EUROPEAN CHEMICALS AGENCY

~~Confidential~~

Helsinki, 25 August 2020

Addressees
Registrants of RMDPGDBDEGDBTEGDB as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
20/01/2020

Registered substance subject to this decision ("the Substance")
Substance name: Reaction mass of 2-[2-(benzoyloxy)ethoxy]ethyl benzoate, 1-[2-(benzoyloxy)propoxy]propan-2-yl benzoate, and 2-[2-[2-(benzoyloxy)ethoxy]ethoxy]ethyl benzoate
List number: 907-434-8

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

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***30 August 2022***.

Requested information must be generated using the Substance unless otherwise specified.

A. Information required from 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/OECD GD 29)

2. Partition coefficient n-octanol/water (Annex VII, Section 7.8.; using an appropriate test method)

3. Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.; test method: EU C.2./OECD TG 202)

4. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: [EU C.3./OECD TG 201 // EU C.26./OECD TG 221])

B. Information required from all the Registrants subject to Annex VIII of REACH

1. Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.; test method: OECD TG 203)

C. Information required from all the Registrants subject to Annex IX of REACH

1. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: EU C.20./OECD TG 211)

2. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: OECD TG 210)

D. Information required from all the Registrants subject to Annex X of REACH

1. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method: OECD TG 414) by oral route, in a second species (rabbit)

Reasons for the request(s) are explained in the following appendices:

- Appendix entitled "Reasons common to several requests";
- Appendices entitled "Reasons to request information required under Annexes VII to X of REACH", respectively.

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you, and in accordance with Articles 10(a) and 12(1) of REACH:

- the information specified in Annexes VII to X to REACH, for registration at more than 1000 tpa.

You are only required to share the costs of information that you must submit to fulfil your information requirements.

How to comply with your information requirements

To comply with your information requirements you must submit the information requested by this decision in an updated registration dossier by the deadline indicated above. You must also update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information.

You must follow the general testing and reporting requirements provided under the Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes". In addition, you should follow the general recommendations provided under the Appendix entitled "General recommendations when conducting and reporting new tests for REACH purposes". For references used in this decision, please consult the Appendix entitled "List of references".

Appeal

This decision, when adopted under Article 51 of REACH, may be appealed to the Board of Appeal of ECHA within three months of its notification to you. Please refer to http://echa.europa.eu/regulations/appeals for further information.

Failure to comply

If you do not comply with the information required by this decision by the deadline indicated above, ECHA will notify the enforcement authorities of your Member State.

Authorised[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 to request information required under Annex VII of REACH

1. Water solubility

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

You have provided a key study using flask method (Fox and White 2010) conducted according to OECD Test Guideline (TG) 105 with the Substance.

To fulfil the information requirement, a study must comply with the OECD TG 105 or the EU Method A.6 (Article 13(3) of REACH). Therefore, the following requirements must be met:

- Three flasks are included which are shaken/stirred for 24, 48 and 72 hours, respectively;
- The results are considered acceptable, if the results of the flasks shaken for 48 and 72 hours differ by ≤ 15%. If the results shows a tendency of higher solubility with longer shaking/stirring period, the test is repeated with longer equilibration times;
- The analytical method used for the quantification of the substance is described. The specificity, recovery efficiency, precision, limits of determination (i.e. detection and quantification) and working range are reported;
- The equilibration time and the individual results from each of the three flasks are reported.

You have not reported the parameters listed above. The provided information does not allow ECHA to assess solubility of the substance during the course of the study, variation of the solubility in the test flasks, reliability of the analytical method or time to reach equilibrium in invidual test flasks.

Therefore, the information requirement is not fulfilled.

2. Partition coefficient n-octanol/water

Partition coefficient n-octanol/water (Annex VII, Section 7.8) is a standard information requirement in Annex VII to REACH.

You have provided a key study (Fox and White 2010) conducted according to OECD Test Guideline (TG) 117 with the Substance.

