ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000002664-72-04/F Helsinki, 19 September 2013

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

For Naphthenic acids, CAS No 1338-24-5 (EC No 215-662-8), 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 Naphthenic acids, CAS No. 1338-24-5 (EC No. 215-662-8), submitted by [redacted] (Registrant), submission number [redacted], for [redacted].

This compliance check resulted in a decision adopted by ECHA in accordance with Article 41(1) of the REACH Regulation (4 November 2011, CCH-D-0000002053-87-04/F). According to that decision, the Registrant was requested to clarify the identity of the specific naphthenic acids distillate which the registration referred to.

Pursuant to Article 42(1) of the REACH Regulation, ECHA has examined the information submitted in consequence of that decision and has concluded that further ambiguity on the identity of the naphthenic acids covered by the registration has been introduced in the current dossier. ECHA considers that the registration cannot be associated to any specific substance, which renders the evaluation of information on the hazards and risks necessary to ensure a high protection of human health and the environment unachievable. In light of these observations, ECHA would normally consider the current registration invalid. However, ECHA considers that the present decision is necessary in order to ensure that the Registrant is fully informed of the legal consequences of its persisting failure to unambiguously identify the substance registered.

This decision is based on the registration dossier as submitted with submission number [redacted], for the tonnage band of [redacted]. This decision does not take into account any updates after 20 June 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 registration at a later stage.

The compliance check was initiated on 21 November 2012

On 27 November 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.

On 28 December 2012 ECHA received comments from the Registrant. ECHA considered the Registrant's comments received. The comments are reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

On 20 June 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

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. The name or other identifier of each substance (Annex VI, 2.1) as specified under section III.1)(a) below.
   b. The composition (Annex VI, 2.3.), as specified under section III.1)(b) below;
   c. The spectral data (Annex VI, 2.3.5.), as specified under section III.1)(c) below; and
   d. The description of the analytical methods (Annex VI, 2.3.7.), as specified under section III.1)(d) below.

Taking into consideration the data currently available in the dossier, 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, 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.

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 **19 December 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 [redacted] in accordance with Article 6 of the REACH Regulation of the REACH Regulation, does not comply with the requirements of Articles 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.

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.

ECHA points out that the purpose of the REACH Regulation is to ensure a high level of protection of human health and the environment. In order to achieve this objective, the REACH Regulation imposes the determination of hazards and risks of substances manufactured or imported into the European Union. In order to allow the determination of the actual hazards posed by a substance, it is therefore of utmost importance that the dossier identifies precisely the registered substance.

The unambiguous identification of the registered substance subject to the present decision is therefore fundamental to establish what the substance manufactured or imported actually consists of, and to set the basis on which the hazards and risks shall be determined with regard to that substance. Where the substance is not unambiguously identified, the Registrant, ECHA or the National Competent Authorities may not be able to determine the hazard and risks that are really relevant for the substance that was intended to be registered.

(a) Name or other identifier of each 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, which is required to be provided according to Annex VI, section 2.1 of the REACH Regulation, shall consist of two parts: the chemical name and the 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 1.2; march 2012), referred to thereinafter as "the Guidance". ECHA observes that the Registrant did not provide sufficient and appropriate information on the naming of registered substance, as explained under points (i) and (ii) thereinafter.

(i) Information on the chemical name to be submitted by the Registrant

- A chemical name representative for the registered substance must be submitted

  The Registrant did not specify the chemical name of the UVCB substance which shall be provided in the "IUPAC name" field, as indicated in chapter 8.2.4 of the Guidance. The chemical name "naphthenic acids" associated with the EC and CAS numbers

assigned in the dossier is a generic name covering any substance consisting of (carboxylic) acid functionalised cycloalkanes. As also underlined under point (ii) thereinafter, a multitude of substances may be generally described as "naphthenic acids". ECHA therefore concludes that an appropriate chemical name defining unambiguously the specific substance covered with this registration is currently missing from the dossier.

The Registrant shall accordingly specify a chemical name designating the specific naphthenic acids covered by the registration. The Registrant shall ensure that the chemical name is sufficiently specific to differentiate the naphthenic acids covered by the registration from any other naphthenic acids corresponding to different substances.

