EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000004622-78-03/F Helsinki, 20 August 2014

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

For 1,2-dichloropropane, CAS No 78-87-5 (EC No 201-152-2), 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 1,2-dichloropropane, CAS No 78-87-5 (EC No 201-152-2), submitted by [redacted] (Registrant).

ECHA notes that in the joint submission covering the current registration, the Chemical Safety Report (CSR) is not provided by the lead registrant on behalf of the member registrants. The scope of this compliance check is limited to the standard information requirements of Annex I and Section 2 of Annex VI, while the compliance check concerning the information requirements laid down in Annexes VII to X was done on the lead registrant dossier of this joint submission.

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band 1000 tonnes or more per year. This decision does not take into account any updates submitted after 6 March 2014, 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 13 November 2013.

On 13 December 2013 ECHA sent the draft decision to the Registrant and invited him to provide comments within 45 days of the receipt of the draft decision.

By 27 January 2014 the Registrant did not provide any comments on the draft decision to ECHA.

On 6 March 2014 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 for amendment of the draft decision within 30 days of the receipt of the notification.

As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

A. Information in the technical dossier related to the identity of the substance

Pursuant to Articles 41(1), 41(3), 10(a)(ii) and Annex VI, Section 2 of the REACH Regulation the Registrant shall submit the following information for the registered substance subject to the present decision:

1. Spectral data (infra-red) (Annex VI, 2.3.5.), as specified in section III.A.1 below;
2. High-pressure liquid chromatogram, gas chromatogram (Annex VI, 2.3.6.), as specified in section III.A.2 below;
3. Description of the analytical methods (Annex VI, 2.3.7.), as specified in section III.A.3 below.

B. Information related to chemical safety assessment and chemical safety report

Pursuant to Articles 41(1), 41(3), 10(b), 14 and Annex I of the REACH Regulation the Registrant shall submit in the chemical safety report:

1. Revised environmental exposure assessment and risk characterisation as specified in section III.B.1 below (Annex I, sections 5 and 6 of the REACH Regulation);
2. Missing elements for consumer exposure assessment and a revised consumer exposure assessment and risk characterisation as specified in section III.B.2 below (Annex I, sections 5 and 6 of the REACH Regulation).

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **27 February 2015**.

III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirements.

A. Information in the technical dossier related to the identity of the substance

Pursuant to Article 10(a)(ii) of the REACH Regulation, the technical dossier shall contain information on the identity of the substance as specified in Annex VI, Section 2 of the REACH Regulation. In accordance with Annex VI, Section 2 the information provided shall be sufficient to enable the identification of the registered substance.

1. Spectral data (infra-red) (Annex VI, 2.3.5.)

"Spectral data" is an information requirement as laid down in Annex VI, Section 2.3.5. of the REACH Regulation. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

ECHA notes that the Registrant included a ^{1}H NMR spectrum in IUCLID section 1.4, nevertheless the registration does not contain infra-red (IR) spectral data to support the indicated substance identity.

ECHA regards this required information scientifically relevant for the identification of the registered substance since the IR spectrum will display characteristic vibration bands of covalent bonds in the molecule. Indeed, each chemical substance has a unique "spectral finger print" absorption in the IR portion of the spectrum which is an important element for its identification.

As for the reporting of the IR spectral data in the registration dossier, the information should be attached in IUCLID section 1.4.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the information derived from the registered substance subject to the present decision: correct infra-red spectral data as specifically explained above. The Registrant shall ensure that the information is consistent throughout the dossier.

2. High-pressure liquid chromatogram, gas chromatogram (Annex VI, 2.3.6.)

"High-pressure liquid chromatogram, gas chromatogram" is an information requirement as laid down in Annex VI, Section 2.3.6. of the REACH Regulation. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

ECHA notes that the registration does not contain appropriate high-pressure liquid chromatogram (HPLC) or gas chromatogram (GC) data to support the indicated substance identity. ECHA notes that a certificate of analysis obtained through a qualitative gas chromatography-mass spectrometric (GC-MS) analysis has been attached in Section 1.4 of the IUCLID dossier. However, ECHA observes that the Registrant did not include any chromatogram.

Therefore, the Registrant is requested to provide a high-pressure liquid chromatogram (HPLC) or gas chromatogram (GC), including a peak list with the corresponding retention time and peak area.

