EUROPEAN CHEMICALS AGENCY

Helsinki, 31 May 2017

Addressee: [redacted]

Decision number: CCH-D-2114362182-56-01/F
Substance name: FATTY ACIDS, C16-18, COMPDS. WITH C16-18-ALKYL AMINES
EC number: 800-984-9
CAS number: 1428547-35-6
Registration number: [redacted]
Submission number: [redacted]
Submission date: 30.05.2013
Registered tonnage band: 100-1000T

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA requests you to submit information on

1. **Description of the analytical methods (Annex VI, Section 2.3.7) of the registered substance; Identification and quantification of the constituents**

2. **Water solubility (Annex VII, Section 7.7.) with the registered substance;**

3. **Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method: Fish, early-life stage (FELS) toxicity test, OECD TG 210) with the registered substance;**

4. **Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD TG 216) and carbon transformation test, EU C.22/OECD TG 217) with the registered substance.**

You may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring and conforming to the appropriate rules in the respective Annex, and an adequate and reliable documentation.

You are required to submit the requested information in an updated registration dossier by **7 June 2018**. You shall also update the chemical safety report, where relevant. The timeline has been set to allow for sequential testing.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2. Advice and further observations are provided in Appendix 3.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, shall be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under http://echa.europa.eu/regulations/appeals.

Authorised[1] by Kevin Pollard, Head of Unit, Evaluation E1

[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.

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Appendix 1: Reasons

IDENTITY OF THE SUBSTANCE

1. Description of the analytical methods (Annex VI, Section 2.3.7.) -Identification and quantification of the constituents

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.

Description of the analytical methods is a formal information requirement of Annex VI Section 2.3.7 of the REACH Regulation.

According to Annex VI Section 2 of the REACH Regulation, for each substance, the information given in this section shall be sufficient to enable each substance to be identified. This means that the information included in the analytical report needs to enable understanding how the constituents required to be reported in the composition section of the IUCLID dossier have been identified and quantified.

In the present dossier you have not included information on the quantitative analytical method(s) used to derive the composition of your substance as reported in section 1.2. Also the results of that analysis were not provided.

Without quantitative analytical data, it is not possible to establish the identity and concentration levels of the constituents required to be reported in the dossier.

You are accordingly requested to provide the description and results of quantitative analytical methods used to verify the composition of the registered substance as reported in section 1.2.

Taking into account the complexity of the composition of the registered substance, quantitative analytical data, *i.e.* information on the identification and quantification of its constituents may be derived by combining information on the manufacturing process and results of the qualitative and quantitative analysis of the starting materials.

For example, the composition of the substance, including the carbon chain distribution, can be determined based on quantitative analysis of the starting materials [redacted] and the respective statistical calculations made based on the carbon chain distribution of both of the starting materials.

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.

For chromatographic methods the following information is expected to be provided:

- Results of analysis: chromatogram and peak table including peak identification, retention times, peak area and area %.
- Description of the method: details of sample/standard preparation, column specification, and identity of carrier gas/eluent and detector type.

You shall ensure that the composition reported in section 1.2 of the dossier is consistent with the analytical results obtained.

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

PROPERTIES OF THE SUBSTANCE

2. Water solubility (Annex VII, Section 7.7)

"Water solubility" is a standard information requirement as laid down in Annex VII, Section 7.7 of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have identified that the registered substance is surface active. Consequently, you have provided an endpoint study record for a preliminary study in which you have tried to determine the critical micelle concentration (CMC) as a surrogate for the water solubility limit of your substance. However, you have concluded the following: "*The first step to determine the CMC is to prepare a stock solution of the test substance in water. However, it was not possible to dissolve the test substance in water at stock concentrations (even after sonication, heating with shake, high shear mixing). Also, since the test item is a complex mixture, it was expected that there would be no sharp transition on a graph of surface tension (mN/M) versus log10 [concentration (g/L)], due to the large range in the critical micelle concentration of each of the numerous test item components. Therefore, it can be concluded that the test substance has too low water solubility for determination of CMC and surface tension.*"

In that preliminary study you have tried to prepare stock solutions of your substance at 1 g/L and 100 mg/L and relied on visual observations like "*colorless solution with much undissolved test item throughout*" or "*Sample 1 was a cloudy, white solution with much test item present near the surface*" to conclude that the substance was not dissolved.

ECHA notes that the CMC can be used as a surrogate for the water solubility limit of your substance. ECHA also notes that although you have observed that at concentrations of 1 g/L and 100 mg/L the registered substance was partially dissolved, you have neither measured the soluble fraction of your substance by any analytical method nor attempted to prepare stock solutions of lower concentrations. ECHA also notes that according to Annex VII, Section 7.7., column 2 "*if the substance appears 'insoluble' in water, a limit test up to the detection limit of the analytical method shall still be performed.*" Therefore, your conclusion that the test substance has too low water solubility to be determined cannot be accepted. ECHA reminds you that measurement of the solubility of sparingly soluble substances requires extreme care to generate saturated solutions and that there are analytical methods available to determine low levels of water solubility (e.g. ppm or ppb).
In addition, ECHA notes that your argument regarding that "*it was expected that there would be no sharp transition on a graph of surface tension (mN/M) versus log$_{10}$ [concentration (g/L)], due to the large range in the critical micelle concentration of each of the numerous test item components*" appears to be a speculation in the absence of any data to support that claim; therefore, it cannot be accepted.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Water solubility (test method: using an appropriate test method).

