EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000004419-69-05/F Helsinki, 21 August 2014

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

For iodomethane, CAS No 74-88-4 (EC No 200-819-5), 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 for iodomethane, CAS No 74-88-4 (EC No 200-819-5), submitted by [redacted] (Registrant).

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 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 19 July 2013.

On 6 November 2013 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

By 9 December 2013 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.

Subsequently, proposal for amendment to the draft decision were submitted.

On 10 April 2014 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 the proposal for amendment within 30 days of the receipt of the notification. The ECHA Secretariat reviewed the proposal for amendment received and did not amend section II of the draft decision but modified section III of the draft decision.

On 22 April 2014 ECHA referred the draft decision to the Member State Committee.

By 12 May 2014 the Registrant did not provide any comments on the proposals for amendment.

A unanimous agreement of the Member State Committee on the draft decision was reached on 26 May 2014 in a written procedure launched on 15 May 2014. ECHA took the decision pursuant to Article 51(6) 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)(a), 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, nuclear magnetic resonance or mass spectrum) (Annex VI, 2.3.5.)
2. Description of the analytical methods (Annex VI, 2.3.7.)

B. Information in the technical dossier derived from the application of Annexes VII to XI

Pursuant to Articles 41(1)(a) 41(3), 10(a)(vi) and/or (vii), 12(1)(e), 13 and Annex VII of the REACH Regulation the Registrant shall submit the following information using the indicated test method and the registered substance subject to the present decision:

- Flash-point (Annex VII, 7.9.; test method: as specified in Section III);

C. Information in the technical dossier related to the classification and labelling of the substance

Pursuant to Articles 41(1)(a), 41(3), 10(a)(iv) and Annex VI, Section 4 of the REACH Regulation in conjunction with Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation) the Registrant shall submit the following information for the registered substance subject to the present decision:

- The hazard classification of the registered substance for acute aquatic toxicity category 1 (with M factor:1) and for chronic aquatic toxicity category chronic 2 based on Title I and II of Regulation (EC) No 1272/2008 (CLP Regulation) and resulting hazard statement in line with the criteria set out in Part 4 of Annex I of the CLP Regulation, as amended by Commission Regulation (EU) No 286/2011 of 10 March 2011 (Tables 4.1.0. (a) and/or (b) and 4.1.4), as specified in section III below). In case that no classification is submitted, the Registrant shall provide the reasons why no classification is given.

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 **2 March 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, nuclear magnetic resonance or mass spectrum) (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 registration does not contain any Infra-red (IR) spectrum as well as any nuclear magnetic resonance (NMR) spectrum or Mass spectrum (MS) which are required to support the identity of the registered substance. ECHA points out that the identity of the substance cannot be confirmed based exclusively on the Ultra-violet spectrum which the Registrant included in section 1.4 of the IUCLID dossier.

ECHA regards this required information scientifically necessary for the identification of the registered substance as the IR spectrum displays characteristic vibration bands for the covalent bonds of organic compounds such as the registered substance. Moreover, NMR spectroscopic analyses such as a ^{1}H-NMR or a ^{13}C-NMR are powerful tools for structure characterisation and elucidation due to characteristic chemical shifts and spin-spin coupling which also reflect the relative abundance of individual atoms. Alternatively, a mass spectrum which is an appropriate analytical method to characterise the substance and determine its elemental composition, can be provided.

Accordingly, the Registrant is requested to provide the missing IR spectral data as well as a NMR spectrum, such as a ^{1}H-NMR or a ^{13}C-NMR or, alternatively, a mass spectrum including the corresponding interpretation of the fragmentation scheme.

As for the reporting of the spectral data in the registration dossier, the information should be included in IUCLID section 1.4. The Registrant shall ensure that the description of the analytical methods used for the recording of the spectra is specified in the dossier, in line with the requirements under Annex VI section 2.3.7.

Therefore, pursuant to Article 41(1)(a) 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 spectral data as specifically explained above. The Registrant shall ensure that the information is consistent throughout the dossier.

2. 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.

Although a gas-chromatographic (GC) analysis has been provided in the registration dossier, the quantification of the main constituent and impurities, in support of the compositional data reported in IUCLID section 1.2, was not included. Moreover, the GC shows two impurities, whilst only one is reported in IUCLID section 1.2.

Consequently, ECHA notes that the compositional information reported in the registration dossier is not supported by adequate analytical data and therefore the identification and quantification of the registered substance could not be confirmed. Additionally, ECHA notes that impurities identified in the chromatographic analysis are not reflected in the compositional information reported in section 1.2 of IUCLID.

The Registrant is requested to provide a description of the analytical methods used to identify and quantify the registered subtance in the form of a peak table and also the calculations undertaken in an updated IUCLID dossier. ECHA underlines that the compositional information reported in IUCLID Section 1.2. shall be consistent with those provided in IUCLID Section 1.4.

As for the reporting of the data in the registration dossier, the information should be attached in IUCLID section 1.4. The information shall be sufficient for the methods to be reproduced and shall therefore include complete details of the experimental protocol followed, the calculation made and the results obtained.

Therefore, pursuant to Article 41(1)(a) 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 in the technical dossier derived from the application of Annexes VII to XI

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) of the REACH Regulation, a technical dossier for a substance manufactured or imported by the Registrant in quantities of 1000 tonnes or more per year shall contain as a minimum the information specified in Annexes VII, VIII, IX, and X of the REACH Regulation.

Flash-point (Annex VII, 7.9.)

