European Chemicals Agency

Decision number: **CCH-D-0000001097-76-04/F**
Decision date: 3 May 2010

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

For 17351-75-6_MASTER_CYCLOHEXANE, 1,4-BIS[(ETHENYLOXY)METHYL]- (IUC4 DSN 405), *CAS* 17351-75-6 (EC Nr. 413-370-7), Registration Number: [redacted]

ADDRESSEE:
[redacted]

I. Procedure

Pursuant to Article 41(1) of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation) the European Chemicals Agency (ECHA) has performed a compliance check of the registration dossier for, **17351-75-6_master_Cyclohexane, 1,4-bis[(ethenyloxy)methyl]- (IUC4 DSN 405)** submitted by [redacted] (the "Registrant").

The registrant submitted to ECHA a registration dossier for the substance for a tonnage band of **1 – 10 tonnes** per year. The registration number of this dossier [redacted] and the registration date is 4 December 2008. The latest submission number is [redacted]

The compliance check was initiated on 25 March 2009.

On 16 December 2009, 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 13 January 2010 the registrant provided to ECHA comments on the draft decision.

ECHA reviewed the further information received and decided not to change the draft decision but to amend the statement of reasons.

On 25 February 2010 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 comments, which did not include proposals for amendments on the draft decision. Following Article 51(3) of the REACH Regulation, ECHA has therefore taken the decision concerning the present compliance check as notified to the Member State competent authorities and issued on 25 February 2010.

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

II. Information required

ECHA has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of the REACH Regulation.

Pursuant to Articles 41(1)(a), 41(3) and Annex VII of the REACH Regulation the Registrant shall submit the information using the test method as indicated on

- Growth inhibition study aquatic plants (Annex VII, 9.1.2.; EU Method C.3.)

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 **[12 months from date of decision]**.

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 in accordance with **Article 6** of the REACH Regulation, does not comply with the requirements of Articles **10, 12 and 13 and with Annexes VII 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.

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 1 – 10 tonnes per year shall contain as a minimum the information specified in Annex VII of the REACH Regulation.

In the technical dossier, a general rule of adaptation of the standard testing regime, according to Annex XI, 1.3. was used for the endpoint on:

- Growth inhibition study aquatic plants (Annex VII, 9.1.2.)

According to the Annex XI, 1.3 of the REACH Regulation, the Registrant may adapt the standard testing regime given in the Annex VII, if results of quantitative structure-activity relationship models (Q)SAR) are provided and when following conditions of the (Q)SAR are met:

- results are derived from a (Q)SAR model whose scientific validity has been established (the first bullet point of Annex XI, 1.3)

  In the registration or in the comment received, the Registrant did not provide information on the validity of ECOSAR model for this endpoint and for this registered substance. To support the documentation and validity of the ECOSAR, in particular the underlying predictive method and the equations used in the model, is necessary.

- the substance falls within the applicability domain of the (Q)SAR model (the second bullet point of Annex XI, 1.3)

  The applicability domain in ECOSAR for the registered substance is considered to be poorly defined, because only two chemicals with unknown identity have been used in the chemical class of the registered substance (vinyl or allyl ethers) to predict the EC50.

- results are adequate for the purpose of classification and labelling and/or risk assessment (the third bullet point of Annex XI, 1.3)

  In general, EC50 is a relevant endpoint for the purpose of classification and labelling and for derivation of PNEC. The registrant has not shown the validity of the model used and the applicability of its domain, and therefore, the estimated EC50 presented in the dossier is not adequate for the purpose of classification and labelling. In addition, the prediction presented in the dossier is based on a wrong structure (correct SMILES code was not used).

- adequate and reliable documentation of the applied method is provided (the fourth bullet point of Annex XI, 1.3)

  The Registrant has documented the version and the name of the software. However, this is not considered sufficient for documenting the method applied. Information on in particular the algorithm and the training set have to be provided as well.

In the registration the EPIWIN QSAR model is used to make predictions for the aquatic toxicity to algae (ECOSAR model). However, information provided by the Registrant in comments received 13/01/2010 do not meet the conditions of Annex XI, 1.3 indicated above.

Further guidance is available on (Q)SARs in "Guidance on information requirements and chemical safety assessment. Chapter R.6: QSARs and grouping of chemicals", available at: http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r6_en.pdf

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

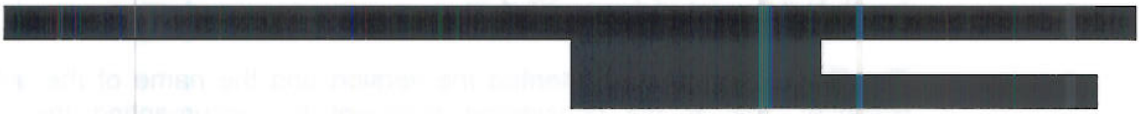
(EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2008 adapted to the technical progress by Commission Regulation (EC) No 761/2009 and use the applicable test methods to generate the information on the endpoints indicated above.

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 at the Board of Appeal website 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,



Executive Director