ECHA
EUROPEAN CHEMICALS AGENCY

Helsinki, 3 September 2018

Addressee: [redacted]

Decision number: CCH-D-2114439578-35-01/F
Substance name: 3,3'-[methylenebis(oxymethylene)]diheptane
EC number: 244-815-1
CAS number: 22174-70-5
Registration number: [redacted]
Submission number: [redacted]
Submission date: 15.09.2017
Registered tonnage band: 10-100 tonnes

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 main constituent(s)**

2. **Water solubility (Annex VII, Section 7.7; test method: EU A.6/OECD TG 105) of the registered substance;Long-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1., column 2; test method: Daphnia magna reproduction test, EU C.20/OECD TG 211) with the registered substance;**

3. **Long-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1., column 2); test method: Daphnia magna reproduction test, EU C.20/OECD TG 211) with the registered substance;**

4. **Long-term toxicity testing on fish (Annex VIII, Section 9.1.3., column 2; test method: Fish, early-life stage (FELS) toxicity test, OECD TG 210) with the registered substance;**

5. **Growth inhibition study aquatic plants (Annex VII, Section 9.1.2; test method: Alga, growth inhibition test, EU C.3/OECD TG 201) with the registered substance;**

6. **Activated sludge respiration inhibition testing (Annex VIII, Section 9.1.4; test method: Activated sludge, respiration inhibition test (carbon and ammonium oxidation), OECD TG 209) 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 ***10 September 2019***. 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 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.

Appendix 1: Reasons

1. Description of the analytical methods (Annex VI, Section 2.3.7.)

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 standard information requirement under Annex VI section 2.3.7. of the REACH Regulation to support the identification of the substance and its composition and therefore to verify the identity of the registered substance. According to chapter 4.2 of the Guidance for identification and naming of substances under REACH and CLP (Version: 1.3, February 2014) – referred to as "the Guidance" thereinafter, description of the analytical methods should also be sufficient to allow also the methods to be reproduced.

You have identified the substance as a mono-constituent substance and indicated that the substance has one main constituent which is present ≥ [redacted]% and three impurities which are present at ≤0.1% or lower.

ECHA notes that you have analysed the composition of the substance with the following chromatographic methods:

- Gas Chromatograph – Thermal Conductivity Detector (GC-TCD)
- Gas Chromatograph – Flame Ionization Detector (GC-FID)
- Gas Chromatograph – Mass Spectrometry (GC-MS)

The GC-TCD shows that one constituent is present at [redacted]% and the amount of other constituents present in the substance is negligible.
The GC-FID shows that one constituent is present at [redacted]% and that there are also five other constituents (one present ca. [redacted]% and the rest <[redacted]%).
The GC-MS shows that one constituent is present at [redacted]%, another at [redacted]% and there are also two other constituents present ([redacted]% and [redacted]%).

ECHA notes that the results of the chromatographic methods provided are not consistent with each other and that you have not provided a method description that would justify the reason for the inconsistency.

More specifically, the results of GC-FID are inconsistent with the reported degree of purity of the substance, concentration of the main constituent and impurities present.
Furthermore, ECHA notes that the results of the GC-MS indicate that the substance has potentially two main constituents (present at [redacted]% and [redacted]%). Therefore the results of the GC-FID and GC-MS chromatographic analyses are inconsistent with the composition given in IUCLID Section 1.2.

Because the results of the three methods are inconsistent with each other and the results of the GC-FID and GC-MS are inconsistent with the composition given and potentially contradict the identity of the substance, ECHA concludes that the identity of the substance and its composition cannot be confirmed.
Accordingly, you are requested to provide a description of the analytical methods used for the identification and quantification of the registered substance. This description should

allow to clarify why there are inconsistencies between the different methods used. You shall ensure that the information is consistent throughout the dossier and that the results of the analytical methods reported are representative for the specific substance which is the subject of this registration.

Furthermore, the identity of the substance and its composition shall reflect the results of analytical methods.

You shall note that according to chapter 4.2 of the Guidance a mono-constituent substance is a substance in which one constituent is present at a concentration of at least 80% (w/w) whereas a substance in which the constituents are present at concentrations ≥ 10% and < 80% (w/w) is considered as a multi-constituent substance. The Registrant shall take this principle into account when using the results of the chromatographic analysis to report the composition of the substance and naming the substance.

