ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114308873-47-01/F Helsinki, 5 October 2015

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

For Tar acids, xylenol fraction, EC No 284-895-5 (CAS No 84989-06-0), 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 Tar acids, xylenol fraction, EC No 284-895-5 (CAS No 84989-06-0), submitted by [redacted] (Registrant). The scope of this compliance check decision 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 after the date when the draft decision was notified to the Registrant under Article 50(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 27 March 2015.

On 17 April 2015 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 22 May 2015 ECHA received comments from the Registrant on the draft decision.

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 23 July 2015 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 for amendment of the draft decision within 30 days of the receipt of the notification.

As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

A. Information in the technical dossier related to the identity of the substance

Pursuant to Articles 41(1), 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:

a. Name or other identifier of the substance (Annex VI, 2.1.), as specified under section III.(a) below;
b. Composition (Annex VI, 2.3.), as specified under section III.(b) below;
c. Description of the analytical methods or the appropriate bibliographical references for the identification of the substance (Annex VI, 2.3.7.), as described under section III.(c) below.

Taking into consideration the data currently available in the dossier, ECHA considers the following. Section III below specifies in detail all the information that ECHA considers appropriate in order to identify any substance of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB). UVCB substances cannot be sufficiently identified by their chemical composition, because the number of constituents is relatively large; and/or the composition is, to a significant part, unknown; and/or the variability of composition is relatively large or poorly predictable. As a consequence, UVCB substances require other types of information for their identification, in addition to what is known about their chemical composition.

As a result, ECHA cannot be in a position, before receiving suitable information, to determine precisely the other types of information that is actually required to identify a specific UVCB substance. Only the Registrant of that UVCB substance knows the details of its identity. Based on this knowledge, he may consider that some of the information requested by ECHA is not suitable and necessary in order to identify the substance. Nevertheless, in that case it is the Registrant's exclusive responsibility 1) to ensure that ECHA is in a position to identify precisely the substance and 2) to justify the reasons for which some information requested may have been omitted.

Therefore, if the Registrant eventually decides to submit only part of the detailed information specified in Section III and if the submitted information does not enable ECHA to establish and verify the identity of the substance actually covered by the dossier, the registration will not be considered valid.

B. Deadline for submitting the required information

Pursuant to Articles 41(4) and 22(2) of the REACH Regulation the Registrant shall submit to ECHA by **12 January 2016** an update of the registration dossier containing the information required by this decision.

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.

A. 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.

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 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.

(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). Information required to be provided according to Annex VI section 2.1 of the REACH Regulation on the naming of UVCB substances such as the registered substance shall consist of two parts: (1) the chemical name and (2) a more detailed description of the manufacturing process, as indicated in chapter 4.3 of the Guidance for identification and naming of substances under REACH and CLP (Version: 1.3, February 2014) - referred to as "the Guidance" thereinafter. ECHA observes that the Registrant did not provide sufficient and appropriate information on the naming of the registered substance (as explained hereinafter).

The Registrant assigned chemical identifiers, including an EC number, CAS number and chemical name, referring to the UVCB substance "Tar acids, xylenol fraction". According to the EC and CAS information, this substance is "*the fraction of tar acids, rich in 2,4- and 2,5-dimethylphenol, recovered by distillation of low-temperature coal tar crude tar acids*".

However the substance identity information as currently reported in the registration dossier is not limited to this specific substance. In particular, ECHA notes the following:

- One of the two samples for which analytical information was attached in section 1.4 of the IUCLID dossier (referred to as "[redacted]" by the Registrant) has very low concentration levels in [redacted] (the overall integral area for these 2 constituents in the attached chromatogram represents only [redacted]% of the total integral area). This sample is instead rich in the [redacted] constituents (the relative integral area for these constituents in the abovementioned chromatogram is [redacted]% and [redacted]%, respectively). This sample can therefore not be described as "[redacted]".
- The upper concentration values specified in section 1.2 of the IUCLID dossier indicate that compositions reaching up to [redacted]%(w/w) of [redacted] are covered by this registration. Furthermore, the information provided in in section 1.2 of the IUCLID dossier also indicate that the content in [redacted] never exceeds [redacted]%(w/w) and [redacted]%(w/w) respectively. The reported composition is therefore not limited to compositions necessarily rich in 2,4- and 2,5-dimethylphenol but can cover other substances such as
    - the mono-constituent substance [redacted] or

- any other substance rich in at least [redacted] (such as for instance the UVCB substance "Tar acids, 3,5-xylenol fraction" referring to the fraction of [redacted]).

