EUROPEAN CHEMICALS AGENCY

Helsinki, 24 October 2017

Addressee: [redacted]

Decision number: CCH-D-2114375719-32-01/F
Substance name: Benzene, ethylenated, by-products from
EC number: 271-802-8
CAS number: 68608-82-2
Registration number: [redacted]
Submission number: [redacted]
Submission date: 02/11/2016
Registered tonnage band: 10-100

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the REACH Regulation), ECHA requests you to submit information on:

1. **Composition of the substance (Annex VI, Section 2.3.);**
   - **Identification and quantification of the constituents**
2. **Vapour pressure (Annex VII, Section 7.5.; test method: EU A.4./OECD TG 104) with the registered substance;**

You have to submit the requested information in an updated registration dossier by **2 May 2018**. You also have to update the chemical safety report, where relevant.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2 and advice and further observations are provided in Appendix 3.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under: http://echa.europa.eu/regulations/appeals.

Authorised[1] by Kevin Pollard, Head of Unit, Evaluation E1.

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

Appendix 1: Reasons

1. Composition of the substance (Annex VI, Section 2.3.)

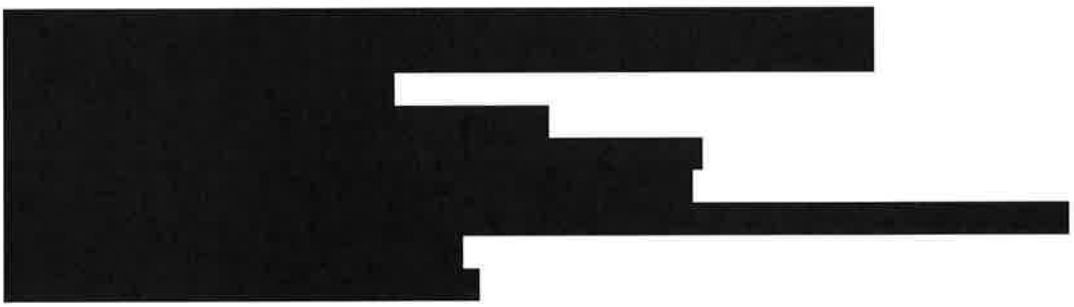
In accordance with Article 10(a)(ii) of the REACH Regulation, the technical dossier must contain information on the identity of the substance as specified in Annex VI, Section 2 to the REACH Regulation. In accordance with Annex VI, Section 2 the information provided has to be sufficient to enable the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

As outlined in chapter 4.3 of the Guidance for identification and naming of substances under REACH and CLP (Version: 2, December 2016) – referred to as "the SID Guidance" from here on, for UVCB substances (substances of Unknown, or Variable Composition, or of Biological origin) with a large number of constituents, the following applies:

- All known constituents and all constituents present at concentrations ≥10% shall be identified;
- The typical concentrations and concentration ranges of the known constituents shall be given;
- Constituents that are relevant for the classification and/or PBT assessment of the substance shall always be identified independently from their concentration;
- Unknown constituents shall be identified as far as possible by a generic description of their chemical nature.

Based on the information included in section 1.2 and in section 1.4 of your registration dossier we observe the following:

1) In the legal entity composition record in section 1.2, you have reported several constituents and group of constituents providing only the concentration ranges and not the typical concentration:



2) The composition was determined with a GC/MS method. The results of the analysis (included in Table I of file name "[redacted]", attached in IUCLID section 1.4.) show that:

   - The constituent/group of constituents reported as "[redacted]", should correspond, based on the provided structural formulae in the GC/MS table, to the group of constituents identified as "peak I", which was reported with an area of [redacted] %.

3) You used EC number 271-802-8 and CAS number 68608-82-2, which are linked to the following description (also reported in the remarks field in IUCLID sections 1.1 and 1.2): "[redacted]".

Based on the facts listed above and on the content of sections 1.2 and 1.4, we identified the following deficiencies in the reporting of information in your registration dossier:

- The value of area % for "peak I" ([redacted]%) is outside of the reported minimum concentration of [redacted]% provided for "[redacted]".
- The constituents/group of constituents corresponding to major "peak J" and other minor peaks such as "peak A" were identified in the chromatogram but were not reported in the composition.
- The constituents [redacted] that, according to the CAS description, shall be the predominant constituents of the registered substance "Benzene, ethylenated, by-products from", were neither reported in the composition, nor identified/quantified in the provided analytical data.

