ECHA
EUROPEAN CHEMICALS AGENCY

Helsinki, 11 March 2020

Addressees
Registrants of RMTAD_JS listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject of this decision
28 November 2018

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Reaction mass of N,N,N',N'-tetrabutylmethylenediamine and dibutylamine
EC number: 948-040-6
CAS number: NS

Decision number: [Please refer to the REACH-IT message which delivered this communication (in format CCH-D-XXXXXXXXXX-XX-XX/D)]

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (REACH), ECHA requests that you submit the information listed below by the deadline of ***17 December 2021***.

A. Requirements applicable to all the Registrants subject to Annex VII of REACH

1. Water solubility (Annex VII, Section 7.7.; test method: EU A.6./OECD TG 105 with the Substance;

2. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method EU C.3./OECD TG 201) with the Substance;

3. Only if study under section A.1 shows that the substance and its constituents are not poorly water soluble, Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.; test method: EU C.2/OECD TG 202) with the Substance

4. Only if study under section A.1 shows that the substance or any of its constituents are poorly water soluble, Long-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1., column 2; test method: EU C.20./OECD TG 211) with the Substance

B. Requirements applicable to all the Registrants subject to Annex VIII of REACH

1. Only if study under section A.1 shows the substance and its constituents are not poorly water soluble, Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.; test method: OECD TG 203) with the Substance

2. Only if study under section A.1 shows the substance or any of its constituents are poorly water soluble, Long-term toxicity testing on fish (Annex VIII, Section 9.1.3., column 2; test method: OECD TG 210) with the Substance

Conditions to comply with the requests

Each addressee of this decision is bound by the requests for information corresponding to the REACH Annexes applicable to their own registered tonnage of the Substance at the time of evaluation of the jointly submitted dossier. You have to comply with the requirements of Annexes VII and VIII of REACH, if you have registered a substance at 10-100 tonnes per year. Registrants are only required to share the costs of information that they must submit to fulfil the information requirements for their registration.

The Appendices state the reasons for the requests for information to fulfil the requirements set out in the respective Annexes of REACH.

The Appendix entitled Observations and technical guidance addresses the generic approach for the selection and reporting of the test material used to perform the required studies and provides generic recommendations and references to ECHA guidance and other reference documents.

You must submit the information requested in this decision by the deadline indicated above in an updated registration dossier and also update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information. The timeline has been set to allow for sequential testing where relevant.

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, has to 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.

Approved[1] under the authority of Christel Schilliger-Musset, Director of Hazard Assessment

[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 A: Reasons for the requests to comply with Annex VII of REACH

Under Articles 10(a) and 12(1) of REACH, a technical dossier registered at 1 to 10 tonnes or more per year must contain, as a minimum, the information specified in Annex VII to REACH.

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

Water solubility is a standard information requirement in Annex VII to REACH.

You have adapted the standard information requirement according to Annex XI, Section 1.3., Qualitative or Quantitative structure-activity relationship ((Q)SAR), by providing the following predictions:

- key study ([redacted] 2018), "*QSAR of the water solubility of Reaction Mass of N,N,N',N'-tetrabutylmethylenediamine and N-butylbutan-1-amine ([redacted]*".

We have evaluated this information in line with the conditions specified in Annex XI, Section 1.3., of the REACH Regulation.

For the use of QSAR models under Annex XI, Section 1.3., the following cumulative conditions must be necessarily met:

1. the substance falls within the applicability domain of the QSAR model;
2. adequate and reliable documentation of the applied method is provided; and
3. the results are adequate for classification and labelling and/or risk assessment.

According to ECHA's Practical guide "How to use and report (Q)SARs", section 3.4, a QSAR Model Reporting Format (QMRF) and a QSAR Prediction Reporting Format (QPRF) are required to establish the scientific validity of the model, to verify that the Substance falls within the applicability domain of the model, and to assess the adequacy of the prediction for the purposes of classification and labelling.