In addition, due to the limited information on the manufacturing process, ECHA cannot conclude that the other substance identity information included in the registration dossier refers to the UVCB substance "Tar acids, xylenol fraction", as explained herein below.

The result from the chromatographic analysis attached in section 1.4 of the IUCLID dossier on the other analysed sample (referred to as [redacted] by the Registrant) indicates that over [redacted]% of the overall integral area originates from only 3 to 4 constituents including, besides [redacted]. The composition of the substance from which this sample originates is therefore expected to be known. According to chapter 4.3 of the Guidance, it shall normally be identified as a well-defined substance and therefore a different substance than the UVCB substance "Tar acids, xylenol fraction", unless the inherent variability in the composition is relatively large or poorly predictable. However, due to the limited information provided by the Registrant on the manufacturing process, the registration does not include any indication that the composition of the substance varies significantly or unpredictably under given manufacturing process conditions. The information on the manufacturing process is indeed currently limited to alternative chemical names of the source ([redacted] according to the EC and CAS information; [redacted] according to the information reported in section 3.1 of the IUCLID dossier) and the process applied [redacted].

Based on the substance identity information currently included in the registration dossier, ECHA therefore concludes that the substance identity information submitted is not limited to the UVCB substance "Tar acids, xylenol fraction".

The Registrant is accordingly requested to clarify the identity of the registered substance. In that respect, ECHA foresees three possibilities:

(i). If, based on the present decision, the Registrant still considers that the substance subject to this registration is the UVCB substance "Tar acids, xylenol fraction", he shall provide a detailed description of the manufacturing process, including:

- The identity of the source used. For that purpose, ECHA considers that the identity of the source shall consist of the chemical name of that source (e.g. "[redacted]") as well as the specifications on relevant information on its origin (including the definition of the source and the process it originates from) and its composition (including the upper and lower concentration levels of its constituents that end up as constituents in the registered distillate); and

- The manufacturing process applied and the relevant process parameters, i.e. every parameter used that determine the composition of the registered substance, as it is normally requested for the identification of any UVCB substance. In the case where the process consists in a distillation, specification of the distillation parameters for collecting the fraction (including the temperature and the pressure) shall be specified.

Taking into account that the composition of the substance is known according to the information provided in the registration, the Registrant shall ensure that the description is sufficiently detailed to demonstrate the UVCB nature of the substance,

i.e. the fact that its composition is inherently variable or poorly predictable under the same operating conditions. The information shall also be sufficient to demonstrate that the registered substance is systematically rich in [redacted] only. ECHA considers that, for substances of known composition, if the identity of the predominant constituents in the registered substance (i.e. in this case of the constituents present at a concentration of 10-80%) cannot be predicted from the manufacturing process or if these constituents do not add up to 80% or more, such substances can be regarded as UVCB substances.

(ii). If, based on the present decision, the Registrant otherwise considers that the substance subject to this registration is a UVCB substance other than "Tar acids, xylenol fraction", he is still requested to provide a manufacturing process description as specified in the abovementioned paragraph.

In addition, the Registrant is also requested to revise the chemical name assigned to the registered substance. The Registrant shall ensure that the chemical name is representative of the specific UVCB substance which is the subject of this registration.

The Registrant is furthermore requested to delete from the dossier the CAS information currently assigned to the substance and provide instead any available CAS information specifically corresponding to the substance.