Furthermore, you shall take into account that impurities present in a concentration ≥ 1% should be specified. In addition impurities that are relevant for the classification and/or for PBT assessment shall always be specified, irrespective of the concentration.

As for the reporting of the information in IUCLID, the following applies:

The results of the analytical results together with the description of the methods shall be included in IUCLID Section 1.4. If necessary, the identity of the substance in IUCLID Section 1.1 and the composition of the substance in IUCLID Section 1.2 shall be revised to be in line with the relevant analytical information reported in IUCLID Section 1.4.

ECHA notes that in your comments on the draft decision you agree with this request. In the current technical dossier, no further information was submitted. ECHA notes all new information in the later update(s) of the registration dossier will be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation (after ECHA had sent the final decision).

2. Water solubility (Annex VII, Section 7.7.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) of the REACH Regulation, a technical dossier registered at 10 to 100 tonnes per year shall contain as a minimum the information specified in Annexes VII to VIII of the REACH Regulation.

"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 reported a key study performed accordingly to OECD 105, column elution method. In the study you provided the following remark in the results section "*The accurate water solubility of the test substance, 2-ethylhexylal, could not be determined and is under the limit of detection of the method (<1mg/L) according to OECD TG 105.* "

ECHA 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 2017) indicates that the detection limit when using the column elution method is 1 µg/l.

ECHA considers that you should have used a more accurate analytical method to determine the exact water solubility. 1mg/L is a high limit of detection, and you can use more precise analytical methods to determine a more accurate value for water solubility.

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.

ECHA acknowledges your comments on the draft decision and the current technical dossier clarifying some of the aspects in trying to determine the water solubility of the registered substance. You commented that the limit of detection of the HPLC-MS method was determined experimentally to be of 1 mg/L. However, ECHA notes that nowadays the instrument limit of detection for HPLC-MS instruments is far below 1 mg/L; therefore, you should make more efforts in finding an appropriate method (and instrument parameters) to quantify the substance below 1 mg/L. Furthermore, ECHA observes that the justification included in the IUCLID dossier for not using the gas-chromatography method for determination of the water solubility, it is not clear and does not appear scientifically sound.

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: EU A.6./OECD TG 105).

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 2017).

3. Long-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1., column 2)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 10 to 100 tonnes per year shall contain as a minimum the information specified in Annexes VII to VIII of the REACH Regulation.

The "*guidance note on fulfilling the requirement of Annexes VI to XI*" laid down in Annex VI to the REACH Regulation, explicitly indicates that "*in some cases, the rules set out in Annexes VII to XI may require certain tests to be undertaken earlier than or in addition to the standard requirements*". More specifically, column 2 entries in Annexes VII-X of the REACH Regulation provide that the standard information required in Column 1 of those Annexes may in some cases be adapted, *i.e.* waived or augmented, when appropriately justified. In particular, Column 2 of Annex VII, Section 9.1.1. of the REACH Regulation ('Short-term toxicity testing on invertebrates') indicates that:

> "*The long-term aquatic toxicity study on* Daphnia *(Annex IX, section 9.1.5) shall be considered if the substance is poorly water soluble.*"

ECHA notes that the registered substance is poorly water soluble as the water solubility is below 1 mg/L. Poorly soluble substances require longer time to be taken up by the test organisms and the 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. Information on long-term toxicity testing on aquatic invertebrates shall be considered for the risk assessment and for the classification and labelling of the substance. ECHA notes that no reliable PNEC can currently be derived for the registered substance. Information on algae (see section 5 of the present decision) and on long-term toxicity to fish and *Daphnia* need to be generated in order to derive reliable PNECs.

Therefore, pursuant to Column 2 of Annex VII, Section 9.1.1. of the REACH Regulation, it is considered that a long-term aquatic toxicity study on invertebrates (Annex IX, Section 9.1.5) is warranted.