For your predictions, you have not provided a QSAR Prediction Reporting Format (QPRF) containing:

1. An assessment of the applicability of the model to the Substance and the reliability of the individual model prediction, and
2. An assessment of the adequacy of the prediction for classification and labelling and/or risk assessment.

Due to the above deficiencies, it is not possible to confirm that the conditions according to Annex XI, Section 1.3. are met. Therefore, your adaptation is rejected and the information requirement is not fulfilled.

You submitted a QPRF as part of your comments on the draft decision. ECHA has assessed the documentation and the model. The model has separately assessed the water solubility of the two constituents of the multiconstituent Substance. You have also provided a calculation for "apparent water solubility of the constituent when they are together within the mixture". The calculation uses the QSAR predicted water solubility values of the constituents as input values.

ECHA agrees that the prediction for the water solubility of [redacted] constituent 1) is acceptable. However, for [redacted] (constituent 2) ECHA identified the following issue.

For a substance to be included in the applicability domain of a QSAR model it has to, among other conditions, fall within the ranges of the descriptor domain (ECHA Guidance R.6, section R.6.1.5.3). The structures (fragments) of a substance must also be included in the model training set.

The model uses log Kow as descriptor to predict water solubility. The log Kow value of [redacted] (constituent 2) falls within the range considered within applicability domain of the model, however the model for water solubility does not include any [redacted], such as constituent 2. Constituent 2 hence falls outside the structural domain, and consequently the applicability domain of the model. The prediction for the Substance based on its constituents or as a mixture is hence uncertain and is not adequate for classification and labelling and/or risk assessment as required in Annex XI, section 1.3.

You should select the appropriate method(s) included in the requested test guideline, following ECHA Guidance R.7a, to determine the water solubility range of the different constituents of the Substance, which is a multi-constituent. The information provided in the dossier indicates that the water solubility of the constituents would differ in several orders of magnitude.

2. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)

Growth inhibition study aquatic plants is a standard information requirement in Annex VII to REACH.

You have provided a key study ([redacted] 2018) conducted according to OECD TG 201 with the Substance.

We have assessed this information and identified the following issue(s).

Tests on substances must be conducted in accordance with the OECD test guidelines or another recognised international test method (Article 13(3) of REACH). OECD TG 201 is the preferred guideline to fulfil this information requirement. The guideline specifies that for difficult to test substances (such as multi-constituents, surfactants, adsorptive and poorly water-soluble), OECD GD 23 is to be followed. The OECD TG 201 and the OECD GD 23, require that you must (among others):

- provide analytical monitoring of the substance, including its constituents, to verify the initial concentrations and maintenance of the exposure concentrations during the test;
- provide evidence that exposure concentrations have been maintained throughout the test (within ±80-120 % of the nominal or initial measured concentration);
- if the concentrations were not within ±80-120 %, analysis of the results should be based on geometric mean measured concentration during exposure or on models describing the decline of the concentration of the test substance.

The Substance is a 'difficult to test' substance: it is a multi-constituent including cationic surfactant constituents (surface tension is 57.2 mN/m) hence adsorptive. In addition, although the information provided on water solubility is not acceptable as explained in section A.1 above, there are indications that the Substance can be considered as poorly/sparingly water-soluble. The reported water solubility of one of the two main constituents of the Substance ([redacted]) is 28.5 mg/L, which is < 100 mg/L indicating difficulties for test solution preparation and testing based on Table 2 of OECD GD 23. Although this water solubility value is not reliable, this constituent is expected to be

poorly/sparingly water-soluble based on the chemical structure (four alkyl chain substituents). Furthermore, you report the presence of undissolved particles at the two highest test concentrations (i.e. 31.3 and 100 mg/L WAF loadings).

You have carried out analytical monitoring of the test concentrations only for one of the constituents of the Substance (i.e. [redacted], typical concentration [redacted]%). However, you have not provided analytical monitoring nor any evidence that the exposure concentrations have been maintained for the Substance including the other main constituent of the Substance (i.e[redacted], typical concentration [redacted]%).