(ii) A detailed manufacturing process description to be submitted by the Registrant

- The chemical identity of the source used (in terms of chemical name, description and composition of the constituents and groups of constituents) and a detailed description of the manufacturing processing steps applied for the manufacturing of the registered substance must be submitted

ECHA observes that the description of the manufacturing process is not sufficiently detailed for the identification of the registered substance. In particular, in the registration update submitted following ECHA decision with decision number CCH-D-0000002053-87-04/F, the Registrant no-longer defined the petroleum stream which is the source for the manufacturing of the registered substance. The Registrant instead generically described the source as "petroleum distillates". In addition, the Registrant extended the manufacturing process description originally specified in the registration from distilled naphthenic acids to crude naphthenic acids which have not been subject to any distillation process. ECHA notes in particular that the information in IUCLID section 3.1 presents the distillation step only as a mere possibility and that trade names including both "Crude naphthenic acids" and "Purified (distilled) naphthenic acids" have been added in IUCLID section 1.1. Furthermore, the Registrant did not define the exact process circumstances under which the final distillation step is carried out. The current manufacturing process description would therefore indicate that the Registrant intends to cover naphthenic acids manufactured according to different manufacturing processes[1] (referred to thereinafter as "grades") with this registration. However, the substance identity information reported in the dossier does not enable the identification of any specific naphthenic acids to be associated with the current registration. ECHA points out that a process description for the manufacturing of a UVCB substance where the source is not specifically defined, the exact processing steps applied to that source are ambiguous and the process circumstances under which these steps are carried out are not described in details, as it is the case in the current registration, could cover a multitude of substances under REACH.

The Registrant is accordingly requested to provide details of the source used and the processing steps that are applied to that source, in the order they occur, for the manufacturing of the specific naphthenic acids covered by the registration. This must include the following:

[1] A manufacturing process is considered different whenever different sources are used and/or different processing steps and/or processing parameters are applied.

- The chemical identity of the petroleum distillate source used for the manufacturing of the registered substance. The information shall include the chemical name of that source, any available and appropriate EC and CAS number, details of its origin (the stream and the refinery process from which it is derived), a description of its composition (in terms of identity and concentration levels, in the form of concentration ranges, of the different hydrocarbon classes and any other constituent and group of constituents present), the carbon number range, boiling point range and other appropriate physical characteristics. If the source used is a mixture of petroleum distillates, the chemical identity of each source and their relative ratio in the mixture, shall be specified;
- A description of each manufacturing step which is applied to the source for the manufacturing the specific naphthenic acids fraction covered by the registration. For each step, information on the ratio of starting materials (whenever relevant) and any other process parameter determining directly or indirectly the chemical composition of the registered substance shall be specified. For instance, the description of the distillation step shall include information on the distillation type and boiling point range of the isolated distillate.

The Registrant indicated in his comments submitted according to Article 50(1), that he is unable to provide production details from his supplier of the "*recovered naphthenic acids*" he imports to the level required by ECHA due to confidentiality claims. The Registrant accordingly asked for the deletion of the abovementioned information requirements on the manufacturing process or the rewording of the requirement to a less mandatory form.

ECHA would like to remind the Registrant that a core objective of the REACH Regulation is to place on manufacturers and importers of substances a primary responsibility to ensure that these substances, as well as the hazards and risks they pose, are identified. More specifically Recital 16 stipulates unambiguously that "*this Regulation is based on the principle that industry should manufacture, import or use substances or place them on the market with such responsibility and care as may be required to ensure that, under reasonably foreseeable conditions, human health and the environment are not adversely affected.*" The starting element of this responsibility is, of course, the unambiguous identification of the substance concerned. Based on the principle that operators should only manufacture or import substances that are properly identified and that only manufacturers or importers are in a position to properly identify their substances, Section II of the present decision stresses the exclusive responsibility of the Registrant 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.

Regarding more specifically the identification of the "*recovered naphthenic acids*" substance(s), ECHA underlines that, for the identification of such UVCB substances, the manufacturing process description, including the identification of the origin or source, the most relevant manufacturing steps carried out and any other relevant information remains an essential identifier of the substance, as underlined in chapter 4.3 of the Guidance. This information is required for the identification of such UVCB substances and therefore needs to be available to any Registrant to establish and fulfil his duties under the REACH Regulation.

This being said, although operators may face practical constraints to fulfil applicable obligations, such constraints are recognised by the REACH Regulation which provides for specific solutions. This is notably the case with regard to confidentiality of information relating to the identity of imported substances. Indeed, Article 8 of the REACH Regulation

allows any non-EU manufacturer of a substance to appoint an only representative in order to endorse, on his behalf, the registration obligations that normally apply to the importers of his substance into the Community, thereby avoiding providing such importers with information that he considers confidential. Accordingly, in so far as the REACH Regulation provides practical solutions to address sensitive information on substance identity, the confidentiality of information claimed by a supplier cannot relieve an importer from its obligation to identify unambiguously the substance he registers. In the present case, confidentiality issue could for instance be avoided by the non-EU manufacturer appointing another only representative to whom he would provide sensitive information in confidence.

