European Chemicals Agency

For final decision: CCH-D-0000001421-87-05/F Helsinki, 1 July 2011
Decision date: 1 July 2011

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

For Chlorobenzene [redacted] CAS 108-90-7 (EC Nr. 203-628-5), 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 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration dossier for Chlorobenzene [redacted] CAS 108-90-7 (EC Nr. 203-628-5) submitted [redacted] (Registrant), latest submission number [redacted] for above 1000 tonnes per year.

The compliance check was initiated on 24 August 2010.

On 7 January 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 7 February 2011, the Registrant provided comments on the draft decision to ECHA. ECHA has considered the information received and amended the draft decision accordingly.

On 18 February 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 a proposal for amendment to the draft decision.

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On 23 March 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 amend the draft decision.

On 4 April 2011, the draft decision was referred to the Member State Committee.

On 20 April 2011 the Registrant provided comments on the proposed amendment.
The Member State Committee took the comments of the Registrant into account.

The Member State Committee reached a unanimous agreement on the draft decision, on 10 May 2011 in a written procedure launched on 28 April 2011.

This decision does not imply that the information provided by the Registrant in his registration dossier is in compliance with the REACH requirements. The decision does not prevent ECHA to initiate a compliance check on the present dossier at a later stage.

II. Information required

Pursuant to Articles 41(1)(c) and 41(3) as well as Annex I of the REACH Regulation the Registrant shall submit for the registered substance:

- Identified professional/consumer use(s) of the substance in formulation(s) and the Exposure assessment/risk characterization for this use(s) (including if relevant waste life-cycle stage following this use(s)) in the CSR
- Waste management measures to reduce or avoid exposure of humans and the environment to the substance during waste disposal and/or recycling
- The exposure estimation for the waste life-cycle stage for all relevant exposure scenarios provided in the CSR
- PNECs (aqua and sediment) for marine compartment
- The exposure estimation and the risk characterisation for marine compartment for the relevant exposure scenarios

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 **1 December 2011 - 6 months from the date of the 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 Article 10 and with Annex I thereof. Consequently, the Registrant is requested to submit the information mentioned above that is necessary to bring the registration into compliance with the relevant information requirements.

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Missing information related to Chemical Safety Report

Annex I sets out the general provisions for assessing substances and preparing chemical safety reports.

a. The exposure assessment of missing life-cycle stages of the substance

Pursuant to Annex I, section 5 of the REACH Regulation the exposure assessment shall entail two steps, which shall be clearly identified as such in the CSR – generation of exposure scenario(s) and exposure estimation. 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.

In the comments on ECHA's draft decision, the Registrant identifies that formulation(s) containing chlorobenzene is used in the European Union (EU). The Exposure Scenario 3 "Industrial use of chlorobenzene as solvent" and relevant exposure estimation provided in the CSR cover an industrial use of the substance as a solvent. The professional and/or consumer use of formulation(s) containing the registered substance is not identified in the registration dossier and the exposure assessment for this use (including possible waste life-cycle stage following this use) is not provided in the CSR.

Therefore, the Registrant shall identify in the registration dossier professional/consumer use(s) of the substance in a formulation(s) and provide the Exposure assessment/risk characterization for this use(s) (including if relevant waste life-cycle stage following this use(s)) in the CSR.

b. Waste management measures and the exposure estimation of the waste life-cycle stage

Pursuant to Annex I, section 5.1.1 of the REACH Regulation the exposure scenario includes, where relevant, a description of the risk management measures including the waste management measures to reduce or avoid exposure of humans and the environment to the substance during waste disposal and/or recycling. Section 5.2.2 provides that the emission estimation shall consider the emissions during all relevant parts of the life-cycle of the substance resulting from the manufacture and each of the identified uses. The life-cycle stages resulting from the manufacture and identified uses cover, where relevant, the waste stage.

For all exposure scenarios provided in the CSR, a statement that any wastes and solutions that contain residues of the substance are disposed in accordance with national and international legislation is provided by the Registrant and indicates that the waste containing the substance is generated and the waste life-cycle stage is relevant for the exposure estimation. As mentioned above according to the Annex I of the REACH regulation the Registrant has to describe suitable conditions of waste treatment and assess the related exposure arising from the waste stage following manufacture and all the identified uses of the substance.

Therefore, the Registrant shall describe in the CSR the waste management measures to reduce or avoid exposure of humans and the environment to the substance during waste disposal and/or recycling in the generated exposure scenarios. Furthermore, in the exposure estimation for the provided exposure scenarios the Registrant has to consider and quantify

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exposure of humans and the environment arising from the emissions in the waste life-cycle stage.

c. PNECs (aqua and sediment) for marine compartment and the exposure estimation/risk characterisation for marine compartment

Pursuant to Annex I, section 3.3.1 of the REACH Regulation based on the available information, the PNEC for each environmental sphere shall be established. If it is not possible to derive the PNEC, then this shall be clearly stated and fully justified. Pursuant to Annex I, section 0.6 of the REACH Regulation, if the substance meets the criteria for classification as dangerous according to Directive 67/548/EEC or is assessed to be PBT or vPvB, the chemical safety assessment shall also consider the Exposure assessment and Risk characterization steps. Pursuant to Annex I, section 5.0 of the REACH Regulation 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 hazards identified.

The PNECs for marine compartment are not established and no justifications provided in the registration dossier and/or the CSR why it is not possible to derive these PNECs or why these PNECs are not applicable. The results of exposure assessment and risk characterisation for marine compartment are not provided in the CSR.

On the basis of the criteria for classification as dangerous according to Directive 67/548/EEC the substance is classified as dangerous for the aquatic environment, which is also relevant for the marine water environment. Some of the exposure scenarios provided in the CSR are foreseen to cover the use of the substance by unknown downstream users. Therefore, the location of these sites of use of the substance is assumed to be unknown and possible exposure of marine environment shall be considered in the exposure assessment and following risk characterisation shall be provided in the CSR for these relevant exposure scenarios. Furthermore, PNECs marine compartment are needed for the risk characterisation for the relevant exposure scenarios – for a comparison of the predicted environmental concentrations in the marine compartment with the established respective PNECs.

Therefore, the Registrant shall:

- establish the PNECs (aqua and sediment) for marine compartment; and
- perform estimation of the exposure levels for marine compartment for the relevant exposure scenarios; and
- carry out the risk characterisation for marine compartment for the relevant exposure scenarios.

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."*

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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 as adapted to 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 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.

Done at Helsinki,

[redacted]

Jukka Malm
Director of Regulatory Affairs

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