In your comments on the draft decision, you explain that you have attempted to develop a method to monitor both constituents. You note that it was not technically feasible to develop and validate a method to analyse constituent 2 at the concentrations required for aquatic toxicity testing. You have hence used constituent 1 as a "marker compound" to verify the behaviour of both constituents in the test media. You state that the two constituents of the substance have different physicochemical properties and that you considered the differences in test design.

We have assessed this information from your comments and identified the following issue.

Under the OECD TG 201 and the OECD GD 23, the concentration of each of the dissolved fractions should be confirmed analytically after the separation technique wherever possible. In order to depart from this principle, you would have to scientifically justify why such analytical measurements cannot be performed. As set out in the OECD TG 23 (paragraph 38) "*options may include providing a statement from an analytical chemist in the study report confirming that the analytical methods used were state of the art, and a justification as to why lower detection limits were not feasible (any preliminary analytical efforts should also be described in the report)*".

Regarding method development, you summarise the steps of analytical method development in relation to improving chromatography (GC-FID) for oral dosing formulations. You succeeded in measuring the total test item in formulations, such as corn oil, at relatively high concentrations (500 mg/l), but failed to monitor the constituents separately. For the purpose of the aquatic studies, in a different medium and at lower concentrations, further method development and validation took place. Due to failed attempts to monitor the (whole) test item below concentration of 100 mg/L, you considered the GC-MS method as not suitable to analyse either of the constituents, and consequently developed an HPLC-MS/MS method which was able to analyse constituent 1 but not constituent 2. You indicate that due to the time already taken in developing the GC-MS method, you went forward with the approach of analysing only constituent 1 as a "marker compound". You did not attempt to develop the HPLC method further. You consider it justified to have only analysed constituent 1 as "supporting information" and to use the loading rates to express the effect levels in the studies.

However, you describe the method development for GC-MS primarily for oral dosing applications. For the purpose of the aquatic studies you developed a HPLC method with which you were able to measure constituent 1, but you do not describe the HPLC method development and do not explain why it was not possible to measure constituent 2 with HPLC. In addition, according to literature[2] HPLC methods have been developed to analyse tertiary

[2] Qihua Wu et al, Determination of secondary and tertiary amines as N-nitrosamine precursors in drinking water system using ultra-fast liquid chromatography–tandem mass spectrometry, Talanta, Vol. 131, 2015, p. 736-741. M. Kagan, et al. ,Optimization of normal-phase chromatographic separation of compounds with primary, secondary and tertiary amino groups, Journal of Chromatography A, Vol. 1194, Iss. 1, 2008,p. 80-89.)

amines, such as constituent 2. The aquatic studies have been conducted in 2018 when the methods described in literature were available. You have hence not used state of the art methods. At last, you do not explain why analysing constituent 1 would be representative of constituent 2, despite the differences in physicochemical properties. You also do not explain why constituent 1 can be used as a "marker compound" despite the decrease in concentration. For all these reasons ECHA cannnot accept your justification for a departure from the principle need for analytical measuring.

Regarding exposure concentrations for [redacted] you have claimed that: "*Measured concentrations were* [redacted] *% of nominal.*" However, Table 8 of the robust study summary shows that after 72h, the exposure concentrations have been maintained within ±80-120% of nominal only at the highest test concentration (i.e. loading rate of 100 mg/L). You have not based the analysis of the results on geometric mean concentration during exposure or on models describing the decline of the concentration of the test substance.

In your comments on the draft decision you acknowledge that concentrations of [redacted] (constituent 1) were not maintained within [redacted] %. You still intend to base the analysis of results on loading levels.

As described above, ECHA finds this approach unjustified.

In addition, your approach of using constituent 1 as a "marker compound" to verify the behaviour of both constituents in the test media and to hence base the analysis of results on loading levels is further not justfied due to the decrease in concentration.

