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Helsinki, 25 July 2012

Decision number: CCH-D-0000001900-81-06/F

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

For 1,2-dichlorobenzene CAS 95-50-1 (EC Nr. 202-425-9), 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 dossier for 1,2-dichlorobenzene CAS 95-50-1 (EC No 202-425-9) submitted by [redacted] (the Registrant), latest submission number [redacted], for 1000 tonnes or more per year.

The compliance check was initiated on 21.02.2011.

On 13 October 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 11 November ECHA received comments from the Registrant agreeing to ECHA's draft decision.

On 2 March 2012 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, one Competent Authority of a Member State submitted a proposal for amendment to the draft decision.

On 4 April 2012 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 on that proposal for amendment within 30 days of the receipt of the notification.

ECHA
EUROPEAN CHEMICALS AGENCY

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

On 16 April 2012 ECHA referred the draft decision to the Member State Committee.

On 3 May 2012 the Registrant provided comments on the proposal for amendment. The Member State Committee took the comments of the Registrant into account.

A unanimous agreement of the Member State Committee on the draft decision was reached on 21 May 2012 in a written procedure launched on 10 May 2012.

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

II. Information required

Pursuant to Articles 41(1)(c), 10 (b), 14 as well as Annex I of the REACH Regulation the Registrant shall submit in the Chemical Safety Report (CSR):

1) NOAELs and NOAECs (90-day repeated dose toxicity and 2-generation reproductive toxicity via inhalation studies, respectively) and relevant DNELs which take into account the observed effects in the studies and conclusions of international/national assessments of these studies. Otherwise provide a valid justification for deviating from these studies and conclusions.
2) PNECs (aqua and sediment) for marine compartment.
3) The exposure estimation and the risk characterisation for marine compartment for the relevant exposure scenarios.
4) Waste management measures to reduce or avoid exposure of humans and the environment to the substance during waste disposal and/or recycling.
5) The exposure estimation for the waste life-cycle stage for all relevant exposure scenarios provided in the CSR.
6) Documentation that risks to workers are adequately controlled. Personal protective equipment, such as gloves to be worn need to be specified clearly when handling the substance or mixture, including:
    - The type of material and its thickness,
    - The typical or minimum breakthrough times of the glove material.

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 **25 January 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 1000 tonnes or more per year 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 needed to bring the registration into compliance with the relevant information requirements.

ECHA
EUROPEAN CHEMICALS AGENCY

In his comments to the draft decision, the Registrant consented to meet the requirements of ECHA's draft decision.

Missing information related to Chemical Safety Report

Annex I sets out the general provisions for assessing substances and preparing CSR.

1) Selection of No Observed Adverse Effect Level/Concentration (NOAEL/NOAEC)

Pursuant to section 1.0.1 of Annex I of the REACH Regulation one of the objectives of the human health hazard assessment is to derive levels of exposure to the substance above which humans should not be exposed. This level of exposure is known as the Derived No-Effect Level (DNEL). According to section 1.1.4 of Annex I of the REACH Regulation if several studies addressing the same effect are available, normally the study or studies giving rise to the highest concern shall be used to establish the DNEL. Furthermore, according to section 0.5 of Annex I of the REACH Regulation available information from assessments carried out under other international and national programmes shall be included. Where available and appropriate, an assessment carried out under Community legislation (e.g. risk assessments completed under Regulation (EEC) No 793/93) shall be taken into account in the development of, and reflected in, the CSR. Deviations from such assessments shall be justified.

According to the Guidance on information requirements and chemical safety assessment Chapter R.8: Characterisation of dose [concentration]-response for human health (May 2008, ECHA) the DNEL can be considered as an 'overall' No-(Adverse-) Effect-Level (N(A)EL) for a given exposure (route, duration, frequency), accounting for uncertainties/variability in these data and the human population exposed. The observed threshold dose or effect level in a toxicity test will be influenced by the sensitivity of the test system and is a surrogate for the NAEL. The NOAEL/NOAEC identified in a particular test is the highest dose level or concentration of the substance used in that test at which no statistically significant adverse effects were observed.

a. Sub-chronic repeated dose toxicity (90-day)

In section 7.5.1 of the IUCLID dossier the Registrant provided two key studies on 90-day repeated dose toxicity in rats. For the first key study (NTP, 1989) the Registrant selected NOAEL to be 125 mg/kg bw/day where for the second study (Robinson et al., 1991) the selected NOAEL was 100 mg/kg bw/day. The Registrant used NOAEL of 125 mg/kg bw/day for the DNEL derivation.

The same key studies as provided in section 7.5.1 of the IUCLID dossier were assessed by the Organisation for Economic Co-Operation (OECD), and Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and in regard of a relevant NOAEL these organisations came to a different conclusion than the Registrant.

Regarding the provided NTP study, it should be noted that the NOAEL for male and female should be 60 mg/kg bw/day (the same was concluded by the OECD and NICNAS assessments), since at the next dose level of 125 mg/kg bw/day hepatocellular necrosis was observed in the test animals. Where regarding the provided Robinson et al., 1991 study, it is to be noted that the NOAEL selected for male and female should be 25 mg/kg bw/day (the same was concluded by the OECD and NICNAS assessments), since at the

ECHA
EUROPEAN CHEMICALS AGENCY

next dose level of 100 mg/kg bw/day number of adverse effects were observed (increased absolute and relative liver weight, increased absolute and relative kidney weight for females and increased plasma Alanine transaminase (ALT) levels for males). Therefore the overall NOAEL for the DNEL derivation for this endpoint would be the 60 mg/kg bw/day.