The Registrant shall however not remove or modify at this stage this EC entry for technical reasons, the registration being linked to that EC entry in REACH-IT. To ensure unambiguous identification of the registered substance, the Registrant shall however indicate, in the "Remarks" field of the reference substance in IUCLID section 1.1, the following: "The EC entry 284-895-5 currently assigned does not specifically correspond to the registered substance. This identifier cannot be modified or deleted at this stage in the present registration update for technical reasons". The Registrant shall also specify, in the same "Remarks" field, any available and appropriate EC number for the substance.

(iii). If, based on the present decision, the Registrant alternatively considers that the substance subject to this registration is a well-defined substance, the Registrant shall specify a chemical name according to the naming conventions specified in Chapter 4.1 or 4.2 of the Guidance, depending on whether the registered substance is a mono-constituent substance or a multi-constituent substance.

The Registrant is furthermore requested to delete from the dossier the CAS information currently assigned to the substance and provide instead any available CAS information specifically corresponding to the substance.

The Registrant shall however not remove or modify at this stage this EC entry for technical reasons, the registration being linked to that EC entry in REACH-IT. To ensure unambiguous identification of the registered substance, the Registrant shall however indicate, in the "Remarks" field of the reference substance in IUCLID section 1.1, the following: "The EC entry 284-895-5 currently assigned does not specifically correspond to the registered substance. This identifier cannot be modified or deleted at this stage in the present registration update for technical reasons". The Registrant shall also specify, in the same "Remarks" field, any available and appropriate EC number for the substance.

Finally, the Registrant shall revise the selected substance type from UVCB substance to mono-constituent substance or multi-constituent substance, as appropriate.

ECHA recognises that the Registrant may cover different grades of the same substance in a registration based on different sources and/or different manufacturing processes. In these cases, the Registrant shall provide the required information on the source, manufacturing process and constituents of each grade. ECHA underlines that the reporting of a generic process description covering the manufacturing of different grades may prevent ECHA from concluding that the manufacturing of other substances is not covered by that description. In addition, ECHA highlights that grades for which a description would not be provided may eventually not be considered as being covered by the registration. ECHA points out that it has set up a process enabling registrants to adapt existing registrations covering eventually several substances. Should the Registrant consider that his dossier actually concerns several substances, he is thus encouraged to contact ECHA for a possible adaptation of the registration.

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

The Registrant shall ensure that the name and other identifiers reported in section 1.1 of the IUCLID dossier are consistent with the compositional information on the substance which is the subject of this registration.

(b) Composition (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 cornerstone of all the REACH obligations.

ECHA notes that the registration does not contain sufficient and appropriate 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, ECHA notes that the Registrant did not provide any information on the minimum concentration levels of the constituents or groups of constituents reported in the dossier. Without this information, ECHA cannot conclude on the variability in the composition of the specific substance covered by this registration.

In addition, ECHA notes that the Registrant reported so broad concentration levels that more than one substance is covered by the composition as reported in the registration dossier. In particular, the Registrant specified that [redacted] has a typical concentration of < [redacted]% (w/w) whilst the specified upper concentration level is < [redacted]%. The registration would thus cover compositions where the content in [redacted] is very low up to compositions where [redacted] is the only main constituent. These compositional differences are so significant that they cannot refer to a unique substance.

Furthermore, the Registrant did not report individually each constituent required to be reported in the composition. In particular, according to the result of the chromatographic analysis of the sample named [redacted] by the Registrant, the overall concentration of [redacted] exceeds [redacted]%. This implies that at least one of these two constituents is present at a concentration of ≥[redacted]%. Regardless of whether the registered substance is a well-defined or a UVCB substance, the Registrant shall note that such constituent must be individually identified and quantified. It follows that the concentration levels of at least [redacted] are currently missing. Depending on the content of the substance in the two other isomers of cresol, the concentration levels of these other isomers may also be required to be reported individually in the composition, as specified in the Guidance and further indicated below.

ECHA therefore concludes that the reported composition is not appropriate and has not been provided to the required level of detail.

According to chapter 4 of the Guidance, the Registrant shall note that, for UVCB substances, 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 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 other 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 well-defined substances, the following applies:

- Each main constituent (i.e. the constituent present at ≥80% for mono-constituent substance or each constituent present at ≥10% and 80% for multi-constituent substance) shall be identified and reported individually; and
- Each impurity present at ≥1% or relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually.