In conclusion, the information requirement is not fulfilled.

Test design
The Substance is difficult to test due to the low water solubility, surface activity and adsorptive properties as explained above. OECD TG 201 specifies that for difficult to test substances, the OECD GD 23 is to be followed. To get reliable results, the substance properties need to be considered when performing the test, in particular in test design including exposure system and test solution preparation, and sampling. OECD GD 23 (Table 1) describes testing difficulties related to a specific property of the substance. You may use the approaches described in OECD GD 23 or other approaches, if more appropriate for your substance. The approach selected must be justified and documented. Due to the substance properties it may be difficult to achieve and maintain the exposure concentrations. Therefore, you have to demonstrate that the concentration of the substance is stable throughout the test (i.e. measured concentrations remains within 80-120% of the nominal concentration). If it is not possible to demonstrate the stability, you must express the effect concentration based on measured values as described in the applicable test guideline. In case the dose-response relationship cannot established (no observed effects), you must demonstrate that the test solution preparation method applied was sufficient to maximise the concentration of the Substance in the test solution.

3. Only if study under section A.1. shows the substance and its constituents are not poorly water soluble, Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1).

Short-term toxicity testing on aquatic invertebrates is a standard information requirement in Annex VII to REACH.

You have provided a key study ([redacted] 2018) conducted according to OECD TG 202

with the Substance.

We have assessed this information and identified the following issue(s).

Tests on substances must be conducted in accordance with the OECD test guidelines or another recognised international test method (Article 13(3) of REACH). OECD TG 202 is the preferred guideline to fulfil this information requirement. The guideline specifies that for difficult to test substances (such as multi-constituents, surfactants, adsorptive and poorly water-soluble), OECD GD 23 is to be followed. The OECD TG 202 and the OECD GD 23, require(s) that you must (among others):

- provide analytical monitoring of the substance, including its constituents, to verify the initial concentrations and maintenance of the exposure concentrations during the test;
- provide evidence that exposure concentrations have been maintained throughout the test (within ±80-120 % of the nominal or intial measured concentration).

The Substance is a 'difficult to test' substance: it is a multi-constituent including cationic surfactant constituents hence adsorptive and there are indications that it can be considered as poorly/sparingly water-soluble, as explained under section A.2 above.

You have carried out analytical monitoring of the test concentrations only for one of the constituents of the Substance (i.e. [redacted] typical concentration [redacted]%). However, you have not provided analytical monitoring nor any evidence that the exposure concentrations have been maintained for the Substance including the other main constituent of the Substance (i.e. [redacted], typical concentration [redacted]%).

In your comments on the draft decision you note that in the test design you considered that the substance contains constituents of varying physicochemical properties such as solubility and partitioning. You explain that no undissolved test item was observed. You indicate that only constituent 1 was analytically monitored, and that the concentration remained within 20 % of nominal. You note that it was not technically feasible to develop and validate a method for constituent 2. You describe the attempts made to develop a method for monitoring constituent 2.

ECHA has addressed your comments on method development under request A.2. and considered the information provided as not sufficient. While in this particular study the concentration of constituent 1 remained within 20 % and no undissolved test item was observed in the test solutions, ECHA still considers that the requirements regarding analytical monitoring given in the OECD TG 202 and the OECD GD 23 have not been fulfilled as constituent 2 has not been monitored. The analysis of constituent 1 cannot be used to prove that the concentration of constituent 2 has been adequately maintained in the test system.

Therefore, the information requirement is not fulfiled.

The request for the short-term toxicity testing is dependent on the result of request A.1. In that respect, as explained under request A.1, your dossier currently does not include a reliable value on the water solubility of the Substance. However, based on the information currently contained in the dossier, the Substance may be poorly water soluble or might contain poorly water soluble constituent(s).