To fulfil the information requirement, a study must comply with the OECD TG 117 or EU Method A.8 (Article 13(3) of REACH). Therefore, the following requirements must be met:

- The test and reference substances used are reported, including their purity, structural formula and CAS number;
- The test conditions are reported, including details on the analytical column, the guard column, the mobile phase, the detection method, the temperature range and pH;
- Details on the fitted regression line (log k *versus* log P_{ow}), including the correlation coefficient and the confidence intervals, are reported;
- Details of the calculation of the reported log P_{ow} are provided;
- For multi-constituent substances, which result in an unresolved band(s), upper and lower limits of log P_{ow}, and the area % of each log P_{ow} peak is reported;

You have not reported the parameters listed above. In the absence of this information it is not clear what the test substance was and how it covers the constituents of the Substance. Neither is it clear what confidence there is in the values derived without the other information listed above on the test conditions, regression and calculations.

Therefore, the provided information does not fulfil the information requirement.

3. Short-term toxicity testing on aquatic invertebrates

Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1) is a standard information requirement in Annex VII to REACH.

You have provided three key studies using OECD Guideline 202 (*Daphnia* sp., Acute Immolisation Test) by [redacted] 2001:

i. Key study - [redacted] (TEGDB, EC:204-408-1): Acute Toxicity to *Daphnia magna*
ii. Key study - [redacted] (DEGDB, EC: 204-407-6): Acute Toxicity to *Daphnia magna*
iii. Key study - [redacted] (DPGDB, EC: 248-258-5): Acute Toxicity to *Daphnia magna*

We have assessed this information and identified the following issues:

To fulfil the information requirement, a study must comply with OECD TG 202 (Article 13(3) of REACH). Therefore, the following requirements must be met:

- The effect values can only be based on nominal or measured initial concentration if the concentration of the test material has been satisfactorily maintained within 20 % of the nominal or measured initial concentration throughout the test (see also ECHA Guidance R.7b, Section R.7.8.4.1);

Your registration dossier provides three key studies performed as per OECD TG 202 showing the following:

For the study i. you report:
- At the beginning of the static test the measured concentrations were 26-55% of the nominal concentrations;
- At the end of the 48 hour experiment the measured concentrations were 0-29% of the nominal concentrations;
- The effect concentrations were based on nominal concentrations.

For the study ii. you report:
- At the beginning of the static test the measured concentrations were 9-76% of the nominal concentrations;
- At the end of the 48 hour experiment the measured concentrations were 3-61% of the nominal concentrations;
- The effect concentrations were based on nominal concentrations.

For the study iii. you report:
- At the beginning of the static test the measured concentrations were 14-49% of the nominal concentrations;
- At the end of the 48 hour experiment the measured concentrations were 7-28% of the nominal concentrations;
- The effect concentrations were based on nominal concentrations.

In the reported static invertebrate tests, the test material concentrations were not maintained within 20% of the measured initial concentration throughout the test.

However, the effect concentrations were based on nominal concentrations which is not following the OECD TG 202. As a result the reported studies i, ii and iii are not considered as valid.

Therefore, the information requirement is not fulfilled.

Study design

Your Substance is considered a difficult to test substance since the exposure concentrations could not be maintained in the static or semi-static tests you performed. OECD TG 202 specifies that for difficult to test substances, the OECD Guidance 23 is to be followed. To get reliable results, the substance properties need to be considered when performing the test, in particular with regard to the test design; including exposure system, 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 a dose-response relationship cannot be 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.

4. Growth inhibition study aquatic plants

Growth inhibition study aquatic plants (Annex VII, Section 9.1.2) is a standard information requirement in Annex VII to REACH.