For each constituent or group of constituent, the typical, minimum and maximum concentration levels shall be specified regardless of the substance type.
ECHA underlines those constituents that are isomers of each other are regarded as distinct constituents under the REACH Regulation. Accordingly, the above-mentioned requirements on the constituents required to be identified and quantified also apply to each individual isomer.

The Registrant is accordingly requested to provide the missing compositional information of the registered substance and to remove from the dossier any compositional information referring to a different substance than the specific substance covered by this registration.

Where the Registrant covers different grades of the substance in a registration based on different constituents, the Registrant shall report separately the source, manufacturing process and the compositional information of each grade. ECHA underlines that the reporting of the composition of different grades under one generic composition may prevent ECHA from verifying that compositions referring to other substances are not covered by this registration. In addition, ECHA highlights that grades for which an individual composition would not be provided may eventually not be considered being covered by the registration.

More generally, the Registrant should note that substances manufactured according to different manufacturing processes may indicate multiple substances and consequently the requirement for multiple registrations. ECHA has established processes, subject to certain conditions, enabling Registrants to adapt an existing registration, while maintaining the regulatory rights already conferred to the substance concerned. Should the Registrant consider that his dossier actually concerns several substances, he is thus encouraged to contact ECHA for a possible adaptation of the registration.

Regarding how to report the composition in IUCLID, the following applies, the 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: 1.0, June 2010) on the ECHA website. The Registrant shall follow these technical details.

The Registrant shall ensure that the composition is verifiable and therefore supported by a description of the analytical methods for the quantification of the constituents required to be reported, as required under Annex VI, section 2.3.7.

(c) Description of the analytical methods (Annex VI, section 2.3.7.)

ECHA observes that the Registrant did not provide sufficient and appropriate 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, as requested according to Annex VI section 2.3.7.

As already indicated in section III.(a), ECHA notes that the Registrant provided spectral and chromatographic data recorded on two different samples. Based on the results of these analyses and the substance identity information currently reported in the registration, the analysed samples are expected to refer to different substances. The inclusion of these two sets of analytical data therefore is considered inappropriate for the identification of the registered substance.

ECHA also notes that the Registrant relied on the gas chromatographic (GC) analytical technique for the quantification of the substance and attached copies of chromatograms including also a peak list with the retention time, peak area and identity of constituents to selected peaks. However the description of the experimental protocol followed to make this analysis has not been provided. For chromatographic methods, ECHA normally requires details of sample/standard preparation, column specification, and identity of carrier gas/eluent and detector type.

In addition the quantification of constituents required to be reported individually (including at least m-cresol and/or p-cresol as well as [redacted]) cannot be derived from the GC data due to the overlapping of the peaks.

ECHA also notes that, for the GC analysis of the "[redacted]" substance, the Registrant specified the percentage area of the [redacted] constituents eluting at the same time under the experimental conditions used for the analysis. The Registrant however did not explain how this calculation was made.

Furthermore, the Registrant reported the specific isomer "[redacted]" in the composition. In the GC analysis, only "[redacted]" without further specification on the regioisomerism has been reported. It is therefore unclear how this isomer was identified and quantified.

ECHA therefore concludes that the description of the analytical method is not sufficient for the identification and quantification of the constituents required to be reported in the composition.

The Registrant is accordingly requested to delete from IUCLID section 1.4 any analytical information which does not refer to the registered substance. The Registrant is also 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. 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.

As for the reporting of the data in the registration dossier, the information should be attached in IUCLID section 1.4.

The Registrant shall ensure that the composition reported in the dossier is consistent with the analytical results obtained.

In the comments to the draft decisions the Registrant agreed with the information requirement in the draft decision. He indicated his intension to address the information requirements on composition, analytical data and reflecting this data in the composition description by naming all the constituents in the revised dossier.

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://www.echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Authorised[1] by Ofelia Bercaru, Head of Unit, Evaluation E3

[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.