Therefore the compositional information of the substance cannot be unambiguously confirmed.

In your comments, following the procedure set out in Article 50(1) of the REACH Regulation, you have indicated your agreement and commitment to provide the information requested in this decision.

Consequently, you are requested to revise the information on the composition of the registered substance in order to establish a precise chemical representation of what the substance consists of. In particular you are required to:

- Identify and report individually all known constituents and constituents with a concentration ≥10% (w/w).
- Report the constituents/group of constituents with the typical, minimum and maximum concentration levels.
- Specify how the group of constituents named "[redacted]" were identified and quantified.
- Correctly report in section 1.2 the constituents/group of constituents that were identified/quantified in the provided analytical report.
    - For that reason additional chemical analyses may be needed to support the unambiguous establishment of the composition of the registered substance (e.g. using analytical methods that could discriminate between isomers, unlike mass spectrometry).

- Consider if, in the absence of [redacted] constituents, your substance could be described better by other identifiers (name, CAS and EC number).

The information on the composition of the substance shall be included in section 1.2 of the registration dossier.
In any case, you must ensure that the information provided in sections 1.1, 1.2 and 1.4 of the IUCLID dossier is consistent.

If you conclude that the identifiers (chemical name, CAS and EC number) are not representative of the substance you have registered, such identifiers should be changed. In case the current CAS entry (i.e. 68608-82-2) does not identify the registered substance, it should be moved under the "Related CAS information" field in IUCLID section 1.1. Similarly, where the current EC number does not correctly identify the registered substance, it will need to be revised. However, for technical reasons, it will not be possible to remove or modify at this stage the EC entry currently assigned to this registration, as the registration is linked to that EC entry in REACH-IT. You are requested to include in the "Remarks field" of the reference substance the following: "The EC entry currently assigned does not specifically correspond to the registered substance. This identifier cannot be modified in the present registration at this stage for technical reasons". You shall note that ECHA has established a process, subject to certain conditions, enabling registrants to adapt an existing registration, while maintaining the regulatory rights already conferred to the substance concerned.

2. Vapour pressure (Annex VII, Section 7.5.)

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 10 to 100 tonnes per year must contain, as a minimum, the information specified in Annexes VII to VIII to the REACH Regulation.

"Vapour pressure" is a standard information requirement as laid down in Annex VII, Section 7.5 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.

You have provided in IUCLID section 4.6 an experimental study to determine the vapour pressure of the registered substance which was performed according to the dynamic method (twin ebulliometric technique) obtaining as a result 0.0011 mmHg at 25 °C.

According to the OECD guideline 104 (and EU A.4 test methods) the dynamic method is applicable to substances having a vapour pressure in the ranges 10^3 Pa - 2 x 10^3 Pa and 2 x 10^3 Pa – 10^5 Pa. The measured vapour pressure corresponds to a value of 0.147 Pa which is clearly outside the ranges of applicability of the method.

Due to the relevance of the vapour pressure as a key physicochemical parameter for hazard, exposure and risk assessment, it is of outmost importance to obtain a reliable measurement of the vapour pressure of the registered substance.

As explained above, the information provided 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.

You shall have particular regard for the recommended range of applicability of each measuring method.

In your comments, following the procedure set out in Article 50(1) of the REACH Regulation, you have indicated your agreement to perform the test requested in this decision.

In your comments you also requested an extension of the deadline to submit the information. However, ECHA considers that the extension of the deadline is not justified and that it is appropriate and proportionate to the tests requested.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Vapour pressure (test method: EU A.4./OECD TG 104).

Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 28 February 2017.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

ECHA notified you of the draft decision and invited you to provide comments.

ECHA took into account your comments and did not amend the requests.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA took the decision according to Article 51(3) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

2. Failure to comply with the requests in this decision, or to otherwise fulfil the information requirements with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.

3. In relation to the information required by the present decision, the sample of the substance used for the new tests must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the range of substance compositions manufactured or imported by the joint registrants.

   It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition. In addition, it is important to ensure that the particular sample of the substance tested in the new tests 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 or imported by each registrant.

   If the registration of the substance by any registrant covers different grades, the sample used for the new tests must be suitable to assess these grades. Finally there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the tests to be assessed.