You have provided three key studies using OECD Guideline 201 (Alga, Growth Inhibition Test) by [redacted] 2001:

i. Key study - [redacted](TEGDB, EC:204-408-1): Algal Growth Inhibition
ii. Key study - [redacted](DEGDB, EC: 204-407-6): Algal Growth Inhibition
iii. Key study - [redacted](DPGDB, EC: 248-258-5): Algal Growth Inhibition

We have assessed this information and identified the following issues:

To fulfil the information requirement, a study must comply with OECD TG 201 and the requirements of OECD GD 23 (ENV/JM/MONO(2000)6/REV1) if the substance is difficult to test (Article 13(3) of REACH). Therefore, the following requirements must be met:

Validity criteria

- Exponential growth in the control cultures is observed over the entire duration of the test;
- At least 16-fold increase in biomass is observed in the control cultures by the end of the test;
- The mean coefficient of variation for section-by-section specific growth rates (days 0-1, 1-2 and 2-3, for 72-hour tests) in the control cultures is ≤ 35%;
- The coefficient of variation of average specific growth rates during the whole test period in replicate control cultures is ≤ 7% in tests with *Pseudokirchneriella subcapitata*.

Characterisation of exposure

- The results can be based on nominal or measured initial concentration only if the concentration of the test material has been maintained within 20 % of the nominal or measured initial concentration throughout the test;

- The concentrations of the test material are measured at least at the beginning and end of the test:
  1) at the highest, and
  2) at the lowest test concentration, and
  3) at a concentration around the expected EC_{50}.

  For volatile, unstable or strongly adsorbing test substances, additional samplings for analysis at 24 hour intervals is required;
- If the concentration of the test material has not been maintained within 20 % of the nominal or measured initial concentration throughout the test, results must be based on the geometric mean of measured concentrations during exposure or on a model describing the decline of the concentration of the test material.

Reporting of the methodology and results

- The results of algal biomass determined in each flask, at least daily during the test period are reported in a tabular form;
- Adequate information on the results of the analytical determination of exposure concentrations is provided;

Specific requirements under OECD GD 23

- If losses of the test material are expected within the timeframe of the test, a preliminary stability study is conducted, which meets the following requirements:
  1) the test solutions are prepared under conditions equivalent to those to be used in the test,
  2) a saturated solution of the test material is used,
  3) samples are analysed at the beginning and at 24-hour intervals for the duration of the test period,
  4) the possibility of losses during sampling, sample treatment and analysis are assessed and documented,
  5) the stability under storage conditions are determined;

Your registration dossier provides two key studies performed according to the OECD TG 201 showing the following:

For the study i. you report:

- Growth rates for each replicate and their averages in number of cells for all concentrations and control (measured via flow cytometry) and inhibition reported as area under the curve and growth rate between 0 and 72 h and 0 and 96 h;
- Some increase in area under the growth curve at both 72 and 96 h;
- The measured test substance concentrations only at the beginning (0 h) and at the end (96 h) of the test;
- The measured concentrations at the beginning varied from 13% to 49% of the nominal concentrations;
- The measured concentrations were 0% from of the nominal concentrations at the end of the 96-hour experiment;
- The effect concentrations were based on nominal concentrations and you did report the results (NOELR and EL50) obtained at 72 and 96h based on the growth rate and cell number;

- The measured test concentration of the substance was reported as a percentual share of the nominal concentration (one value at the beginning and end);
- A preliminary range finding study with initial loading rates of test substance and that the results were used to determine the conditions for the definitive study.

For the study ii. you report:

- Growth rates for each replicate and their averages in number of cells for all concentrations and control (measured via flow cytometry) and inhibition reported as area under the curve and growth rate between 0 and 72 h and 0 and 96 h;
- Some increase in area under the growth curve at both 72 and 96 h;
- The measured test substance concentrations only at the beginning (0 h) and at the end (96 h) of the test;
- The measured concentrations at the beginning varied from 18% to 403% of the nominal concentrations;
- The measured concentrations were 0% from of the nominal concentrations at the end of the 96-hour experiment;
- The effect concentrations were based on nominal concentrations and you did report the results (NOELR and EL50) obtained at 72 and 96h based on the growth rate and cell number;
- The measured test concentration of the substance was reported as a percentual share of the nominal concentration (one value at the beginning and end);
- A preliminary range finding study with initial loading rates of test substance and that the results were used to determine the conditions for the definitive study.