"Flash-point" is a standard information requirement as laid down in Annex VII, Section 7.9. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

ECHA notes that the Registrant has provided the results of an experimental study in order to fulfil the information requirements of the endpoint, flash point. ECHA notes as well that the experimental study was performed according to EU test method A.9, following the equilibrium method, closed cup, and that the study is compliant to the Good Laboratory Practises (GLP). Nevertheless, as regard to the reporting, ECHA notes that the endpoint

study record reports the following result: "No flash-point up to 32°C. Test item is not flammable".

ECHA underlines that the reporting is not satisfactory since the Registrant did not provide the exact value of the flash point measurement and instead he is indicating that the substance has no flash point up to 32 °C. The flash point is defined as the lowest temperature at which a liquid evolve vapours in such an amount that flammable vapour/air mixture is produced. As descried in EU test method A.9, and in the Guidance for information requirements and chemical safety assessment, R.7a (version 2.2, August 2013), paragraph R.7.1.9.6, the reporting shall include the result, i.e. the flash point of the substance, and unit and any additional remarks relevant for the interpretation of the results.

As explained above, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

Therefore, pursuant to Article 41(1)(a) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: Flash-point. ECHA notes that the EU test method A.9 – Flash point from the Regulation (EC) 440/2008 may be used; moreover, suitable methods are listed in the CLP regulation Annex I, 2.6.4.4, Table 2.6.3. The reporting shall include the value of the flash point measurement.

C. Information in the technical dossier related to the classification and labelling of the substance

Pursuant to Article 10(a)(iv) of the REACH Regulation the technical dossier shall contain information on classification and labelling of the substance as specified in Annex VI, Section 4 of the REACH Regulation in conjunction with Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation).

Lack of coherence between the data on aquatic toxicity and the hazard classification included in the dossier:

Pursuant to Article 10(a)(iv) and Annex VI, section 4 of the REACH Regulation, the technical dossier of the registration shall include information on the classification and labelling of the substance. Annex VI, section 4.1 clarifies that the hazard classification of the substance shall result from the application of Title I and II of the CLP Regulation. In addition, Annex VI, section 4.1, provides that for each entry, reasons why no classification is given for a hazard class or differentiation of a hazard class should be provided. According to Article 5(1) of Title I and recitals 20 and 21 of the CLP Regulation, a substance shall be classified on the basis of available information.

Furthermore, the technical dossier must include the resulting hazard label for the substance in line with Title III of the CLP Regulation (Annex VI, section 4.2 of the REACH Regulation).

In the present case, ECHA notes that the technical dossier includes an aquatic acute toxicity study which is considered reliable by the Registrant (Klimisch score 1) indicating an $L(E)_{50}$ equal to or lower than 1 mg/l. However, the Registrant has not classified the substance as Aquatic Acute Hazard Category 1 (M-factor 1) and he has not used the resulting hazard statement "H400: Very toxic to aquatic life", which would be in line with the criteria set out in Part 4 of Annex I of the CLP Regulation, as amended by Commission Regulation (EU) No 286/2011 of 10 March 2011 (see Tables 4.1.0. and 4.1.4 of the CLP Regulation).

Furthermore, in the present case, ECHA notes that the technical dossier includes an aquatic chronic toxicity study, considered reliable by the Registrant (Klimisch score 1), providing NOEC values in the toxicity range of 0.1 < NOEC ≤ 1.0 mg/L and on the basis of information provided in the registration dossier the substance is considered to be not rapidly degradable. However, the Registrant has not classified the substance as Aquatic Chronic Category 2, and he has not used the resulting Hazard statement: "H411 Toxic to aquatic life with long lasting effects", which would be in line with the criteria set out in Part 4 of Annex 1 of the CLP Regulation, as amended by Commission Regulation (EU) No 286/2011 of 10 March 2011 (see Tables 4.1.0. (b) and 4.1.4 of the CLP Regulation).

Therefore, the Registrant is requested to submit a hazard classification for aquatic toxicity of the registered substance which results from the application of Title I and II of the CLP Regulation and that is consistent with the data on aquatic toxicity available in the registration dossier. The Registrant shall also provide resulting hazard statement in line with the criteria set out in Part 4 of Annex I of the CLP Regulation, as amended by Commission Regulation (EU) No 286/2011 of 10 March 2011 (Tables 4.1.0. (a) and/or (b) and 4.1.4). In case that no classification is submitted, the Registrant shall provide the reasons why no classification is given (i.e. data lacking, inconclusive, conclusive but not sufficient for classification).

ECHA notes that in reviewing whether the Registrant has complied with Sections 4.1. and 4.2. of Annex VI to the REACH Regulation with regard to classification and labelling for aquatic toxicity, it can only base its assessment on data on aquatic toxicity that is available in the registration dossier. Any other data on aquatic toxicity of the substance that the Registrant does not submit in his registration dossier but that he may need to consider in his classification, cannot be taken into consideration by ECHA. If there is any other data available on aquatic toxicity of the substance, the Registrant is required to include the data in the registration dossier in line with the second introductory paragraph of Annexes VI to X and step 1 of Annex VI to the REACH Regulation.

IV. Adequate identification of the composition of the tested material

In carrying out the studies required by the present decision it is important to ensure that the particular sample of substance tested 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. If the registration of the substance covers different grades, the sample used for the new studies must be suitable to assess these.

Furthermore, there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the studies to be assessed.

Finally there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the studies 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/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

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