

Decision number: CCH-D-0000003658-64-03/F

Helsinki, 11 November 2013

**DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006****For 1,2-Benzenedicarboxylic acid, di-C9-11-branched and linear alkyl esters, CAS No 68515-43-5 (EC No 271-085-1), 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 for 1,2-Benzenedicarboxylic acid, di-C9-11-branched and linear alkyl esters, CAS No 68515-43-5 (EC No 271-085-1) submitted by [REDACTED] (Registrant). The scope of this compliance check is limited to the standard information requirements of Annex VI, Section 2 of the REACH Regulation.

This decision is based on the registration 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 submitted after 1 August 2013, 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 19 December 2012.

On 13 May 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.

On 10 June 2013 ECHA received comments from the Registrant.

The ECHA Secretariat considered the Registrant's comments. The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

On 1 August 2013 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.

## II. Information required

### **Information in the technical dossier related to the identity of the substance**

Pursuant to Articles 41(1)(a), 41(3), 10(a)(ii) and Annex VI, Section 2 of the REACH Regulation the Registrant shall submit the following information for the registered substance subject to the present decision:

1. Name or other identifier of the substance (Annex VI, 2.1.) as further specified in Section III., 1. below.
2. Composition of the substance (Annex VI, 2.3.) as further specified in Section III., 2. below.
3. Chromatogram (Annex VI, 2.3.6.).
4. Description of the analytical methods or the appropriate bibliographical references for the identification of the substance (Annex VI, 2.3.7.).

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 **11 February 2014**.

## 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.

### **Information in the technical dossier related to the identity of the substance**

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

1. Name or other identifier of the substance (Annex VI, 2.1.)

The name and other identifiers are used to identify the substance in an unambiguous manner and are therefore essential parts of substance identification and the corner stone of all the REACH obligations.

ECHA notes that the Registrant identified the registered substance as a mono-constituent substance. In line with the Guidance for identification and naming of substances under REACH and CLP (Version: 1.2, March 2012), mono-constituent substances are well-defined substances in which one constituent is present at a concentration  $\geq 80\%$  (w/w) (referred to thereafter as "main constituent"). A mono-constituent substance is named after the name of its main constituent.

However, ECHA observes that the given substance identifiers indicate clearly the type of the substance as a substance of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB).

More specifically, the Registrant assigned EC and CAS entries and the chemical name corresponding to "1,2-Benzenedicarboxylic acid, di-C9-11-branched and linear alkyl esters". ECHA observes that such name and identifiers refer to a UVCB substance as the grade of branching of the C9-C11 branched alkanes is not further defined.

The naming of UVCB substances shall consist of two parts: (1) the chemical name and (2) a detailed description of the manufacturing process, as indicated in chapter 4.3 of the above mentioned Guidance. ECHA observes that the Registrant did not provide sufficient information on the naming of the registered substance for the following reasons:

The alcohol starting material used to produce the registered substance needs to be described in more detail. The Registrant identifies the alcohol starting material as "██████████". As the composition of the specific starting material is one of the factors determining the composition of the registered substance, compositional information of that starting material (in terms of identity and upper and lower concentration levels of the alcohols of different chain length and branching) is a necessary element for its identification that has not been provided yet and therefore for the identification of the registered substance itself.

In his comments to the draft decision, the Registrant considered the request by ECHA as reasonable and provided further information on the composition of the starting material. As this information is currently not included in the registration dossier, it needs to be provided in the manufacturing process description of the dossier.

Other elements of the manufacturing process description which are essential for the identification of the registered substance are also missing from the dossier. In particular, the ratio of reactants used, the nature of the catalyst used and specifications of any other relevant manufacturing process parameters e.g. determining the degree of completion of the esterification reaction (such as the acid and saponification values) have not been indicated.

ECHA therefore concludes that the manufacturing process has not been provided to a sufficient level of detail for the identification of the registered UVCB substance.

In line with the above observation, the Registrant shall provide the missing information on the manufacturing process description. This information shall include:

- Compositional information of the starting material in terms of identity and upper and lower concentration levels of the individual linear or groups of branched alkyl alcohol, and
- Ratio of reactants, and
- Specifications of nature of the catalyst used and the process parameters determining the degree of completion of the esterification, such as the acid and saponification values.

Regarding the compositional information of the alkyl alcohol starting material and its designation in the chemical name of the registered substance specified the IUPAC name field of IUCLID, ECHA points out that constructing the chemical name of that starting material on the basis of the main constituents and groups of constituents (i.e. those presenting an upper concentration level  $\geq 10\%$  (w/w) in the starting material) presenting the same carbon number and same backbone type is considered appropriate as long as they altogether compose at least 80 % (w/w) of the substance. Otherwise, all alkyl chain lengths shall be considered for the naming of the alkyl alcohol. Where the starting material is composed of one specific alkyl alcohol at an upper concentration level of  $\geq 80\%$  (w/w), this starting material shall then be designated by the chemical name of that alkyl alcohol starting material. The Registrant shall ensure that these principles are respected.

In his comments to the draft decision the Registrant provided as well additional information on the manufacturing process. This information needs to be included in the registration dossier as already mentioned above. Based on the additional information provided by the Registrant in his comments, ECHA has derived the following conclusion regarding the chemical name and EC and CAS identifiers:

The chemical name, assigned by the Registrant to the registered substance, "1,2-Benzenedicarboxylic acid, di-C9-11-branched and linear alkyl esters", refers to a dialkyl dicarboxylate substance where the alkyl groups are linear and branched. However, the Registrant provided the following clarifications in his comments to the draft decision, "[t]he substance object of this registration is produced by [REDACTED]".