For the study iii. you report:

- Growth rates for each replicate and their averages in number of cells for all concentrations and control (measured via flow cytometry) and inhibition reported as area under the curve and growth rate between 0 and 72 h and 0 and 96 h;
- Some increase in growth rate at both 72 and 96 h;
- The measured concentrations at the beginning of the test varied between 99 to 69 % of the nominal concentrations;
- The measured concentrations were of 41 up to 66 % of the nominal initial concentrations applied, at the end of the 96 hour experiment;
- The effect concentrations were based on nominal concentrations and you did report the results (NOELR and EL50) obtained at 72 and 96 h based on the growth rate and cell number;
- The measured test concentration of the substance was reported as a percentual share of the nominal concentration (one value at the beginning and end);
- You report a preliminary range finding study with initial loading rates of test substance and that the results were used to determine the conditions for the definitive study.

As you have not provided the results of algal biomass determined in each flask at 24 hour intervals, the variability between replicates for the entire duration of the testing, or information to show a variation factor of less than 35%, it is not possible to verify that the validity criteria of OECD TG 201 were met.

In addition, you have provided information indicating that exposure was not stable from the beginning of the experiment. However, you have not conducted measurement at 24 hours intervals. Therefore, the information provided does not support that effect values can be based on nominal concentrations for both studies.

Furthermore, with regard to OECD GD 23, you have reported that a preliminary range-finding study was performed before the definitive study. However, detailed information on the test concentrations during the 24-hour intervals or possibility of losses during sampling, sample treatment analysis and the stability under storage conditions of the preliminary study were not assessed and documented.

Therefore, the information requirement is not fulfilled.

Study design

As already explained above, the Substance is difficult to test. OECD TG 201 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. Therefore, you must fulfil the requirements described in 'Study design' under Section A.3.

Appendix B: Reasons to request information required under Annex VIII of REACH

1. Short-term toxicity testing on fish

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

You have provided four key studies using OECD Guideline 203 (Fish, Acute Toxicity Testing) by [redacted] 2001:

i. [redacted] (TEGDB, EC:204-408-1): Acute Toxicity for Rainbow Trout (*Oncorhynchus mykiss*);
ii. [redacted] (TEGDB, EC:204-408-1): Acute Toxicity to Fathead Minnow (*Pimephales promelas*);
iii. [redacted] (DEGDB, EC: 204-407-6): Acute Toxicity for Rainbow Trout (*Oncorhynchus mykiss*);
iv. Dipropyleneglycol dibenzoate (DPGDB, EC: 248-258-5): Acute Toxicity for Fathead Minnow (*Pimephales promelas*).

We have assessed this information and identified the following issues:

To fulfil the information requirement, a study must comply with OECD TG 203 and the requirements of OECD GD 23 (ENV/JM/MONO(2000)6/REV1) if the substance is difficult to test (Article 13(3) of REACH). Therefore, the following requirements must be met:

- Effect concentrations should be based on the measured values rather than nominal values unless the test concentrations are maintained within ± 20 % of the nominal: if this requirement is not met, analysis of the highest and lowest test concentrations and a concentration around the expected LC50 is considered the minimum requirement.

Your registration dossier provides for the key studies i, ii and iii performed according to the OECD TG 203 the following:

For the study i. you report:

- At the beginning of the test the measured concentrations of the test substance varied from 14% to 55% of the nominal concentrations;
- After 24 hours of exposure the measured concentrations of the test substance varied from 0 to 4% of the nominal concentrations;
- The effect concentrations were based on nominal concentrations.

For the study ii. you report:

- At the beginning of the test the measured concentrations of the test substance varied from 11% to 65% of the nominal concentrations;
- After 24 hours of exposure the measured concentrations of the test substance were 0% of the nominal concentrations;
- The effect concentrations were based on nominal concentrations.

For the study iii. you report:

- At the beginning of the test the measured concentrations of the test substance varied from 45% to 87% of the nominal concentrations;

- After 24 hours of exposure the measured concentrations of the test substance varied form 13 to 73% of the nominal concentrations;
- The effect concentrations were based on nominal concentrations.

Regarding the requirements of OECD TG 203, the measured concentrations of the test material(s) were not maintained within the required 20% of the initial concentrations at semi-static test conditions in the studies i, ii, and iii as explained above. However, the effective concentrations were based on nominal concentrations. As a result the key studies i, ii and iii are not considered as valid.