In addition, in its comment on the draft decision, the Registrant stated that "*the available literature data combined with the analytical data will provide sufficient information to properly identify the substance*". However, in order to achieve the objectives of the REACH Regulation, the information required to be provided shall be representative of the substance actually imported. Should it be sufficient for registrants to identify the substance on the basis of generic information publically available, the legislation would not impose on each individual registrant to submit information specific to the substance he specifically manufactures or imports. Substance identity information can therefore not be based on generic literature data.

As a result of the above, ECHA considers that the comments made by the Registrant on the draft decision do not justify the omission of the information required for the description of the manufacturing process. As a result, the information required above shall be submitted by the Registrant.

If different grades of the same substances are intended to be covered by the registration, then the detailed description of the source and the manufacturing process respectively required under points (i) and (ii) hereinabove shall be reported separately for each manufacturing process.

ECHA reminds the Registrant that, in line with the Guidance, any significant change of the source or process used for the manufacturing of UVCBs would be likely to lead to different substances which shall be registered separately. The application or non-application of a distillation step is for example a change in the process which can result in differences at the level of the compositions that would be likely to lead to different substances. ECHA also underlines that crude naphthenic acids identified with the EC number 265-218-2 and CAS number 64754-89-8, which refer to naphthenic acids isolated without prior distillation, are recognised as distinct substances or groups of substances from other naphthenic acid substances. It is the responsibility of the registrant to demonstrate that each grade reported in the registration refers to the same substance. If the Registrant cannot demonstrate scientifically that none of the compositional differences between naphthenic acids manufactured from different sources and/or using different manufacturing process conditions is scientifically relevant to conclude on every physicochemical property and hazard associated with each fraction, including each relevant physico-chemical, toxicological and ecotoxicological hazard under REACH, such naphthenic acids shall be registered separately. Such demonstration shall be included in order for ECHA to verify that the compositions reported in IUCLID section 1.4 are limited to one substance.

Regarding how to report the information in IUCLID, the chemical name and the description of the manufacturing process of a UVCB substance shall be included in the IUPAC name field and the Description field in IUCLID section 1.1, respectively. If the substance covered by the registration is manufactured according to different manufacturing processes, the scientific explanation as to why each grade covered by the registration refers to the same

substance shall be attached in IUCLID section 1.4.

ECHA highlights that failure to report separately the manufacturing process description specific for each grade and to provide robust and exhaustive justification as to why each grade refers to the same substance may result in one or more grades not being covered by this registration and a possible invalidation of the registration.

(b) Composition of the registered 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 observes 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 Registrant indicated that the unsaponifiable fraction "is composed of aliphatic and aromatic petroleum hydrocarbons". However, the composition reported in section 1.2 of the IUCLID dossier does not provide any further structural and quantitative information on the different hydrocarbon classes present in this fraction. Regarding the saponifiable fraction, the reported composition does not specify any information on the concentration range and carbon number distribution of the groups of carboxylic acid constituents presenting the same number of hydrocarbon cycles. ECHA note that the analytical information provided in the dossier demonstrates that such a subdivision of the carboxylic acid constituents is technically possible.

Following section 4.3 of the Guidance, for UVCB substances presenting a large number of constituents, 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 constituents relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually; and
- Other 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 in order to allow ECHA to establish the composition of the substance as manufactured and to use the compositional information as one identifier for the registered substance. This information must also allow ECHA to verify that the composition is consistent with the chemical name reported for the registered substance. The Registrant must provide any information which is suitable and necessary to meet these objectives. For UVCB substances, such as the registered substance, the reporting of the hydrocarbon constituents according to the hydrocarbon class to which they belong (linear alkanes, branched alkanes as well as the cycloalkanes and aromatic hydrocarbons presenting the same number of cycles is necessary for this purpose. Regarding the saponifiable fraction (the naphthenic acid constituents), the carboxylic acid constituents presenting the same number of cycles shall be reported separately. For each hydrocarbon class, the carbon number range shall at least be reported in order to set the limits of the constituents covered.

For each constituent and group of constituents, the typical, minimum and maximum concentration levels shall be specified. The concentration values must be representative for the registered substance as manufactured and it shall be clarified how the minimum and maximum values for each constituent and group of constituents were obtained (i.e.

information on the batch selection, sampling procedure, the measured values, calculations used etc.). Without this information ECHA may not be able to conclude on the representativeness of these values and ultimately on the identity of the specific substance covered by the registration.

In line with the above, the Registrant is requested to provide any information which is suitable and necessary to allow ECHA to establish and verify the composition and the name of the registered substance.