In case the Substance or any of its consituents prove to be poorly water soluble (*i.e.* water solubility is not above 1 mg/L) then long-term toxicity study on aquatic invertebrates instead of acute test is required (Annex VII, section 9.1.1., column 2 in conjunction with Annex IX,

Section 9.1.5.). Poorly water soluble substances or constituents require longer time to reach steady-state conditions. Hence, the short-term tests may not give a true measure of toxicity for multi-constituent substances with poorly water soluble constituents.

Therefore, a short-term toxicity testing on aquatic invertebrates must only be conducted if the data generated under request A.1. demonstrate that the Substance and its constituents are not poorly water soluble (*i.e.* water solubility above 1 mg/L).

Test design
The substance is difficult to test due to the low water solubility, surface activity and adsorptive properties as explained above. OECD TG 202 specifies that for difficult to test substances, the OECD GD 23 is to be followed, as described above under request A.2.

4. **Only if study under section A.1. shows the substance or any of its constituents are poorly water soluble, Long-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1., column 2).**

Short-term toxicity testing on aquatic invertebrates is a standard information requirement in Annex VII to REACH. However, pursuant to Annex VII, section 9.1.1., column 2, for poorly water soluble substances a long-term toxicity study on aquatic invertebrates (Annex IX, Section 9.1.5.) must be considered instead of an acute test.

You have not provided any data on long-term toxicity to aquatic invertebrates.

The request for the long-term toxicity testing is dependent on the result of request A.1., as already explained under request A.3.

In case the Substance or any of its consituents prove to be poorly water soluble (*i.e.* water solubility is not above 1 mg/L) then long-term toxicity study on aquatic invertebrates instead of acute test is required (Annex VII, section 9.1.1., column 2 in conjunction with Annex IX, Section 9.1.5.). Poorly water soluble substances or constituents require longer time to reach steady-state conditions. Hence, the short-term tests may not give a true measure of toxicity for multi-constituent substances with poorly water soluble constituents.

In your comments on the draft decision you consider this request as not applicable since the water solubility of the Substance is above 1 mg/L. As discussed in request A.1 the water solubility of the Substance is still unclear, and therefore, this request is applicable.

Therefore, if the information requested on water solubility (request A.1.) confirms that the Substance or any of its constituents are poorly water soluble (*i.e.* water solubility is not above 1 mg/L), a long-term test must be conducted.

OECD TG 211 is the preferred guideline to fulfil this information requirement.

Test design
The Substance is difficult to test due to the low water solubility, surface activity and adsorptive properties as explained above. OECD TG 211 specifies that for difficult to test substances, the OECD GD 23 is to be followed, as described above under request A.2.

Appendix B: Reasons for the requests to comply with Annex VIII of REACH

Under Articles 10(a) and 12(1) of REACH, a technical dossier registered at 10 to 100 tonnes or more per year must contain, as a minimum, the information specified in Annexes VII and VIII to REACH.

1. **Only if study under section A.1. shows the substance and its constituents are not poorly water soluble, Short-term toxicity testing on fish (Annex VIII, Section 9.1.3).**

Short-term toxicity testing on fish is a standard information requirement in Annex VIII to REACH.

You have provided a key study (2018) conducted according to OECD TG 203 with the Substance.

We have assessed this information and identified the following issue(s).

Tests on substances must be conducted in accordance with the OECD test guidelines or another recognised international test method (Article 13(3) of REACH). OECD TG 203 (2019) is the preferred guideline to fulfil this information requirement. The OECD TG 203 specifies that for difficult to test substances (such as multi-constituents, surfactants, adsorptive and poorly water-soluble), OECD Guidance 23 is to be followed. The OECD TG 203 and the OECD GD 23, require(s) that you must (among others):

- provide analytical monitoring of the substance, including its constituents, to verify the initial concentrations and maintenance of the exposure concentrations during the test;
- provide evidence that exposure concentrations have been maintained throughout the test (within ±20 % of the nominal or intial measured concentration).