Therefore, the information requirement is not fulfilled.

Study design

OECD TG 203 specifies that for difficult to test substances OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design' under Section A.3.

Appendix C: Reasons to request information required under Annex IX of REACH

1. Long-term toxicity testing on aquatic invertebrates and 2. Long-term toxicity testing on fish

Long-term toxicity testing on aquatic invertebrates and on fish are standard information requirement in Annex IX to the REACH Regulation.

- You have adapted this information requirement based on Annex IX, Section 9.1.5 and 9.1.6., Column 2 with the following justifications:

  For data waiving concerning long-term testing in invertebrates:
  "In Annex IX of Regulation (EC) No 1907/2006, it is laid down that long-term toxicity testing shall be proposed by the registrant if the chemical safety assessment indicates the need to investigate further the effects on aquatic organisms. According to Annex I of this regulation, the chemical safety assessment triggers further action when the substance or the preparation meets the criteria for classification as dangerous according to Directive 67/548/EEC or Directive 1999/45/EC or is assessed to be a PBT or vPvB. The hazard assessment of this substance reveals neither a need to classify the substance as dangerous for the environment, nor is it a PBT or vPvB substance. Therefore a long-term toxicity study with invertebrates is not proposed."

  For data waiving concerning long-term testing in fish:
  "In Annex IX of Regulation (EC) No 1907/2006, it is laid down that long-term toxicity testing shall be proposed by the registrant if the chemical safety assessment indicates the need to investigate further the effects on aquatic organisms. According to Annex I of this regulation, the chemical safety assessment triggers further action when the substance or the preparation meets the criteria for classification as dangerous according to Directive 67/548/EEC or Directive 1999/45/EC or is assessed to be a PBT or vPvB. The hazard assessment of this substance reveals neither a need to classify the substance as dangerous for the environment, nor is it a PBT or vPvB substance. Therefore, and for animal welfare reasons, a long-term toxicity study in fish is not proposed."

We have assessed this information and identified the following issues:

To adapt this information requirement the Chemical Safety Assessment (CSA) must demonstrate that risks towards the aquatic compartment arising from the manufacture and use of the Substance are controlled (Annex IX, Section 9.1., Column 2; Annex I, Section 0.1). The justification must be documented in the Chemical Safety Report (CSR) and include all of the following elements:

- the predicted no effect concentrations (PNEC) for the aquatic compartment is based on:
  - reliable information on the hazardous properties of the Substance on at least three trophic levels, and
  - an appropriate assessment factor as explained in ECHA Guidance R.10, Section R.10.3), and
- an exposure assessment leading to derivation of predicted environmental concentrations (PECs),
- the outcome of the risk characterisation demonstrating that the risks are adequately controlled (*i.e.* PEC < PNEC).

For the reasons explained under request A3.-4. and B1., your technical dossier does not include adequate hazard information for the Substance. Such information includes reliable data on short-term toxicity on at least three trophic level or on long-term toxicity on at least

one trophic level (fish or Daphnia) if it has been generated. Hence, a reliable PNEC cannot be derived for your substance. Therefore, your adaptation is rejected.

Without this information your CSA does not demonstrate that the risks of the Substance are adequately controlled for the aquatic compartment. As a consequence, your adaptation is rejected as it does not meet the specific rules for adaptation of Annex IX, Section 9.1., Column 2.

On this basis, your adaptation is rejected.

Therefore, the information requirement is not fulfilled.

Study design :

OECD TG 211 and 210 specify that for difficult to test substances OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design' under Section A3-4 and B1.

Appendix D: Reasons to request information required under Annex X of REACH

1. Pre-natal developmental toxicity study in a second species

Pre-natal developmental toxicity (PNDT) studies (OECD TG 414) in two species is a standard information requirement under Annex X to REACH.

