ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000002144-84-03/F Helsinki, 8 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 for [redacted] submitted by [redacted] (Registrant), latest submission number [redacted] for over 1000 tonnes 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 11 November 2011.

On 2 December 2011 ECHA sent a draft decision to the Registrant for comments. On 28 December 2011 the Registrant provided comments on the draft decision.

ECHA considered the Registrant's comments and did amend the draft decision.

On 20 January 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.

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 the substance (Annex VI, 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 **8 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 and 11(2) 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.

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, 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] The Registrant shall note that, by describing the result of the reaction as [redacted] the position of [redacted] remains unidentified. Furthermore, the identity of the specific starting material used requires further clarification because by referring to the starting materials as [redacted] the identity of the starting material remains unknown. Due to the above mentioned issues the name given [redacted] together with limited information on the starting material used may indicate that the substance does not refer to one specific substance but corresponds to a generic chemical name potentially covering several substances under REACH, including UVCB substances obtained from different manufacturing processes or having different structural representations.

The Registrant, in the comments submitted according to Article 51(1) of the REACH Regulation for this registration, 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 the reaction products of different [redacted] substances or [redacted] substances [redacted] according to the same process conditions 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 identity of the specific starting material, the parameters used to control the degree of polymerisation, including the ratio of reactants, and information on any processing step applied to isolate the manufactured substance have not all been specified.

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 his own registration.

The Registrant also summarised, in its comments submitted according to Article 51(1), the manufacturing process description. However, the identity of the starting material(s), which is part of the process description, remains ambiguous. In addition, all relevant process parameters, such as the ratio of reactants, have not been indicated.

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 used in the process. The Registrant shall note that such reactant can only be named and described by 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 different [redacted] substances with phenol 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 registered substance. The registrant may, however, specify the CAS entry with CAS name [redacted]

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

[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, 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 specified, for the constituents reported in IUCLID section 1.2, only the typical and the upper concentration levels. The concentration ranges are then so broad (up to [redacted] that several substances can be represented by the composition reported in the dossier. ECHA observes in addition that the Registrant included analytical information for substances identified as [redacted] and [redacted] It is unclear whether the analysed spot samples refer to different substances represented by the reported composition.

The comments received from the Registrant in accordance with Article 51(1) include more detailed compositional information, including lower concentration levels, for the substances mentioned hereinabove. 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 materials used and the missing information on the manufacturing process description. Furthermore, the composition of the registered substance remains ambiguous as the presence of constituents such as "tetrameric" reaction products suggested by the Registrant is not reflected in the reported compositions for the different substance.

In line with the above, the Registrant is requested to revise the composition information and provide the minimum, maximum and typical concentration for each constituent or group of constituents required to be identified. The Registrant shall ensure that the compositional information solely represents the registered substance and can be used as an identifier for that substance.

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 also ensure that the information provided on the composition of the substance is consistent with the chemical name and description of the registered substance and 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

[2] http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/registration

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