The Registrant shall ensure that the description of the analytical method used for the chromatographic analysis, including the experimental set-up (i.e. the column type, length and diameter; injection volume; mobile phase/carrier gas; GC temperature programme; flow rate; concentrations of standard solutions; detection technique; run time) and preparation of solutions and identity of standards, is specified, in line with the requirements of Annex VI section 2.3.7. of the REACH Regulation.

As for the reporting, the information should be included in IUCLID section 1.4 of the registration dossier.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the information derived from the registered substance subject to the present decision: correct chromatographic data as specifically explained above. The Registrant shall ensure that the information is consistent throughout the dossier.

3. Description of the analytical methods (Annex VI, 2.3.7.)

"Description of the analytical methods" is an information requirement as laid down in Annex VI, Section 2.3.7. of the REACH Regulation. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

ECHA notes that the Registrant did not provide any description of the analytical method used for the identification and quantification of the main constituent and impurities present in the composition of the registered substance.

The Registrant instead provided in IUCLID section 1.4 a certificate of analysis based on a GC-MS analysis. However, ECHA observes that the Registrant did not provide details of the protocol followed to translate the results from the GC analysis into concentration values of the main constituent and impurities present in the composition of the registered substance and reported in IUCLID section 1.2. In addition, ECHA notes that the impurity identified in the analytical certificate as "[redacted]" was not reported in the compositional information provided for the registered substance in the IUCLID dossier. On the other hand the impurity "[redacted]" was reported in the compositional information of the registration dossier and not identified/quantified in the analytical certificate attached in IUCLID section 1.4. ECHA therefore concludes that the provided certificate of analysis cannot be used as such to draw any conclusion on the composition of the registered substance, as reported in IUCLID section 1.2. Moreover, the registration does not include sufficient description of the analytical methods required for the identification and quantification of the registered substance.

Therefore, the Registrant is accordingly requested to provide a description of the analytical methods used for the identification and quantification of the constituents required to be reported in the composition of the registered substance. The Registrant is reminded that the description of the analytical method used for the recording of the IR spectrum, which is required according to Annex VI, Section 2.3.5. of the REACH Regulation (see section III.A.1 above), shall be provided as well. The description shall be sufficient for the method to be reproduced and shall therefore include details of the experimental protocol followed, any calculation made and the results obtained.

As for the reporting in the registration dossier, the information should be included in IUCLID section 1.4.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the information derived from the registered substance subject to the present decision: correct description of the methods used to identify and quantify the registered substance as specifically explained above. The Registrant shall ensure that the information is consistent throughout the dossier.

B. Information related to the chemical safety assessment and chemical safety report

Pursuant to Articles 10(b) and 14(1) of the REACH Regulation the registration shall contain a chemical safety report which shall document the chemical safety assessment conducted in accordance with Article 14(2) to (7) and with Annex I of the REACH Regulation.

Annex I sets out the general provisions for assessing substances and preparing chemical safety reports (CSR). ECHA has observed following omissions and inconsistencies in the CSR:

1. Revised environmental exposure assessment and risk characterisation

According to Article 14(4) of the REACH Regulation, if the substance fulfils the criteria for any of the hazard classes of Annex I to Regulation (EC) No 1272/2008 listed in Article 14(4) or is assessed to be a PBT or vPvB, the chemical safety assessment (CSA) shall include an

exposure assessment and risk characterisation. ECHA notes that the registered substance is classified as Flam Liquid 2, Acute Tox 4 (oral and inhalation), fulfilling the criteria set out in Article 14(4). The exposure assessment shall be carried out according to section 5 of Annex I and shall include 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. Annex I, section 6 of the REACH Regulation requires the Registrant to characterise the risk for each exposure scenario.

ECHA notes that there are 10 exposure scenarios (ES) provided in the CSR:
ES 1 - Manufacturing process;
ES 2 - Formulation process;
ES 3 - Spray application of solvent-based degreasers, cleaners and painting products at industrial sites;
ES 4 - Treatment of articles by dipping with solvent-based degreasers and cleaners at industrial sites;
ES 5 - Spray application of solvent-based degreasers, cleaners and painting products by professional users;
ES 6 - Treatment of articles by dipping with solvent-based degreasers and cleaners by professional users;
ES 7 - Roller application, brushing or by dispensing systems of solvent-based degreasers, cleaners, painting products, paint removers, stain removers and adhesives at industrial sites;
ES 8 - Roller application, brushing or by dispensing systems of solvent-based degreasers, cleaners, painting products, paint removers, stain removers and adhesives by professional workers;
ES 9 - Printing process; and
ES 10 - Roller application, brushing or by dispensing systems of solvent-based degreasers, cleaners, painting products, paint removers, stain removers and adhesives by consumers.