You have sought to adapt this information requirement in line with Annex XI, Section 2 governing situations when testing not technically possible. You provided the following justification for the adaptation: *"At this time, an acute toxicity test to algae is the only in vivo aquatic toxicity test available. In this test, 2-ethylhexylal has been tested at concentration higher than the water solubility limit. Water solubility of the test item has been determined as lower than the LOD (<1 mg/L) of the developed method and an accurate solubility limit is in progress.*
According to OECD TG 211 (Daphnia magna Reproduction Test), substances should not be tested above their solubility limit in test medium.
According to point 9.1.1 of Annex VII of REACH, the short-term toxicity test with Daphnia does not need to be conducted if there are mitigating factors indicating that aquatic toxicity is unlikely to occur, for instance if the substance is highly insoluble in water or the substance is unlikely to cross biological membranes. At more, the long-term aquatic toxicity study on Daphnia (Annex IX, section 9.1.5) shall be considered if the substance is poorly water soluble".

However, ECHA notes that your adaptation does not meet the general rule for adaptation of Annex XI, Section 2 as you have not shown why it is not technically possible to conduct the long-term testing on aquatic toxicity as a consequence of the properties of the registered substance. As indicated under section 2 above, based on your comments on the draft decision and the updated dossier, ECHA has outlined you should have used a more accurate analytical method to determine the exact water solubility. Moreover, contrary to what seems to be indicated in the waiving statement, above, no dossier update containing an accurate water solubility determination has been received by ECHA by the date when this draft decision was notified to you under Article 50(1) of the REACH Regulation (as also explained under section 2 above).

Therefore, your adaptation of the information requirement cannot be accepted.

In your comments on the draft decision and the current technical dossier, you question the relevance of long-term aquatic testing without measured concentrations and quote OECD protocols stating that the highest test concentration should be set by the maximum solubility in water. As explained above, under section 2, ECHA does not agree that this is a valid reason not to perform aquatic testing. ECHA considers long-term aquatic toxicity testing necessary at Annex VIII level, for the registered substance.

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.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 2.0, November 2014) *Daphnia magna* reproduction test (test method EU C.20. / OECD TG 211) is the preferred test to cover the standard information requirement of Annex IX, Section 9.1.5.

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: *Daphnia magna* reproduction test (test method: EU C.20./OECD TG 211).

4. Long-term toxicity testing on fish (Annex VIII, Section 9.1.3., column 2)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 10 to 100 tonnes per year shall contain as a minimum the information specified in Annexes VII to VIII of the REACH Regulation.

The "*guidance note on fulfilling the requirement of Annexes VI to XI*" laid down in Annex VI to the REACH Regulation, explicitly indicates that "*in some cases, the rules set out in Annexes VII to XI may require certain tests to be undertaken earlier than or in addition to the standard requirements*". More specifically, column 2 entries in Annexes VII-X of the REACH Regulation provide that the standard information required in Column 1 of those Annexes may in some cases be adapted, *i.e.* waived or augmented, when appropriately justified. In particular, Column 2 of Annex VIII, Section 9.1.3. of the REACH Regulation ('Short-term toxicity testing on fish') indicates that:

> "*Long-term aquatic toxicity testing as described in Annex IX* [of the REACH Regulation] *shall be considered if the chemical safety assessment according to Annex I* [of the REACH Regulation] *indicates the need to investigate further effects on aquatic organisms. The choice of the appropriate test(s) will depend on the results of the chemical safety assessment.*
>
> *The long-term aquatic toxicity study on fish (Annex IX, Section 9.1.6) shall be considered if the substance is poorly water soluble*".

ECHA notes that the registered substance is poorly water soluble as the water solubility is below 1 mg/L. Poorly soluble substances require longer time to be taken up by the test organisms hence 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. Information on long-term toxicity testing on fish shall be considered for the risk assessment and for the classification and labelling of the substance. ECHA notes that no reliable PNEC can currently be derived for the registered substance. Information on algae (see section 5 of the present decision) and on long-term toxicity to fish and *Daphnia* need to be generated in order to derive reliable PNECs.

Therefore, pursuant to Column 2 of Annex VIII, Section 9.1.3. of the REACH Regulation, it is considered that a long-term aquatic toxicity study on fish (Annex IX, Section 9.1.6) is warranted.

You have sought to adapt this information requirement Annex XI, Section 2. You provided the following justification for the adaptation: "*At this time, an acute toxicity test to algae is*

the only in vivo aquatic toxicity test available. In this test, 2-ethylhexylal has been tested at concentration higher than its water solubility limit. Water solubility of the test item has been determined as lower than the LOD (<1 mg/L) of the developed method and an accurate solubility limit is in progress.
According to OECD TG 229 (Fish Short Term Reproduction Assay), the highest test concentration should be set by the maximum solubility in water.
According to point 9.1.3 of Annex VIII of REACH, the short-term toxicity test with fish does not need to be conducted if there are mitigating factors indicating that aquatic toxicity is unlikely to occur, for instance if the substance is highly insoluble in water or the substance is unlikely to cross biological membranes. The long-term aquatic toxicity study on fish (Annex IX, section 9.1.6) shall be considered if the substance is poorly water soluble".