The substance would therefore consist of dialkyl dicarboxylates where the alkyl groups are to a major part (>80 %) linear.

In line with the naming convention given above, the chemical name "1,2-Benzenedicarboxylic acid, di-C9-11-branched and linear alkyl esters" is therefore not appropriate as it does not describe the actual composition of the registered substance. The substance would rather be better described by EC number 272-012-6 with the corresponding substance name "1,2-Benzenedicarboxylic acid, di-C9-11-alkyl esters".

The Registrant is therefore requested to replace the chemical name currently specified for the registered substance by a chemical name which is representative of the identity of the registered substance, including its composition.

Furthermore, the chemical names associated with the EC and CAS numbers currently assigned in the dossier refer to the substance "1,2-Benzenedicarboxylic acid, di-C9-11-branched and linear alkyl esters". In accordance with the explanations provided above, ECHA considers that these identifiers do not correspond to the registered substance.

The Registrant is accordingly requested to delete from the dossier the CAS number currently assigned to the registered substance. The registrant shall not remove or modify at this stage the EC entry currently assigned to this registration for technical reasons, the registration being linked to that entry in REACH-IT. To ensure an unambiguous identification of the registered substance, the Registrant shall however specify in the dossier that the EC entry currently assigned does not correspond to the registered substance and shall refer to any available and appropriate EC number specifically corresponding to the substance.

As for the reporting of the information in IUCLID, the chemical name and the description should be specified in the "IUPAC name" and "Description" fields in IUCLID section 1.1, respectively.

Any available CAS information should be reported under the CAS information header of the reference substance in IUCLID section 1.1. The Registrant should specify, in the "Remarks" field of the reference substance in IUCLID section 1.1, the following: "The EC entry 271-085-1 currently assigned does not specifically correspond to the registered substance. This identifier can technically not be modified or deleted at this stage in the present registration update. The corresponding EC entry for this substance is 272-012-6". The Registrant shall also specify, in the same IUCLID field, any available and appropriate EC number for the substance.

## 2. 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 registered substance and therefore its identity, as required under Annex VI, Section 2.3. of the REACH Regulation. More specifically, the provided chemical name indicates that the substance contains branched and linear alkyl groups having a carbon number range of C9 to C11. However, ECHA observes that in the composition information of the IUCLID dossier the Registrant has provided information only on the presence of a generic group of constituents corresponding to "1,2-Benzenedicarboxylic acid, di-C9-11-branched and linear alkyl esters". ECHA points out that the Registrant did not specify any information on the specific groups of constituents present in the substance. Typical concentration and concentration ranges of the specific constituents/groups of constituents bearing linear and branched alkyl chains and presenting the same carbon number have not been given in the registration dossier. It follows that the composition of the registered substance cannot be established and is therefore considered missing from the dossier.

According to chapter 4.3 of the Guidance for identification and naming of substances under REACH (Version: 1.2, March 2012), 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  $\geq 10\%$  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 identified and reported individually; and
- Unknown constituents shall be identified as far as possible by a generic description of their chemical nature. The identification of these unknown constituents must be provided for ECHA to establish the composition of the substance as manufactured and to use the compositional information as one identifier for the registered substance. For substances such as the registered substance, a distinction of the unknown constituents according to the carbon number and backbone type (linear, branched) is necessary for this purpose as a baseline. The ratio of the linear and branched constituents shall be provided for each individual carbon number.

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

In his comments the Registrant consented to provide this information.

Further technical details on how to report the composition of UVCB substances in IUCLID are available in paragraphs 2.1 and 2.2.2 of the Data Submission Manual – Part 18: How to report the substance identity in IUCLID 5 for registration under REACH (version: 2.0, July 2012) on the ECHA website.

### 3. Chromatogram (Annex VI, 2.3.6.)

ECHA notes that a copy of a gas-chromatogram (GC) has been attached to the dossier. However, ECHA observes that the Registrant did not provide any report from this chromatographic analysis. In particular, a peak table with the associated retention times and peak area has not been included in the IUCLID dossier. ECHA points out that this information is required since it constitutes a numerical representation of the chromatogram.

The Registrant is accordingly requested to provide the report from the chromatographic analysis of the registered substance.

In his comments the Registrant consented to provide this information.

As for the reporting in the registration dossier, the information shall be included in IUCLID section 1.4.

### 4. The description of the analytical methods or the appropriate bibliographical references for the identification of the substance (Annex VI, 2.3.7.)

The Registrant did not provide any appropriate description of the analytical methods used for the identification and quantification of the constituents required to be reported in the composition of the registered substance, as requested according to Annex VI section 2.3.7. of the REACH Regulation.

More specifically ECHA notes the description of the analytical methods used for the identification and quantification of each group of constituents expected to be present in the composition of the registered substance and quoted under point III., 1. of this decision is missing from the dossier.

The Registrant is accordingly requested to provide a description of the analytical methods used for the identification and quantification of the constituents and groups of constituents required to be reported in the composition of the registered substance, according to the carbon number and backbone type (linear, branched). The description shall be sufficient for the methods to be reproduced and shall therefore include details of the experimental protocol followed, any calculation made and the results obtained.

In his comments the Registrant consented to provide this information.

As for the reporting of the data in the registration dossier, the information shall be attached 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](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.



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