The Substance is a 'difficult to test' substance: it is a multi-constituent including cationic surfactant constituents hence adsorptive and there are indications that it can be considered as poorly/sparingly water-soluble, as explained under section A.2 above.

You have carried out analytical monitoring of the test concentrations only for one of the constituents of the Substance (i.e. [redacted], typical concentration [redacted] However, you have not provided analytical monitoring nor any evidence that the exposure concentrations have been maintained for the Substance including the other main constituent of the Substance (i.e. [redacted], typical concentration [redacted]).

In your comments on the draft decision you note that in the test design you considered that the substance contains constituents of varying physicochemical properties such as solubility and partitioning. You explain that no undissolved test item was observed. You indicate that only constituent 1 was analytically monitored, and that the concentration remained within 20 % of nominal. You note that it was not technically feasible to develop and validate a method for constituent 2. You describe the attempts made to develop a method for monitoring constituent 2.

ECHA has addressed your comments on analytical method development under request A.2. and considered the information provided as not sufficient. While in this particular study the concentration of constituent 1 remained within 20 % and no undissolved test item was observed in the test solutions, ECHA still considers that the requirements regarding analytical monitoring given in the OECD TG 203 and the OECD GD 23 have not been fulfilled as

constituent 2 has not been monitoried. The analysis of constituent 1 cannot be used to prove that the concentration of constituent 2 has been adequately maintained in the test system.

Furthermore, the OECD GD 23 requires that when the water accommodated fraction approach (WAF) is used the test solutions must be prepared separately for each dose level (loading rate).

In your comments you indicate that due to an error by the laboratory a 100 mg/L stock solution was used to serially dilute the remaining test concentrations of 4.64, 10.0, 21.5 and 46.4 mg/L.

The WAF preparation did thus not follow the required procedure.

Therefore, the information requirement is not fulfiled.

The request for the short-term toxicity testing is dependent on the result of request A.1., as already explained under request A.3.

In case the Substance or any of its constituents prove to be poorly water soluble (*i.e.* water solubility is not above 1 mg/L) then long-term toxicity study on fish instead of acute test is required (Annex VIII, section 9.1.3., column 2 in conjunction with Annex IX, Section 9.1.6.). Poorly water soluble substances or constituents require longer time to reach steady-state conditions. Hence, the short-term tests may not give a true measure of toxicity for multi-constituent substances with poorly water soluble constituents.

Therefore, a short-term toxicity testing on fish must only be conducted if the data generated under request A.1. demonstrate that the Substance and its constituents are not poorly water soluble (*i.e.* water solubility above 1 mg/L).

Test design
The substance is difficult to test due to the low water solubility, surface activity and adsorptive properties as explained above. OECD TG 203 specifies that for difficult to test substances, the OECD GD 23 is to be followed, as described above under request A.2.

2. Only if study under section A.1. shows the substance or any of its constituents are poorly water soluble, Long-term toxicity testing on fish (Annex VIII, Section 9.1.3., column 2).

Short-term toxicity testing on fish is a standard information requirement in Annex VIII to REACH. However, pursuant to Annex VIII, section 9.1.3., column 2, for poorly water soluble substances a long-term toxicity study on fish (Annex IX, Section 9.1.6.) must be considered instead of an acute test.

You have not provided any data on long-term toxicity to fish.

The request for the long-term toxicity testing is dependent on the result of request A.1., as already explained under request A.3.

In case the Substance or any of its consituents prove to be poorly water soluble (*i.e.* water solubility is not above 1 mg/L) then long-term toxicity study on fish instead of acute test is required (Annex VIII, section 9.1.3., column 2 in conjunction with Annex IX, Section 9.1.6.). Poorly water soluble substances or constituents require longer time to reach steady-state

conditions. Hence, the short-term tests may not give a true measure of toxicity for multi-constituent substances with poorly water soluble constituents.