However, ECHA notes that your adaptation does not meet the general rule for adaptation of Annex XI, Section 2 as you have not shown why it is not technically possible to conduct the long-term testing on aquatic toxicity as a consequence of the properties of the registered substance. As indicated under section 2 above, you should have used a more accurate analytical method to determine the exact water solubility.

Therefore, your adaptation of the information requirement cannot be accepted.

In your comments on the draft decision and the current technical dossier, you question the relevance of long-term aquatic testing without measured concentrations and quote OECD protocols stating that the highest test concentration should be set by the maximum solubility in water. As explained above under section 2, ECHA does not agree that this is a valid reason not to perform aquatic testing. ECHA considers long-term aquatic toxicity testing necessary at Annex VIII level, for the registered substance.

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.

Among these test methods, ECHA considers that the FELS toxicity test according to OECD TG 210 is the most sensitive of the standard fish tests available as it covers several life stages of the fish from the newly fertilised egg, through hatch to early stages of growth and should therefore be used (see ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), Chapter R7b, Section R.7.8.4.1). The test method OECD TG 210 is also the only suitable test currently available for examining the potential toxic effects of bioaccumulation (ECHA Guidance Chapter R7b, version 2.0, November 2014). For these reasons, ECHA considers the FELS toxicity test using the test method OECD TG 210 as most appropriate and suitable.

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).

5. <u>Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)</u>

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 10 to 100 tonnes per year shall contain as a minimum the information specified in Annexes VII to VIII of the REACH Regulation.

"Growth inhibition study aquatic plants" is a standard information requirement as laid down in Annex VII, Section 9.1.2. 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.

In the technical dossier you have provided a study record for an OECD TG 201 study (Alga, growth inhibition test). However, this study does not provide the information required by Annex VII, Section 9.1.2., because
1) all concentrations tested are (far) higher than the estimated water solubility (<1 mg/L),
2) only nominal concentrations are reported.

Given the substance properties (high logKow, poor water solubility), nominal concentrations are not sufficient, especially since all test concentrations are above the water solubility and effects are observed. In analogy with Annex XI, 1.1.2, first indent, of the REACH Regulation this study should be adequate for the purpose of classification and labelling and risk assessment. The study you have provided does not fulfil this condition as for this substance a reliable ECx or NOEC value cannot be derived from this study without (measured) test concentrations.

In your comments on the draft decision and the current technical dossier, you indicate how the test solutions were prepared. Therefore, ECHA has amended the draft decision accordingly. In your comments on the draft decision, you also question the relevance of a growth inhibition study on aquatic plants without measured concentrations and quote OECD protocols stating that the highest test concentration should be set by the maximum solubility in water. As explained above under section 2, ECHA does not agree that this is a valid reason not to perform aquatic testing. ECHA considers aquatic toxicity testing necessary at Annex VII level, for the registered substance.

As explained above, the information provided on this endpoint for the registered substance in the current technical dossier does not meet the information requirement. 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, Chapter R.7b* (version 4.0, June 2017) Algae growth inhibition test (test method EU C.3. / OECD TG 201) is the preferred test to cover the standard information requirement of Annex VII, Section 9.1.2.
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: Algae growth inhibition test, EU C.3./OECD TG 201).

Notes for your consideration for aquatic toxicity testing

Due to the high logKow and likely poor water solubility 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 4.0, June 2017), Chapter R7b, Table R.7.8-3 summarising aquatic toxicity testing of difficult substances for choosing the design of the requested ecotoxicity test(s) and for calculation and expression of the result of the test(s).

Before conducting any of the tests mentioned above in points 3 and 4 you shall consult the ECHA *Guidance on information requirements and chemical safety assessment (version 4.0,*

June 2017), Chapter R7b, Section R.7.8.5 to determine the sequence in which the aquatic toxicity tests are to be conducted and the necessity to conduct long-term toxicity testing on fish.