Guidance for determining appropriate test methods for the water solubility is available in the ECHA Guidance on information requirements and chemical safety assessment R.7a, chapter R.7.1.7 (July 2015).

3. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.)

"Long-term toxicity testing on fish" is a standard information requirement as laid down in Annex IX, Section 9.1.6. of the REACH Regulation. Adequate information on Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1.), or Fish, short-term toxicity test on embryo and sac-fry stages (Annex IX, 9.1.6.2.), or Fish, juvenile growth test (Annex IX, 9.1.6.3.) needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex IX, Section 9.1.6., column 2. You provided the following justification for the adaptation: *"According to Annex IX, 9.1.6 to the REACH Regulation long-term toxicity testing with fish shall be proposed only if the CSA indicates the need to investigate further the effects on aquatic organisms. However, as the CSA does not indicate the need for further testing of vertebrates, long-term toxicity testing with fish is waived. Waiving is supported by the low bioaccumulation potential of the substance and the fact that the acute toxicity data demonstrate that fish are less sensitive to the linear alkyl amines compared to daphnia and algae.*
For the calculation of the PNEC aquatic it is considered unlikely that fish toxicity will be critical for primary alkyl amines and thus for the registered substance. Hence any additional toxicity testing with fish will not add scientific value to the ecotoxicity profile of the test substance other than for obtaining a lower assessment factor. It is therefore concluded that for scientific reasons and in accordance to REACH legislation further testing on fish has to be avoided for reasons of animal welfare."

According to Annex IX, 9.1. to the REACH Regulation long-term toxicity testing shall be proposed if the chemical safety assessment (CSA) indicates the need to investigate further the effects on aquatic organisms. ECHA notes that experimental data on water solubility is insufficient in your chemical safety assessment (IUCLID Section 4.8). However you have indicated that for the registered substance the log Kow is above 7 (in IUCLID Section 4.7). Thus ECHA considers that the substance is likely to be poorly soluble in water. Annex VIII, Section 9.1.3. of the REACH Regulation explicitly recommends that long-term aquatic toxicity tests shall be considered if the substance is poorly water soluble. Poorly soluble substances indeed require longer time to be significantly taken up by the test organisms and so steady state conditions are likely not to be reached within the duration of a short-term toxicity test. For this reason, short-term tests may not give a true measure of toxicity for poorly soluble substances and toxicity may actually not even occur at the water solubility limit of the substance if the test duration is too short.

Therefore, ECHA considers that the available information in your chemical safety assessment does not rule out long-term effects to aquatic organisms and that further long-term effects on aquatic organisms need to be investigated. Consequently ECHA concludes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.1., column 2 and cannot be accepted.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

The following test methods can cover the standard information requirement of Annex IX, Section 9.1.6. for long-term toxicity testing on fish: fish early-life stage (FELS) toxicity test (Annex IX, section 9.1.6.1. of the REACH Regulation), fish short-term toxicity test on embryo and sac-fry stages (Annex IX, section 9.1.6.2. of the REACH Regulation) and fish juvenile growth test (Annex IX, section 9.1.6.3. of the REACH Regulation). ECHA considers that the FELS toxicity test (Annex IX, section 9.1.6.1. of the REACH Regulation) is more appropriate than the fish, short-term toxicity test on embryo and sac-fry stages, or than the fish, juvenile growth test, as it covers several life stages of the fish from the newly fertilised egg, through hatch to early stages of growth. Moreover, the FELS toxicity test is preferable for examining the potential toxic effects of substances which are expected to cause effects under a longer-term exposure, or which require a longer period of time to reach steady state (for example for those substances with a high log Kow). The revised OECD test guideline 210 (adopted on 26 July 2013) is a suitable test method for addressing the information requirements of Annex IX, section 9.1.6.1. of the REACH Regulation.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Fish, early-life stage (FELS) toxicity test (test method: OECD TG 210).

Notes for your consideration
Due to the low solubility and surface-active properties of the substance in water you should consult OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, February 2016), Chapter R7b, Table R.7.8-3 summarising aquatic toxicity testing of difficult substances for choosing the design of the requested ecotoxicity tests and for calculation and expression of the result of the tests.