No specific testing was performed on the Substance, which is a reaction mass of Diethylene glycol dibenzoate (DEGDB) and Triethylene Glycol Dibenzoate (TEGDB) and oxydipropyl dibenzoate (DPGDB). However, in your registration dossier you provided a prenatal developmental toxicity study in a second species (rabbit) with DPGDB EC no. 248-258-5, that is one of the constituents of the Substance.

We have assessed this information and identified the following issue:

Annex XI, Section 1.5 requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must provide a justification for the read-across including a hypothesis, explanation of the rationale for the prediction of properties and robust study summary(ies) of the source study(ies).[2]

You provided information on a substance (DPGDB) other than your Substance, in order to comply with the REACH information requirements. You have not provided documentation as to why this information is relevant for your Substance.

In the absence of such documentation, ECHA cannot verify that the properties of your Substance can be predicted from the data on the source substance, which is only one of the constituents of the Substance.

Therefore, the information requirement is not fulfilled.

Information on study design

A PNDT study according to the OECD TG 414 study should be performed in the rabbit or rat as the preferred species. The test in the first species was carried out by using a rodent species (rat). Therefore, a PNDT study in a second species must be performed in the rabbit as preferred non-rodent species.

The study shall be performed with oral[3] administration of the Substance.

[2] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.6.1
[3] ECHA Guidance R.7a, Section R.7.6.2.3.2.

Appendix E: Requirements to fulfil when conducting and reporting new tests for REACH purposes

A. Test methods, GLP requirements and reporting

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

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

3. 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 on How to report robust study summaries[4].

B. Test material

Before generating new data, you must agree within the joint submission on the chemical composition of the material to be tested (Test Material) which must be relevant for all the registrants of the Substance.

1. Selection of the Test material(s)

   The Test Material used to generate the new data must be selected taking into account the following:
   - the variation in compositions reported by all members of the joint submission,
   - the boundary composition(s) of the Substance,
   - 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.

2. Information on the Test Material needed in the updated dossier
   - You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
   - The reported composition must include all constituents of each Test Material and their concentration values and other parameters relevant for the property to be tested.

This information is needed to assess whether the Test Material is relevant for the Substance and whether it is suitable for use by all members of the joint submission.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[5].

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

Appendix F: General recommendations when conducting and reporting new tests for REACH purposes

A. Testing strategy for aquatic toxicity testing

You are advised to consult ECHA Guidance R.7b, (Section R.7.8.5) which describes the Integrated Testing Strategy, to determine the sequence of aquatic toxicity tests and testing needed.

B. Environmental testing for substances containing multiple constituents

Your Substance contains multiple constituents and, as indicated in ECHA Guidance R.11 (Section R.11.4.2.2), you are advised to consider the following approaches for persistency, bioaccumulation and aquatic toxicity testing:

- the "known constituents approach" (by assessing specific constituents), or
- the "fraction/block approach, (performed on the basis of fractions/blocks of constituents), or
- the "whole substance approach", or
- various combinations of the approaches described above

Selection of the appropriate approach must take into account the possibility to characterise the Substance (i.e. knowledge of its constituents and/or fractions and any differences in their properties) and the possibility to isolate or synthesize its relevant constituents and/or fractions.

Appendix G: Procedure

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

ECHA followed the procedure detailed in Articles 50 and 51 of REACH.

The compliance check was initiated on 08 January 2020.

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

ECHA did not receive any comments within the notification period.

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 H: List of references - ECHA Guidance[6] and other supporting documents

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 where relevant.

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 where relevant.

Read-across assessment framework (RAAF, March 2017)[7]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[7]

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.

Data sharing
Guidance on data-sharing (version 3.1, January 2017), referred to as ECHA Guidance on data sharing in this decision.

OECD Guidance documents[8]

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

Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

Guidance document on transformation/dissolution of metals and metal compounds in aqueous media – No 29, referred to as OECD GD 29.

Guidance Document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption – No 150, referred to as OECD GD 150.

Guidance Document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test – No 151, referred to as OECD GD 151.

Appendix I: Addressees of this decision and the corresponding information requirements applicable to them

You must provide the information requested in this decision for all REACH Annexes applicable to you.

Registrant Name	Registration number	Highest REACH Annex applicable to you
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.