Thus the Registrant shall:
- take the observed effects in the studies and results of the international/national assessments of the studies into account when selecting NOAELs for DNEL derivation and recalculate the relevant DNEL with the correct NOAEL; or
- provide valid justification why observed effects and conclusions of international/national assessments are disregarded for the purpose of selecting NOAELs and DNEL derivation.

b. Two-generation reproductive toxicity

In section 7.8.1 of the IUCLID dossier the Registrant provided a study (Schroeder R., Daly I., 1989) on two-generation toxicity in rats. The same study was also assessed by OECD and in report of the relevant NOAEC OECD came to a different conclusion than the Registrant. The Registrant selected NOAEC for parent and offspring generations to be >400 ppm. However, it should be noted that the NOAEC for adults should be 50 ppm for F0 and F1 generations based on the liver hypertrophy and kidney effects observed in males at the 150 ppm concentration (the same was concluded by the OECD assessment). The NOAEC for reproduction and offspring growth and development for F1 and F2 should be 150 ppm based on the significantly lower pup weight during lactation at the 400 ppm concentration (the same was concluded by the OECD assessment).

Thus the Registrant shall:
- take the observed effects in the study and results of the international assessment of the study into account when selecting NOAEC for DNEL derivation and recalculate the relevant DNEL with the correct NOAEC; or
- provide valid justification why observed effects and conclusions of international assessment are disregarded for the purpose of selecting NOAECs and DNEL derivation.

2) Predicted No-Effect Concentrations (PNECs) (aqua and sediment) for marine compartment

Pursuant to Annex I, section 3.3.1 and 3.3.2 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.

The PNECs for marine compartment are not established in the dossier. Furthermore, no justifications are provided in the registration dossier and/or CSR why it is not possible to derive these PNECs or why these PNECs are not applicable.

Therefore, the Registrant shall establish the PNECs (aqua and sediment) for marine compartment and include them in the CSR or justify why it is not possible to derive these PNECs.

3) The exposure estimation/risk characterisation for marine compartment

ECHA
EUROPEAN CHEMICALS AGENCY

Pursuant to Article 14(4) and Annex I, section 0.6 of the REACH Regulation, if the substance meets the criteria for certain hazard classes and categories according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, or is assessed to be persistent, bioaccumulative and toxic or very persistent and very bioaccumulative, the chemical safety assessment shall also include 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.

According to Table 3.2 of Annex VI of the Regulation (EC) No 1272/2008 the registered substance has harmonised classification as dangerous for the aquatic environment, which is also relevant for the marine environment. However, the results of exposure assessment and risk characterisation for marine compartment are not provided in the CSR.

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 for this substance is assumed to be unknown and possible exposure of marine environment should be considered. Subsequently, the exposure assessment and risk characterisation for marine compartment for these relevant exposure scenarios shall be provided in the CSR.

Therefore, the Registrant is requested to perform estimation of the exposure levels for the marine compartment for the relevant exposure scenarios and to carry out the risk characterisation for marine compartment for the relevant exposure scenarios. The Registrant is requested to update the CSR accordingly.

4) and 5) 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 is provided by the Registrant that any waste and solutions that contain residues of the substance are disposed in accordance with national and international legislation. Such statement indicates that 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.

ECHA
EUROPEAN CHEMICALS AGENCY

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 exposure scenarios provided the Registrant has to consider and quantify exposure of humans and the environment arising from the emissions in the waste life-cycle stage.

6) Documentation that risks to workers are adequately controlled

Article 14(6) as well as Annex I, 0.1, 5.2.4 and 6.2-6.4 of the REACH Regulation require registrants to identify and apply appropriate measures to adequately control the risks identified in CSR. The exposure shall be estimated and risks shall be characterised in the CSR under the assumption that relevant risk management measures have been implemented.

Pursuant to Annex VI, section 5 of the REACH Regulation the information provided in the registration dossier must be consistent with that in the Safety Data Sheet. The requirements of Safety Data Sheets are specified in Annex II (amended by Commission Regulation (EC) No 453/2010). According to section 8.2.2.2(b) of Annex II, the type of gloves to be worn shall be clearly specified based on the hazard of the substance or mixture and potential for contact and with regard to the amount and duration of dermal exposure, including:

- The type of material and its thickness,
- The typical or minimum breakthrough times of the glove material

The substance is classified as irritant to skin, eyes and respiratory system, and as a skin sensitizer. It is essential for ensuring the safe use of a substance to have detailed guidance on risk management measures (e.g. personal protective equipment). Although the gloves are reported as required personal protective equipment to prevent exposure of the substance in number of Exposure Scenarios (ESs) provided in the Chemical Safety Report (CSR), the type of gloves to be worn when handling the substance is not specified in the CSR.

The Registrant is requested to provide documentation for the recommended material, thickness and breakthrough times for protective gloves, with regard to the amount and duration of dermal exposure in the CSR.

IV. <u>General requirements for the generation of information and Good Laboratory Practice</u>

ECHA always reminds registrants of the requirements of Article 13(4) of the REACH Regulation that ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (GLP). National authorities monitoring GLP maintain lists of test facilities indicating the relevant areas of expertise of each facility.

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

ECHA
EUROPEAN CHEMICALS AGENCY

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 1907/2006 as adapted to technical progress or to other international test methods recognised as being appropriate and use the applicable test methods to generate the information on the endpoints indicated above.

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.

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