ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114292052-56-01/F Helsinki, 27 February 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, 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 tonnes 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.

Subsequently, a proposal for amendment to the draft decision was submitted.

On 10 October 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 amended the draft decision.

On 20 October 2014 ECHA referred the draft decision to the Member State Committee.

By 10 November 2014 the Registrant did not provide any comments on the proposal for amendment.

A unanimous agreement of the Member State Committee on the draft decision was reached on 24 November 2014 in a written procedure launched on 13 November 2014.

ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

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:

1. 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).
2. Documentation for the recommended personal protective equipment when handling the substance, i.e. gloves to be worn and respiratory protection as specified further in Section III, 2. below (Article 14(6), Annex I, 5.1.1.).

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 **3 September 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.

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.

1. Documentation of the exisiting 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 of 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 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.

2. Documentation for the recommended personal protective equipment when handling the substance, i.e. gloves to be worn and respiratory protection (Article 14(6), Annex I, 5.1.1.)

Article 14(6) as well as Annex I, 0.1., 5.1.1., 5.2.4. and 6.2. of the REACH Regulation require registrants to identify and apply appropriate measures to adequately control the risks identified in a CSR. The CSR needs to contain sufficient information to allow ECHA to gain assurance that the risks are adequately controlled and that appropriate risk management measures can be prescribed by actors in the supply chain. Accordingly, the supplier is required to describe the relevant RMM in detail in the Safety Data Sheet in order to minimise the exposure for workers handling the registered substance (e.g. the type of gloves to be worn and respirator filter 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 in accordance with Annex II, section 8.2.2.2. (b)(i) and (c)). The information provided in the Safety Data Sheet (SDS) shall be consistent with information in the Chemical Safety Report (Annex II, section 0.1.2. of the REACH Regulation).

ECHA notes that specific detailed information on the recommended personal protective equipment is missing or inaccurate both from the CSR and from the information on safe use within the IUCLID dossier.

ECHA Secretariat notes that the Registrant has provided information on glove material and respiratory protection within the dossier. The Registrant indicates in Chapter 9 of the CSR "The PPE includes overalls, gloves (e.g. Viton, Silvershield, nitrile, neoprene or butyl), eye protection in the form of goggles or a full face shield and respiratory equipment."

ECHA Secretariat also notes that some of the proposed glove materials are not recommended by glove suppliers for long term use. Specifically nitrile, neoprene, pvc and natural rubber products suffer rapid breakthrough (less than 10 minutes) of 1-bromopropane.

To ensure the safe use of a substance, Annex I Section 5.1.1. requires a description of the risk management measures to reduce or avoid direct and indirect exposure of humans. Gloves are reported in the CSR and IUCLID Section 11 as required personal protective equipment to prevent dermal exposure to the substance. Generally, gloves that are capable of preventing exposure to the skin for a pre-determined duration shall be specified. Typically, this information, as a minimum, has to specify the glove material and, depending on the exposure scenarios, may also need to include the breakthrough time and thickness of the glove material.

Concerning respiratory protection, specific information on filters for purifying respirators is not provided and is required for the substance as such in the CSR as this is an important part of the description of the equipment to be used. The type of equipment is an issue for the safety data sheet and for the downstream user to determine taking account of local conditions.

Therefore, pursuant to Article 41(1)(c) the registrant is required to provide in the CSR a description of the gloves and on an appropriate air purifying filter for respiratory protection to be used when handling the pure substance. The information provided by the Registrant shall be sufficiently detailed to allow suppliers to fulfil their obligations specified under Annex II for the compilation of the safety data sheets.

Notes for consideration by the Registrant

It is the responsibility of the Registrant to ensure consistency of the information within the CSR, and between the CSR and IUCLID section 11.

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.

[redacted]
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