In your comments on the draft decision you consider this request as not applicable since the water solubility of the Substance is above 1 mg/L. As discussed in request A.1 the water solubility of the Substance is still unclear and, therefore, this request is applicable.

Therefore, if the information requested on water solubility (request A.1.) confirms that the Substance or any of its constituents are poorly water soluble (*i.e.* water solubility is not above 1 mg/L), a long-term test must be conducted.

OECD TG 210 is the preferred guideline to fulfil this information requirement.

Test design
The Substance is difficult to test due to the low water solubility, surface activity and adsorptive properties as explained above. OECD TG 210 specifies that for difficult to test substances, the OECD GD 23 is to be followed, as described above under request A.2.

Appendix C: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of registration dossiers after the date on which you were notified the draft decision according to Article 50(1) of REACH.

The compliance check was initiated on 23 April 2019.

ECHA notified you of the draft decision and invited you to provide comments within 30 days of the notification.

ECHA took into account your comments and did not amend the request(s).

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

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

Appendix D: Observations and technical guidance

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

2. Failure to comply with the requests in this decision, or to otherwise fulfil the information requirements with a valid and documented adaptation, will result in a notification to the enforcement authorities of the Member States.

3. Test guidelines, GLP requirements and reporting

   Under Article 13(3) of REACH, all new data generated as a result of this decision needs to be conducted according to the test methods laid down in a European Commission Regulation or according to international test methods recognised by the Commission or ECHA as being appropriate.

   Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses shall be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.

   Under Article 10 (a) (vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide: 'How to report robust study summaries'[3].

4. Test material

   Selection of the test material(s)

   The registrants of the Substance are responsible for agreeing on the composition of the test material to be selected for carrying out the tests required by the present decision. The test material selected must be relevant for all the registrants of the Substance, i.e. it takes into account the variation in compositions reported by all members of the joint submission. The composition of the test material(s) must fall within the boundary composition(s) of the Substance.

   While selecting the test material you must take into account the impact of each constituent/ impurity on the test results for the endpoint to be assessed. For example, if a constituent/ impurity of the Substance is known to have an impact on (eco)toxicity, the selected test material must contain that constituent/ impurity.

   Technical reporting of the test material

   The composition of the selected test material must be reported in the respective endpoint study record, under the Test material section. The composition must include all constituents of the test material and their concentration values. Without such detailed reporting, ECHA may not be able to confirm that the test material is relevant for the Substance and to all the registrants of the Substance.

   Technical instructions are available in the manual "How to prepare registration and PPORD dossiers"[4].

[3] https://echa.europa.eu/practical-guides
[4] https://echa.europa.eu/manuals

5. List of references of the ECHA Guidance and other guidance/ reference documents[5]

Evaluation of available information
Guidance on information requirements and chemical safety assessment, Chapter R.4 (version 1.1., December 2011), referred to as ECHA Guidance R.4 in this decision.

QSARs, read-across and grouping
Guidance on information requirements and chemical safety assessment, Chapter R.6 (version 1.0, May 2008), referred to as ECHA Guidance R.6 in this decision.

ECHA Read-across assessment framework (RAAF, March 2017)[6]

Physical-chemical properties
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Toxicology
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

Environmental toxicology and fate
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017), referred to as ECHA Guidance R.7b in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

PBT assessment
Guidance on information requirements and chemical safety assessment, Chapter R.11 (version 3.0, June 2017), referred to as ECHA Guidance R.11 in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.16 (version 3.0, February 2016), referred to as ECHA Guidance R.16 in this decision.

OECD Guidance documents[7]
Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.
Guidance Document on Mammalian Reproductive Toxicity Testing and Assessment – No 43, referred to as OECD GD 43.

[5] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[6] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[7] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Appendix E: List of the registrants to which the decision is addressed and the corresponding information requirements applicable to them

Registrant Name	Registration number	(Highest) Data requirements to be fufilled
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Note: where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas the decision is sent to the actual registrant.