Regarding how to report the composition of the registered substance in IUCLID, the following applies:
The Registrant shall report the composition of the registered substance in IUCLID section 1.2. For each constituent required to be reported individually, the IUPAC name, CAS name and CAS number (if available), molecular and structural formula, as well as the minimum, maximum and typical concentration, shall be reported in the appropriate fields in IUCLID. For the other constituents to be reported under a generic description, a generic chemical name describing the group of constituents, generic molecular and structural information (if applicable) as well as the minimum, maximum and typical concentration, shall be reported in the appropriate fields in IUCLID. The carbon number range of each group of constituents shall be reported in the Remarks field of the repeatable block for that group. Details of the protocol followed to determine the concentration values of each constituent and group of constituents shall be provided in the same IUCLID field.

Where the Registrant covers different grades of the same substance with this registration, the composition of each grade shall be reported separately. For each grade, the Registrant shall indicate, in the "Brief description" field of the corresponding composition, which of the manufacturing process descriptions required to be specified in the Description field of IULCID section 1.1 refers to that grade. Information on how to report several compositions in IUCLID is specified in paragraph 2.3, Q&A8 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), available on the ECHA website.

ECHA highlights that failure to report separately the compositional information of each grade of a substance may result in one or more grades not being covered by this registration. The Registrant should also note that multiple compositions may indicate multiple substances and consequently the requirement for multiple registrations.

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).

(c) The spectral data (Annex VI, 2.3.5.):

ECHA observes that the Registrant has not provided a nuclear magnetic resonance (NMR) spectrum or mass spectrum (MS). In the previous decision dated 4 November 2011, ECHA requested the Registrant to provide a NMR spectrum or alternatively a mass spectral analysis. The Registrant had provided a description of a method based involving mass spectroscopy for the characterisation of the saponifiable fraction of the substance. However the Registrant did not include any mass spectrum as part of this analysis. ECHA points out that the inclusion of spectra is a formal information requirement under Annex VI section 2.3.5. Spectral data is essential for ECHA to verify and have a true representation of the compositional information for the registered substance.

Taking into account the number of constituents the registered substance consists of, ECHA considers that NMR spectra will provide more appropriate analytical data to fulfil this specific information requirement as opposed to mass spectra. NMR spectra of the substance can provide qualitative information on the presence/absence of certain hydrocarbon classes. In addition, the Distortionless Enhancement by Polarization Transfer (DEPT) technique can be used for determining the number of protons directly attached to individual carbon-13 nucleus. An indicative relative molar ratio between different chemical functionalities present in the substance can also be derived from these techniques.
Therefore, the Registrant is required to provide NMR spectra of the registered substance, including 1H-NMR, 13C-NMR, DEPT 45, DEPT 90 and DEPT 135 spectra as a baseline.

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

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

ECHA notes that the Registrant did not describe all the analytical methods necessary to establish the composition of the substance to the level of detail required to be provided and specified in point III.1)(b). of this decision. In particular, the method used for the identification and quantification of the different hydrocarbon classes (including the linear alkanes, branched alkanes as well as the cycloalkanes and aromatic hydrocarbons presenting the same number of cycles) and their respective carbon number distribution which the unsaponifiable fraction of the registered substance consists of is missing from the dossier.

The Registrant is accordingly requested to provide the missing description of the analytical methods. 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. The information shall therefore include, besides the experimental protocol followed, any spectra and chromatogram generated for that purpose, a report of their analyses, detailed description on how the concentration values of the constituents and groups of constituents required to be reported have been derived and the values obtained for the analysed sample.

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

ECHA underlines that the analytical information currently attached in IUCLID section 1.4 relates to different naphthenic acids-containing samples. The Registrant shall ensure that the analytical information reported in IUCLID section 1.4 is limited to the grade(s) covered by the registration. For each analysis reported in the dossier, the identity of the grade to which the sample refers shall be unambiguously specified. The Registrant shall delete from the dossier any analytical information referring to naphthenic acids corresponding to other substances than the registered substance under REACH.

IV. Issues pending from decision CCH-D-0000002053-87-04/F

ECHA would like to highlight that the Registrant was requested in the previous decision (CCH-D-0000002158-75-03/F) to provide the following missing information which is required for the identification of the registered substance:

- An ultra-violet (UV) spectrum required to be provided according to Annex VI Section

2.3.5. of the REACH Regulation;
- A description of the analytical method used for the recording of the gas chromatogram (GC) of the registered substance, as required under Annex VI section 2.3.7. of the REACH Regulation.

However, this information has not been provided. This fact constitutes a breach of a legally binding decision and can, as such, justify enforcement action. ECHA notes that, irrespective of the persisting breach, the information required in that previous decision is still necessary to identify the substance.

V. 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.

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Jukka Malm
Director of Regulatory Affairs