ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114292016-52-01/F Helsinki, 26 January 2015

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

**For 1-chlorobutane, CAS No 109-69-3 (EC No 203-696-6), 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-chlorobutane, CAS No 109-69-3 (EC No 203-696-6), submitted by [redacted] (Registrant).

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 10-100 tonnes per year. This decision does not take into account any updates submitted after 30 October 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 12 August 2013.

On 29 October 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. That draft decision was based on submission number [redacted].

On 28 November 2013 ECHA received comments from the Registrant on the draft decision.

On 28 February 2014 and on 28 August 2014 the Registrant updated his registration dossier with the submission number [redacted] and [redacted], respectively. In the registration dossier update with submission number [redacted] the tonnage band has been changed from earlier 1000 tonnes or more per year to 10-100 tonnes per year and intermediate uses were clarified.

The ECHA Secretariat considered the Registrant's comments and the updates. On basis of this information, Section II was amended by removing requests for information relevant only for higher tonnage bands than the one registered. The Statement of Reasons (Section III) was changed accordingly.

On 30 October 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

**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:

> Reconsideration of DNELs for workers and for the general population by using the study giving rise to highest concern or a full justification for not using the study giving rise to highest concern in establishing DNELs.

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 August 2015**. The timeline has been set to allow for sequential testing as appropriate.

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 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.

> Reconsideration of DNELs for workers and for the general population by using the study giving rise to highest concern or a full justification for not using the study giving rise to highest concern in establishing DNELs (Annex I, Section 1.1.4. of the REACH Regulation)

Annex I, Section 1.1.4. of the REACH Regulation requires that the study giving rise to the highest concern shall be used to establish the DNELs. Pursuant to this same provision if the study or studies giving rise to the highest concern are not used, then this shall be fully justified and included as part of the technical dossier.

In the present dossier the study giving rise to the highest concern is the reproduction/developmental toxicity screening study (OECD 421), the NOAEL being 2.4 mg/kg bw/day. In contrast, the Registrant has used the 90-day study (NOAEL 120 mg/kg bw/day) to establish the DNELs. No justification was provided why the study giving rise to the highest concern was not used.

The Registrant, in his comments submitted according to Article 50(1) of the REACH Regulation, notes that "a NOAEL of 2.4 mg/kg bw was based on the lack of maternal care observed in the 12 mg/kg bw group and consequently causing depression of viability index and body weight gain in the pups. This finding is secondary effect considered not relevant for derivation of DNELs for worker."
ECHA notes that the substance is an alkylating solvent, damaging several organs (brain, lung, liver kidney, spleen, hematopoetic system). The animals showed clear signs of convulsions.

The Registrant used a NOAEL from the 2-year NTP study with 60 mg/kg bw/d based on clinical signs and mortality at 120 mg/kg bw/d.

However, in the NTP report for non-neoplastic effects, increased incidences could be observed in males already at 60 mg/kg bw/d for effects in spleen and adrenal cortex and clinical signs (NTP does not provide statistical analysis of these effects). In the 2-year study, also convulsion occurred with the following incidences:

| | Control | 60 mg/kg bw/d | 120 mg/kg bw/d |
|---|---|---|---|
| Males: | 1/50 | 3/50 | 27/50 |
| Females | 0/50 | 7/50 | 45/50 |

Concerning the screening study, clinical signs occurred at the doses of 12, 60 and 120 mg/kg bw/d with increasing incidence. Although at 2.4 mg/kg bw/d clinical signs were observed only in 1/10 females at one day of administration, the Registrant has correctly identified this dose as a NOAEL for developmental toxicity. ECHA notes further that the OECD SID report included in the registration dossier concluded a NOEL of less than 2.4 mg/kg bw/d. The clinical signs correlate with lack of pup care but are also an indication for not well-being of the animals. Therefore, 2.4 mg/kg bw/d should be used as the no observed effect level (NOAEL) also for workers and then apply the appropriate assessment factors as described in ECHA guidance Chapter R.8[1]. The Registrant derived the DNEL, however, not based on the available study giving raise to the highest concern.

Based on the above, and in accordance with Annex I, Section 1.1.4., the Registrant is requested to reconsider the DNELs by using the study giving rise to the highest concern, or in the alternative to justify the fact why the study giving rise to the highest concern was not used to establish the DNELs.

**B. Deadline for submitting the information**

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 30 months from the date of adoption of the decision. This period of time took into account the fact that the draft decision also contained a request for a two-generation reproductive toxicity study/extended one-generation reproductive toxicity study and a pre-natal developmental toxicity study. As these endpoints are no longer addressed in the present decision, ECHA considers that a reasonable time period for providing the required information in the form of an updated registration is six months from the date of the adoption of the decision. The decision was therefore modified accordingly.

[1] Link to ECHA guidance document R.8 is: http://echa.europa.eu/documents/10162/17224/information_requirements_r8_en.pdf

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]
Leena Ylä-Mononen
Director of Evaluation