According to the information provided in the technical registration dossier and in the CSR, the following information has not been provided or is not satisfactory:

(i) Operational conditions

Pursuant to the Annex I, section 5.1.1. of the REACH Regulation an exposure scenario includes, where relevant, a description of operational conditions and risk management measures (RMMs). The final exposure scenario shall be presented under the relevant heading of the CSR, and included in an annex to the safety data sheet. Pursuant to the Annex I, section 5.2.2. of the REACH Regulation emission estimation shall be performed under the assumption that the RMMs and operational conditions described in the exposure scenario have been implemented.

ECHA notes that some operational conditions, i.e. information on amount of the substance used per site and the number of emission days of the substance, are not reported in the CSR for exposure scenarios 3-9 as well as the tonnage of use of the substance for exposure scenario 10 is also not reported in the CSR. ECHA deems that information on these operational conditions shall be provided in the CSR allowing ECHA to check the compliance of the exposure estimation performed. Thus, ECHA concludes that this missing information shall be included in respective exposure scenarios.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation, the Registrant is requested to provide in the chemical safety report the missing information on operational conditions as detailed above for exposure scenarios 3-10.

(ii) Release factors used in exposure estimation for exposure scenarios 2-10

Pursuant to the Annex I, section 5.2.1. of the REACH Regulation the exposure estimation entails three elements: (1) emission estimation, (2) assessment of chemical fate and pathways and (3) estimation of exposure levels. Emission estimation shall be performed under the assumption that the RMMs and operational conditions described in the exposure scenario have been implemented.

According to the Guidance on information requirements and chemical safety assessment Chapter R.16: Environmental Exposure Estimation (ECHA, version: 2.1, October 2012) the exposure scenario should contain information (about operational conditions and risk management measures) based on which the assumed release factors and daily use rates can be justified. Furthermore, the Guidance indicates that sector specific environmental release categories (spERCs) developed by industrial sector organisations may be used in place of the more conservative default environmental release categories (ERCs) of ECHA's guidance. As far as possible, spERCs have to be linked to the RMM and the operational conditions driving the release estimation.

ECHA notes that the values of release factors to various environmental compartments used in exposure estimation are not provided at all for exposure scenarios 2-10. ECHA deems that information on release factors used in exposure estimation shall be provided in the CSR allowing ECHA to check the compliance of the exposure estimation, namely the emission estimation part, performed. Thus, ECHA concludes that values of release factors to various environmental compartments used in exposure estimation shall be included in respective exposure scenarios 2-10.

Furthermore, the Registrant should note that non-default environmental release category release factors (as defined in ECHA Guidance on information requirements and chemical safety assessment Chapter R.16: Environmental Exposure Estimation (ECHA, version: 2.1, October 2012)) should be justified e.g. by operational conditions, RMMs, or physico-chemical properties of the substance. If release factors are based on site(s) specific measurements the summary of results of these measurements (detailed enough to understand whether or not it covers relevant scenarios for possible releases from the substance processing according to the relevant exposure scenario) should be provided in the CSR. Further ECHA notes that the Registrant has applied the same exposure estimation for different industrial uses (described by ERC 4) and uses by professional users (described by ERC 8a) and there is no explanation on the applicability of the same exposure estimation to the different uses provided in the CSR.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation the Registrant is requested to specify in the chemical safety report release factors used in exposure estimation for exposure scenarios 2-10.

(iii) Efficiencies of risk management measures

According to Article 3(37) of the REACH Regulation, exposure scenario is defined as "the set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment".

Pursuant to Articles 10(b) and 14(4) as well as Annex I, Section 5.1.1. of the REACH Regulation, generated exposure scenarios shall cover a description of the operational conditions and risk management measures applied to reduce or avoid direct and indirect exposure to humans and the different environmental compartments to the substance.

ECHA notes that efficiencies of RMMs, which were taken into account in environmental exposure estimation, are missing in all exposure scenarios. ECHA deems that information on efficiencies of RMMs shall be provided in the CSR allowing ECHA to check the compliance of the exposure estimation performed and to check adequacy of the proposed RMMs. Thus, ECHA concludes that this missing information on efficiencies of the RMMs shall be included in respective exposure scenarios.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation, the Registrant is requested to provide in the chemical safety report the missing efficiencies of risk management measures for all exposure scenarios.