6. Activated sludge respiration inhibition testing (Annex VIII, Section 9.1.4.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 10 to 100 tonnes per year shall contain as a minimum the information specified in Annexes VII to VIII of the REACH Regulation.

"Activated sludge respiration inhibition testing" is a standard information requirement as laid down in Annex VIII, Section 9.1.4. 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.

Column 2 of Annex VIII, Section 9.1.4 specifies that the study does not need to be conducted if there is no emission to a sewage treatment plant, or there are mitigating factors indicating that microbial toxicity is unlikely to occur, for instance the substance is highly insoluble in water, or the substance is found to be readily biodegradable and the applied test concentrations are in the range of concentrations that can be expected in the influent of a sewage treatment plant.

You have sought to adapt this information requirement Annex XI, Section 2. You provided the following justification for the adaptation: *"According to column 2 of Annex VIII of REACH, activated sludge respiration inhibition testing needs not to be conducted if there is mitigating factors indicating that microbial toxicity is unlikely to occur, for instance the substance is highly insoluble in water. According to OECD TG 209, it may not always be possible to obtain EC50 values with chemical of limited solubility. Analytical support data is required to refine ECx concentration. At more, it may be necessary to measure the concentration of the test substance in the test vessels. It should be noted that in order to characterize the exposure, an analytical estimation of the test substance concentrations in the test vessels is necessary."*

However, ECHA notes that your adaptation does not meet the general rule for adaptation of Annex XI; Section 2 as you have not shown why it is not technically possible to conduct the long-term testing on aquatic toxicity as a consequence of the properties of the registered substance. As indicated under section 3 above, you should have used a more accurate analytical method to determine the exact water solubility. Moreover, contrary to what seems to be indicated in the waiving statement, no dossier update containing an accurate water solubility determination has been received by ECHA by the date when this draft decision was notified to you under Article 50(1) of the REACH Regulation.

ECHA further notes that you have not proven that there are no emissions to a sewage treatment plant or that there are mitigating factors indicating that microbial toxicity is unlikely to occur. Although you mention limited solubility as a potential adaptation in your adaptation justification, this argument can currently not be used since the water solubility in your dossier is only reported as being <1 mg/L (see also section 2 above).

Therefore, your adaptation of the information requirement cannot be accepted.

In your comments on the draft decision and the current technical dossier, you question the relevance of activated sludge respiration inhibition testing without measured concentrations and quote OECD protocols stating that the highest test concentration should be set by the maximum solubility in water. As explained above under section 2 above, ECHA does not agree that this is a valid reason not to perform this testing. ECHA considers testing necessary at Annex VIII level, for the registered substance.

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.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 2.0, November 2014) activated sludge respiration inhibition test (carbon and ammonium oxidation) (test method OECD TG 209) is the preferred test to cover the standard information requirement of Annex VIII, Section 9.1.4.

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: Activated sludge, respiration inhibition test (carbon and ammonium oxidation) (test method: OECD TG 209).

Appendix 2: Procedural history

You were initially notified that the draft decision does not take into account any updates of your registration after the date when draft decision was notified to you under Article 50(1) of the REACH Regulation. Following your comments on the draft decision indicating a tonnage band below 100 tonnes in recent years and related information provided in the updated dossier, ECHA has taken into account the updated tonnage band (submission number: [redacted] 15 September 2017). Based on the average production and/or import volumes for the three preceding calendar years, ECHA has changed as the basis for this draft decision from 100 to 1000 tonnes per year (submission number: [redacted]) to 10 to 100 tonnes per year (Latest submission number: [redacted]).

The compliance check was initiated on 6 November 2015.

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 took into account your comments and all the updated information of submission [redacted]. As a result, the requests for information on vapour pressure, screening study for reproductive/developmental toxicity, sub-chronic (90-day) toxicity, pre-natal developmental toxicity study in first species, simulation testing on ultimate degradation in water, soil simulation testing, sediment simulation testing and identification of degradation products were removed.

As a consequence the deadline for providing the information to meet the requests remaining in the draft decision has been set to 12 months.

As no amendments were proposed, ECHA took the decision according to Article 51(3) 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 carrying out the test(s) required by the present decision it is important to ensure that the particular sample of substance tested 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. If the registration of the substance covers different grades, the sample used for the new test(s) must be suitable to assess these. Furthermore, 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.