ECHA
EUROPEAN CHEMICALS AGENCY

Final decision: CCH-D-0000002127-80-03/F 29 March 2012

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

**For [redacted] 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 the ECHA has performed a compliance check of the registration dossier [redacted] submitted by [redacted] (Registrant), latest submission number [redacted] for 1000 tonnes or more per year.

Article 24(1) of the REACH Regulation provides that the notification is regarded as a registration and ECHA has assigned a registration number.

The compliance check was initiated on 21 November 2011.

On 2 December 2011 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

On 28 December 2011 ECHA received comments from the Registrant.

ECHA considered the Registrant's comments received and amended the draft decision.

On 20 January 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. 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

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. The registrant shall also revise the chemical name of the registered substance, as specified under point III (a) below;

b. Composition of each substance (Annex VI Section 2.3). 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 May 2012.

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 over 1000 tonnes per year in accordance with Article 6 of the REACH Regulation, does not comply with the requirements of Article 10 and 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.

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 specified as chemical name for the substance [redacted] However, the identity of the specific starting material used for its manufacturing requires further clarification. The Registrant shall note that [redacted] does not refer to one specific substance but corresponds to a generic chemical name potentially covering several substances under REACH, including UVCBs obtained from different manufacturing processes or consisting of different hydrocarbon classes, different unsaturation types or different representative structures.

In its comments submitted in accordance with Article 51(1) of the REACH Regulation, the Registrant claimed that modifying the name of the substance would affect other SIEF participants. He thus suggested providing an appropriate name of the substance as a mere remark in the dossier. It is necessary to stress that, in accordance with Articles 3(1) and 11(1) of the REACH Regulation, when products manufactured or imported by several operators correspond to the same chemical element and their compounds are the same, it is the same substance requiring the joint submission of certain information for all the multiple registrants. This regulatory obligation must apply irrespective of any contractual arrangements previously agreed between registrants and potential registrants. Accordingly, the name and other identifiers of the substance in each dossier of all the multiple

registrants of the same substance must demonstrate that the substance is actually the same and each of them must ensure that the information jointly submitted actually covers its own registration.

The Registrant, in the comments submitted according to Article 51(1) of the REACH Regulation for this registration, also proposed to refer to the [redacted] used in the process as [redacted] and described it as mixtures typically consisting of [redacted] as reactive components. ECHA underlines that such identification of the substance remains generic as it can cover several substances for the same reasons as listed above for [redacted]

ECHA also points out that polymerisation reaction products of different [redacted] reactants shall be regarded as different substances under REACH. The unambiguous identification of the specific starting material used is therefore essential.

For the same reason, ECHA also concludes that the assigned CAS entry with CAS name [redacted] is not an appropriate identifier of the registered substance.

In addition, the description of the manufacturing process reported in IUCLID section 3.1 is not sufficiently detailed to identify the substance. In particular, the relevant process parameters used for its manufacturing, including details of the identify of the starting material, the parameters used to control the degree of polymerisation and information on any processing step applied to isolate the manufactured substance have not all been specified.

The Registrant summarised in his comments to the draft decision the manufacture process. However, the identity of the starting material(s), which is part of the process description, remains ambiguous.

The Registrant is accordingly requested to clarify the identity of the registered UVCB substance. For this purpose, the Registrant shall provide a chemical name that is representative of the manufacturing process used. The name shall therefore include details on the specific [redacted] substance that is polymerised. The Registrant shall note that such reactant can only be identified by the description of its composition if it is well defined (within the meaning of chapter 4.2 of the Guidance for identification and naming of substances under REACH[1]). If the reactant is itself a UVCB substance, the Registrant shall refer to the name of that UVCB starting material in the name of the registered substance using the naming conventions in the Guidance.[2] The registrant shall also include information on the manufacturing process and the composition of the UVCB starting material as part of the description of the registered substance. The information shall be sufficient for ECHA to associate that reactant to one specific substance only. The Registrant is reminded that substances manufactured from the reaction of different [redacted] substances shall be regarded as different substances under REACH.

The Registrant shall also delete the CAS entry with CAS name [redacted] and assign instead any available CAS information specifically corresponding to the

[1] http://echa.europa.eu/web/guest/guidance-documents/guidance-on-the-different-methods-under-reach

registered substance. The registrant may however specify the CAS entry with CAS name [redacted] as related CAS information for the registered substance.

The registrant shall, in addition, provide the missing information on the description of the process used for the manufacturing of the substance registered.

Regarding how to report the information in IUCLID, the following applies. The chemical name and description of the registered UVCB substance shall be included in the IUPAC name field and the Description field in IUCLID section 1.1, respectively. Any CAS name and CAS number corresponding to the registered substance should be reported under the "CAS information" header of the reference substance in IUCLID section 1.1. The CAS name [redacted] and CAS number [redacted] can be reported under the "Related CAS information" header of the reference substance 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. More specifically, the Registrant reported a composition which covers, according to the chromatographic information, substances identified as [redacted] However, ECHA observes that the chromatographic fingerprint of these chemicals indicates that they do not refer to the same substance. ECHA notes in particular that while some chromatograms show the clear predominance of certain constituents, such as in the case of [redacted] where a peak assigned to one dimer constitutes [redacted] of the composition, other compositions such as [redacted] do not present the predominance of any specific constituent.

The comments received from the Registrant in accordance with Article 51(1) provide further information on the composition of the substances mentioned above. However, the information does not enable ECHA to conclude that these substances are the same, due in particular to the ambiguity on the identity of the specific starting material used.

Furthermore, while a distinction between monomers, dimers, trimers and higher oligomers has been made in the reported composition, the registrant indicated neither structural information on the chemical nature of these groups of constituents nor values on their upper concentration level.

The comments received from the Registrant also include structural information. While this data provides a generic representation of polymerisations reaction products, it does not allow ECHA to establish which structural information is representative of the registered substance. ECHA points out that the structure of the constituents depends on the identity, including the composition, of the specific [redacted] used in the process.

According to ECHA Guidance chapter 4.3 on the identification and naming of substances under REACH,[2] 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.

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. The registrant shall ensure in particular to remove any analytical information which has not been generated on the substance which is the subject of this registration and replace it with data carried out on the registered substance, as appropriate.

## 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/web/guest/support/dossier-submission-tools/reach-it/registration