(iv) Exposure estimations and risk characterisation for marine water and sediment

Pursuant to Annex I, section 5.0. of the REACH Regulation an 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.

ECHA notes that according to the information provided in the CSR, information on exposure estimations and risk characterisation for marine water and sediment, for all exposure scenarios, is not reported. It is also noted that there is no justification in the CSR provided on why marine water and marine sediment compartments would not be relevant for any of the specific exposure scenarios reported in the CSR.

The predicted no effect concentrations (PNECs) for marine water and sediment are available and reported by the Registrant in the IUCLID registration dossier. Some of the exposure scenarios provided in the CSR might be assumed to cover the use of the substance by unknown downstream users (e.g. uses by professional users and consumers; information on whether or not location of industrial downstream users sites is known is not provided in the CSR). 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.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation, the Registrant is requested to provide quantitative exposure estimations and risk characterisation for marine water and sediment for each exposure scenario. Alternatively, a qualitative argumentation may be provided to explain why these environmental spheres are not relevant or why quantitative exposure estimation/risk characterisation is not relevant for these spheres. The chemical safety report shall be amended accordingly.

(v) Combined environmental risk characterisation

Pursuant to the Annex I, section 6.2. of the REACH Regulation the risk characterisation shall consider the overall environmental risk caused by a substance by integrating the results for the overall releases, emissions and losses from all sources to all environmental compartments.

Chapter R.16: Environmental Exposure Estimation of the Guidance on information requirements and the chemical safety assessment (ECHA, version: 2.1, October 2012) specifies that since all releases to water from each identified wide dispersive use will by default enter into the same sewage system, combined risk should be considered. It further notes that releases from uses in industrial settings are assessed as independent point source releases; it means that each identified use of the substance is assumed to occur at a different site. However, in some cases, it is needed to combine those assessments in the

"combined risk" section of the CSR, e.g. when manufacture and formulation take place at the same site.

The CSR does not contain a combined risk assessment for the environment for the number of wide dispersive uses by consumers and professional users or, if relevant, for all industrial uses of the substance which might take place on the same site.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation, the Registrant is requested to provide a combined risk assessment for the environment in the CSR.

2. Missing elements for consumer exposure assessment and a revised consumer exposure assessment, including risk characterisation

Pursuant to Article 14(4) and Annex I of the REACH Regulation, a CSR shall be provided, including exposure assessment and risk characterisation addressing all identified uses of the substance if the substance fulfils the criteria for any of the hazard classes of Annex I to Regulation (EC) No 1272/2008 listed in Article 14(4) or is assessed to be a PBT or vPvB. The chemical safety assessment (CSA) shall include an exposure assessment and risk characterisation. ECHA notes that the registered substance is classified as Flam Liquid 2, Acute Tox 4 (oral and inhalation), fulfilling the criteria set out in Article 14(4). The exposure assessment shall be carried out according to section 5 of Annex I and shall include 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. Annex I, section 6 of the REACH Regulation requires the Registrant to characterise the risk for each exposure scenario.

Article 14(6) as well as Annex I, 5.2.4. and 6.2. to 6.4. of the REACH Regulation, require registrants to identify and apply appropriate measures to adequately control the risks identified in the 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.

ECHA notes that according to the information provided in the technical registration dossier and in the CSR, there is insufficient information to address consumer exposure assessment and the Registrant needs to provide more detailed descriptions of the exposure scenarios which should include the different tasks and associated duration of exposure. The Registrant shall provide details of the inputs used for the exposure modeling, which are currently not provided. More specifically the inputs used in modeling the exposure estimations for each of the tasks/uses shall be provided separately i.e. the substance used in painting products, degreasers and cleaning products, paint removers, stain removers and adhesives. It needs to be clear how the exposure modeling inputs are used to establish the exposure estimations provided in the CSR. The percentage of registered substance in the mixture and the amount applied for each activity covered needs to be stated in the CSR. Only with this information it will be possible to verify whether the risk to humans can be considered adequately controlled throughout the lifecycle of the substance.

It should be noted that frequency of use should not be used to average out exposure over a longer period of time. Exposure should be calculated for the actual duration of the event, and then expressed as that concentration per day (Guidance on information requirements and chemical safety assessment Chapter R.15: Consumer exposure estimation, version:2.1, October 2012).

Therefore, the Registrant is requested to provide the missing information and revise the consumer exposure assessment and assess the related risks accordingly. The chemical safety report shall be amended accordingly.

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/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

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