCLID dossier. If the Registrant considered that exposure via those uses was negligible such a statement would need to be included in the CSR and scientifically justified in the assessment.

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted by other joint registrants for identifying the substance has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

In relation to the information required by the present decision, the sample of substance used for the new study must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is within the specifications of the substance composition that are given by the joint registrants. It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition.

In addition, it is important to ensure that the particular sample of substance tested in the new study is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new study must be suitable to assess these grades.

Finally there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the study to be assessed.

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 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.

[redacted]
Jukka Malm
Director of Regulatory Affairs