4. Effects on soil micro-organisms (Annex IX, Section 9.4.2.)

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, Section 9.4. of the REACH Regulation. Adequate information on effects on short-term toxicity to invertebrates (Annex IX, Section 9.4.1.), effects on soil micro-organisms (Annex IX, Section 9.4.2.), and short-term toxicity to plants (Annex IX, Section 9.4.3.) needs to be present in the technical dossier for the registered substance to meet the information requirements. Column 2 of Annex IX, Section 9.4 specifies that long-term toxicity testing shall be considered by the Registrant instead of short-term, in particular for substances that have a high potential to adsorb to soil or that are very persistent.

You have waived the standard information requirements of Annex IX, section 9.4.2. using the following justification: "*Short-term and long-term toxicity data on earthworms, and toxicity to terrestrial plants are available. A PNEC soil has been derived using these data. PEC/PNEC ratio for soil obtained in the exposure assessment is below 1. Therefore, no further toxicity testing for soil organisms need to be done.*"

According to column 2 of Annex 9.4. of the REACH Regulation, effects on terrestrial organisms do not need to be conducted if "*direct and indirect exposure of the soil compartment is unlikely*". It further specifies that "*in the absence of toxicity data for soil organisms, the equilibrium partitioning method may be applied to assess the hazard to soil organisms*".

ECHA notes that the substance has known agrochemical uses. Therefore exposure of the soil compartment is expected. Furthermore, based upon the available aquatic toxicity information and the physico-chemical properties of the substance and in relation to section R.7.11.6. of Chapter R.7c of the ECHA Guidance on information requirements and chemical safety assessment (version 2.0, November 2014), ECHA considers that the substance would fall into soil hazard category 4. In the context of an integrated testing strategy for soil toxicity, the Guidance indicates that for substances falling into soil hazard category 4, an assessment based on the equilibrium partitioning method (EPM) is not recommended. Therefore, ECHA considers that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.4., column 2 and your adaptation is rejected.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), Chapter R.7C, Section R.7.11.3.1., p115, the nitrogen transformation test is considered sufficient for most non-agrochemicals. However, as the substance has known agrochemical uses, ECHA considers that both the nitrogen and carbon transformation tests shall be performed simultaneously.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Soil microorganisms: nitrogen transformation test (test method: EU C.21./OECD TG 216), and Soil microorganisms: carbon transformation test (test method: EU C.22./OECD TG 217).

Deadline to submit the requested information in this decision

In the draft decision communicated to you, the time indicated to provide the requested information and to submit the requested information to ECHA in a dossier update was 30 months.

Based on a Member State Competent Authority proposal(s) for amendment and the registrant's comments on Member State Competent Authority proposal(s) for amendment, ECHA modified the draft decision, removing the following draft decision requests: In vitro gene mutation study in bacteria; In vitro cytogenicity study in mammalian cells or in vitro micronucleus study; In vitro gene mutation study in mammalian cells provided that both studies above have negative results; Sub-chronic toxicity study (90-day), oral route in rats; Screening for reproductive/developmental toxicity in rats, oral route; Pre-natal developmental toxicity study in a first species (rat or rabbit), oral route; Growth inhibition study aquatic plants; Ready biodegradability: DOC die-away test, OECD TG 301A or Ready biodegradability: CO2 evolution test, OECD TG 301B or MITI test (I), OECD TG 301C or Closed bottle test, OECD TG 301D or Manometric respirometry test, OECD TG 301F or CO2 in sealed vessels (headspace test), OECD TG 310; Long-term toxicity testing on aquatic invertebrates; Bioaccumulation in aquatic species; Long-term toxicity to terrestrial invertebrates; Long-term toxicity to plants with at least six species tested or, Soil Quality – Biological Methods – Chronic toxicity in higher plants;

Based on the remaining requests in the draft decision: Description of the analytical methods (Identification and quantification of the constituents); Water solubility; Long-term toxicity testing on fish; Effects on soil micro-organisms and carbon transformation test, ECHA has modified the draft decision deadline from 30 months to 12 months. Thus ECHA has set the draft decision deadline for providing the requested information and to submit the requested information to ECHA in a dossier update to 12 months from the date of adoption of the decision.

Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 21 September 2016.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

ECHA notified you of the draft decision and invited you to provide comments.

ECHA did not receive any comments by the end of the commenting period.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

ECHA received proposal(s) for amendment and modified the draft decision.

ECHA invited you to comment on the proposed amendment(s).

ECHA referred the draft decision to the Member State Committee.

Your comments on the proposed amendment(s) were taken into account by the Member State Committee.

In addition, you provided comments on the draft decision. These comments were not taken into account by the Member State Committee as they were considered to be outside of the scope of Article 51(5).

The Member State Committee reached a unanimous agreement on the draft decision during its MSC-53 meeting and ECHA took the decision according to Article 51(6) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

2. Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.

3. In relation to the information required by the present decision, the sample of the substance used for the new test(s) must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the range of substance compositions manufactured or imported by the joint registrants. It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition. In addition, it is important to ensure that the particular sample of the substance tested in the new test(s) is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured or imported by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new test(s) must be suitable to assess these grades. Finally there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the test(s) to be assessed.