ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114298773-32-01/F Helsinki, 14 April 2015

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

For 1-bromopropane, CAS No 106-94-5 (EC No 203-445-0), 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-bromopropane, CAS No 106-94-5 (EC No 203-445-0), 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 of 1000 tonnes or more per year. This decision does not take into account any updates submitted after 4 September 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 3 October 2013.

On 18 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 18 December 2013 the Registrant did not provide any comments on the draft decision to ECHA.

On 4 September 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.

The Registrant informed ECHA on 6 November 2014 that he had decided to "cease the import of the registered substance". Therefore, ECHA suspended the act of informing the Registrant of the decision taken.

On 28 January 2015, ECHA sent a note to the Registrant explaining that according to Article 50(3) of REACH following this decision the respective registration would "*no longer be valid*". The Registrant was given 10 days for re-considering his decision.

By 9 of February 2015, the Registrant had changed the status of the registration in REACH-IT back to "active". As consequence, ECHA resumed informing the Registrant about the decision taken.

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 (ultra-violet, infra-red and nuclear magnetic resonance or mass spectrum) (Annex VI, 2.3.5.);
2. High-pressure liquid chromatogram, gas chromatogram (Annex VI, 2.3.6.).

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

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

> Documentation of the existing and available carcinogenicity studies that are available for the substance subject to the present decision within the Substance Information Exchange Forum (SIEF), justification of how these data were taken into account in the chemical safety assessment (CSA) and documentation in the chemical safety report (CSR).

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 **21 October 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 (ultra-violet, infra-red and 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 dossier does not contain analytical data for the registered substance. No ultra-violet (UV), infra-red (IR) and nuclear magnetic resonance (NMR) or mass spectrum (MS) data, as required under Annex VI, Section 2.3.5 of the REACH Regulation has been submitted.

ECHA regards this required information scientifically relevant for the identification of the registered substance for the following reasons:

- The substance absorbs in the UV range. A UV spectrum representing the absorption of these constituents in the UV range can therefore be recorded.
- The IR spectrum displays characteristic vibration bands of covalent bonds in molecules present in the substance, including characteristic vibration bands from the different chemical functionalities which are present in the registered substance.
- NMR spectroscopic analyses such as a 1H-NMR or a 13C-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. As all reported constituents contain characteristic hydrogen and carbon atoms, NMR is an appropriate analytical method to characterise the substance.

Regarding how to report the spectral data, the information shall be attached 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 such detail to allow the methods to be reproduced, in line with the requirements under Annex VI section 2.3.7.

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: UV, IR and NMR data. Alternatively to NMR, mass spectrum (MS) data could be provided. 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 dossier does not contain high-pressure liquid chromatogram (HPLC) or gas chromatogram (GC) data, as required under Annex VI, Section 2.3.6. of the REACH Regulation.

ECHA regards this required information scientifically relevant for the assessment of the composition of the substance declared in section 1.2 of the IUCLID dossier and the degree of purity of the substance.

Regarding how to report the chromatographic data, the information shall be attached in IUCLID section 1.4. The Registrant shall ensure that the description of the analytical methods used for the recording of the chromatograms is specified in the dossier in such detail to allow the methods to be reproduced, in line with the requirements under Annex VI section 2.3.7.

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.

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 (CSR) which shall document the chemical safety assessment (CSA) conducted in accordance with Article 14(2) to (7) and with Annex I of the REACH Regulation.

Documentation of the existing and available carcinogenicity studies

According to Annex I, section 0.5, the CSA shall be based on the information on the substance contained in the technical dossier and on other available and relevant information.

However, ECHA notes that the following studies that are reported in the technical dossier of the registration of the lead registrant who has submitted the joint part of the registration in agreement with the other assenting registrants of the SIEF pursuant to Article 11(1) of the REACH Regulation, are neither reported nor taken into account in the CSR of the Registrant:

- Garner. C. E., et al. (2006). Metabolism and disposition of 1-bromopropane in rats and mice following inhalation or intravenous administration. Toxicology and Applied Pharmacology 215: 23–36.
- Garner C. E., et al. (2007). CYP2E1-Catalyzed Oxidation Contributes to the Sperm Toxicity of 1-Bromopropane in Mice. BIOLOGY OF REPRODUCTION, 76: 496–505.
- Morgan, D. L. et al. (2009a). NTP TECHNICAL REPORT ON THE TOXICOLOGY AND CARCINOGENESIS STUDIES OF 1-BROMOPROPANE (CAS NO. 106-94-5) IN F344/N RATS AND B6C3F1 MICE (INHALATION STUDIES). NTP TR 564: NIH Publication No. 10-5906. Owner company: National Toxicology Program, National Institutes of Health, Public Health Service, U. S. DEPARTMENT OF HEALTH AND HUMAN SERVICES.

Therefore, the Registrant did not comply with Annex I, 0.5. of the REACH Regulation. Pursuant to Articles 25(2) and 29(3) of the REACH Regulation information related to intrinsic properties of a substance shall be shared between the registrants of the same substance and SIEF participants shall provide each other with existing studies in order to avoid unnecessary testing. On that basis, the Registrant is required to document the existing and available hazard information in the CSR and to justify how these data were taken into account in the CSA.

Notes for consideration by the Registrant

ECHA notes that the carcinogenicity studies mentioned above indicate carcinogenic effects. Therefore there is a need to consider whether such effects are "threshold" or "non-threshold" (for more information, see: "Guidance on information requirements and chemical safety assessment" (Volume 8, R8, 2012)). In case of a threshold effect, identification of Derived no effect levels (DNELs) is necessary. While in case of a non-threshold effect, either a qualitative assessment of the likelihood that carcinogenic effects are avoided when implementing the exposure scenario should be carried out or a DMEL (derived minimal effect level) should be derived.

The ECHA practical Guide "How to undertake a qualitative human health assessment and document it in a chemical safety report" (Practical Guide 15, 2012) provides further details on how to carry out a qualitative assessment. The ECHA "Guidance on information requirements and chemical safety assessment" (Volume 8, R8, 2012) provides further details on DMEL derivation.

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://www.echa.europa.eu/web/guest/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

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