EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000002707-70-03/F Helsinki, 28 January 2013

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

For Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene, CAS No 68411-46-1 (EC No 270-128-1), 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 dossier for Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene, CAS No 68411-46-1 (EC No 270-128-1) submitted by [redacted] (Registrant).

This decision is based on the registration dossier 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 after 2 November 2012, 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.

The compliance check was initiated on 31 October 2011.

On 17 September 2012 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 17 October 2012 the Registrant did not provide any comments on the draft decision to ECHA.

On 2 November 2012 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 to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, Competent Authorities of the Member States did not propose amendments to the draft decision and ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

This compliance check decision does not prevent ECHA to initiate further compliance checks on the present dossier at a later stage.

II. Information required

1) Pursuant to Articles 41(1)(a), 41(3) and 10(a)(ii) as well as Annex VI , section 2 of the REACH Regulation the Registrant shall submit for the registered substance:

   a. Name or other identifier of the substance (Annex VI Section 2.1). The Registrant shall provide sufficient information on the reference substance to enable the substance identity to be determined, as specified under point III (a) below;
   b. Composition of each substance (Annex VI Section 2.1). Any information which is suitable and necessary to allow ECHA to establish and verify the composition and name of the registered substance, as specified under point III (b) below.

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated IUCLID dossier to ECHA by **29 April 2013**.

III. Statement of reasons

Based on the examination of the technical dossier, ECHA concludes that the information therein, submitted by the Registrant for registration of the above mentioned substance for the purpose of registration within the applicable tonnage band of 1000 tonnes or more per year in accordance with Article 6 and 11(2) of the REACH Regulation, does not comply with the requirements of Article 10 and/or with Annex VI thereof. Consequently, the Registrant is requested to submit the information mentioned above that is needed to bring the registration into compliance with the relevant information requirements.

1) Missing information related to substance identity

Pursuant to Article 10(a)(ii) and Annex VI, section 2 of the REACH Regulation, the technical dossier of the registration shall include information on the identity of the substance. Annex VI, section 2 lists information requirements that shall be sufficient to identify the registered substance.

(a) Name or other identifier of the substance (Annex VI Section 2.1):

ECHA notes that the Registrant identified the registered substance as of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB). The naming of UVCB substances shall consist of two parts: the chemical name and the more detailed description of the manufacturing process. ECHA observes that the Registrant did not provide sufficient information on the name and the description of the substance for its proper identification, as required under Annex VI Section 2.1 of the REACH Regulation.

More specifically, the Registrant provided a chemical name indicating that the registered substance corresponds to the reaction products of Benzenamine, N-phenyl- and 2,4,4-trimethylpentene. ECHA observes that the compositional information specified in the analytical report attached in section 1.4 of the IUCLID dossier includes the presence of constituents bearing tertiary butyl groups. The presence of such constituents cannot be explained on the basis of the name and description of the manufacturing process of the substance provided. The Registrant submitted as part of the joint registration a remark in a read-across justification for the endpoint "toxicity to reproduction", in section 7.8.1 of the IUCLID dossier, stating that "during the synthesis conditions that result in cracking of the

2,4,4-trimethylpentene raw material occur and yield a significant portion of tertiary butyl groups in the final product." This statement gives important information for the identification of the substance, however it cannot be associated to the manufacturing of the substance which is subject of this specific registration. ECHA notes also that other information on the manufacturing process has not been provided in the description. In particular details of the ratio of the starting materials, relevant process parameters used to control the reaction and details of the isolation step are missing from such description. The Registrant is therefore requested to provide a process description specifying the ratio of the starting materials and the process conditions under which each step is carried out (*e.g.* solvent, catalyst, temperature and pH value). In addition for each step where a chemical reaction takes place, a description of the specific reactions taking place shall be given. Such information shall be sufficient to explain the presence of the different constituents in the registered substance, in particular constituents bearing tertiary butyl groups. The Registrant shall also provide a description of the isolation and purification steps carried out to manufacture the substance, *e.g.* if a distillation process is involved in the manufacturing, the temperature and pressure under which the substance is collected shall be specified.

Regarding how to report the chemical name and description of the UVCB substance, the information shall be included in the Description field in IUCLID section 1.1.

(b) Composition of the substance (Annex VI Section 2.3):

The substance composition corresponds to the chemical representation of what the substance consists of and is therefore an essential part of substance identification and the corner stone of all the REACH obligations.

ECHA notes that the registration does not contain sufficient information for establishing the composition of the specific registered substance and therefore its identity, as required under Annex VI, Section 2.3 of the REACH Regulation. The reported composition does not correspond to the level of analysis possible and actually performed as reported in the analytical report "[redacted]".

According to ECHA Guidance chapter 4.3 on the identification and naming of substances under REACH,[1] the Registrant should note that, for UVCB substances such as the registered substance, the following applies:

- All constituents present in the substance with a concentration of ≥ 10 % shall be identified and reported individually;
- All known constituents and constituents relevant for the classification and/or PBT assessment of the registered substance shall be reported individually; and
- Unknown constituents shall be identified as far as possible by a generic description of their chemical nature. For substances such as the registered substance, the reporting of unknown constituents according to their degree of polymerisation is suitable. For each group of unknown constituents, a structural representation according to the identity of the constituents of the starting material and the possible reactions involved in the polymerisation is appropriate.

For each constituent and group of constituents, the minimum, maximum and typical concentration, shall be reported.

[1] http://guidance.echa.europa.eu/docs/guidance_document/substance_id_en.pdf

In line with the above, the Registrant is requested to provide any information which is suitable and necessary for ECHA to use the compositional information as one identifier for the registered substance. The registrant must provide any information which is suitable and necessary to meet these objectives.

Regarding how to report the composition of UVCB substances in IUCLID, further technical information is provided in paragraphs 2.1 and 2.2.2 of the Data Submission Manual 18 available on the ECHA website[2].

The Registrant shall ensure that the information provided on the composition of the substance is confirmed by the required analytical data included in IUCLID section 1.4.

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/appeals/app_procedure_en.asp. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]
Jukka Malm
Director of Regulatory Affairs

[2] http://echa.europa.eu/doc/reachit/dsm18/substance_id_report_iuclid_en.pdf