

Helsinki, 30 March 2023

Addressees

Registrant(s) of Diamines_quaternized_C16-18 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision

10/02/2022

Registered substance subject to this decision ("the Substance")

Substance name: Quaternary ammonium compounds, N-(C16-18 and C18-unsatd. alkyl)-N,N,N',N',N'-pentamethyltrimethylenedi-, dichlorides
EC number: 629-716-7

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

DECISION ON TESTING PROPOSAL(S)

Under Article 40 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by **5 January 2027**.

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

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

1. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method: EU C.25./OECD TG 309) at a temperature of 12°C. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and solvents must be provided.
2. Soil simulation testing (Annex IX, Section 9.2.1.3.; test method: EU C.23./OECD TG 307) at a temperature of 12°C. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and solvents must be provided.
3. Sediment simulation testing (Annex IX, Section 9.2.1.4.; test method: EU C.24./OECD TG 308) at a temperature of 12°C. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and solvents must be provided.
4. Identification of degradation products (Annex IX, 9.2.3.; test method: using test methods OECD TG 309, OECD TG 308 and OECD TG 307)

The reasons for the decision(s) are explained in Appendix 1.

Information required depends on your tonnage band

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

their corresponding information requirements based on registered tonnage band are listed in Appendix 3.

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 requirements for testing and reporting new tests under REACH, see Appendix 4. In addition, the studies relating to biodegradation and bioaccumulation are necessary for the PBT assessment. However, to determine the testing needed to reach the conclusion on the persistency and bioaccumulation of the Substance you should consider the sequence in which these tests are performed and other conditions described in this Appendix.

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.

Authorised¹ under the authority of Mike Rasenberg, Director of Hazard Assessment

Appendix 1: Reasons for the decision

Appendix 2: Procedure

Appendix 3: Addressees of the decision and their individual information requirements

Appendix 4: Conducting and reporting new tests under REACH

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 for the decision

Contents

Reasons for the decision(s) related to the information under Annex IX of REACH	4
1. Simulation testing on ultimate degradation in surface water	4
2. Soil simulation testing.....	5
3. Sediment simulation testing	7
4. Identification of degradation products	9
References	11

Reasons for the decision(s) related to the information under Annex IX of REACH**1. Simulation testing on ultimate degradation in surface water**

- 1 Simulation testing on ultimate degradation in surface water is an information requirement under Annex IX to REACH (Section 9.2.1.2.).
- 2 Simulation testing on ultimate degradation in surface water does not need to be conducted if the substance is highly insoluble in water or is readily biodegradable (Annex IX, Section 9.2.1.2, column 2).
- 3 In your technical dossier, you have provided information showing that:
- the Substance is well soluble (critical micelle concentration of 790 mg/L based on OECD TG 115)
 - the Substances is not readily biodegradable (28 % biodegradation after 28 days based on OECD 301D)
- 4 Therefore, the Substance is considered to be well soluble and not readily biodegradable and information on Simulation testing on ultimate degradation in surface water must be provided.

1.1. Information provided to fulfil the information requirement

- 5 You have submitted a testing proposal for an Aerobic mineralisation in Surface Water – Simulation biodegradation test (test method: EU C.25/OECD TG 309). In your testing proposal you further specify that “OECD TG 309 is the preferred first biodegradation simulation study”. In support of your testing proposal, you provided the following justification:
- *The aquatic compartment is considered to be the most relevant environmental compartment due to the large global volume of water: by default water compartment receives significant amount of emissions directly or indirectly, and transports/distributes the substance through e.g. deposition and run-off.*
 - *Based on the relatively high water solubility of [REDACTED] of 790 mg/L (pH 7, 23°C) it is considered that the water compartment is the most relevant environmental compartment.*
 - *Sorption of cationic surfactants can result in the formation of NER. The OECD TG 309 pelagic (with a default concentration of suspended solids of 15 mgdw/L) minimizes potential NER formation.*
 - *OECD TG 309 is conducted under aerobic conditions. This is considered as a relevant test condition as P assessment should first consider aerobic degradation.*

- 6 Your registration dossier does not include any information on aerobic transformation in aquatic surface water systems.
- 7 ECHA agrees that an appropriate degradation simulation study in surface water is needed.

1.2. Test selection and study specifications

- 8 The proposed Aerobic mineralisation in Surface Water – Simulation biodegradation test (test method: EU C.25/OECD TG 309) is appropriate to cover the information requirement for degradation/biodegradation (Guidance on IRs and CSA, Section R.7.9.4.1).

- 9 Simulation degradation studies must include two types of investigations (Guidance on IRs and CSA, Section R.7.9.4.1.):
- 1) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and
 - 2) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.
- 10 You must perform the test, by following the pelagic test option with natural surface water containing approximately 15 mg dw/L of suspended solids (acceptable concentration between 10 and 20 mg dw/L) (Guidance on IRs and CSA, Section R.11.4.1.1.3.).
- 11 The required test temperature is 12°C, which corresponds to the average environmental temperature for the EU (Guidance on IRs and CSA, Section R.16, Table R.16-8) and is in line with the applicable test conditions of the OECD TG 309.
- 12 As specified in Guidance on IRs and CSA, Section R.7.9.4.1., the organic carbon (OC) concentration in surface water simulation tests is typically 2 to 3 orders of magnitude higher than the test substance concentration and the formation of non-extractable residues (NERs) may be significant in surface water tests. Therefore, non-extractable residues (NER) must be quantified. The reporting of results must include a scientific justification of the used extraction procedures and solvents. By default, total NER is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER, such fractions could be regarded as removed when calculating the degradation half-life(s) (Guidance on IRs and CSA, Section R.11.4.1.1.3.). Further recommendations may be found in the background note on options to address non-extractable residues in regulatory persistence assessment available on the ECHA website.
- 13 Relevant transformation/degradation products are at least those detected at $\geq 10\%$ of the applied dose at any sampling time or those that are continuously increasing during the study even if their concentrations do not exceed 10% of the applied dose, as this may indicate persistence (OECD TG 309; Guidance on IRs and CSA, Section R.11.4.1.).

1.3. Outcome

- 14 Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test, as specified above.
- 15 In the comments to the draft decision, you agree with the request.

2. Soil simulation testing

- 16 Soil simulation testing is an information requirement under Annex IX to REACH (Section 9.2.1.3.) for substances with a high potential for adsorption to soil.
- 17 Substances with a $\log K_{oc} > 4$ are considered to have a high potential for adsorption to soil (Guidance on IRs and CSA, Section R.7.9.4.3.).
- 18 The Substance has a high adsorption coefficient ($\log K_{oc}$ of 6) and is ionisable and therefore has high potential for adsorption to soil. Furthermore, you indicate that due to the cationic surface-active properties, the Substance will adsorb strongly onto the solid phase of soil and sediments.

- 19 You have submitted a testing proposal for water simulation testing only. In case of data gap for soil simulation study, it is necessary to request this information as an additional test to ensure compliance with the endpoint.

2.1. Information provided to fulfil the information requirement

- 20 You have omitted this information requirement with the following justification:

"OECD TG 307 would, considering the [REDACTED], be the second biodegradation simulation study to consider but based on the high expected NER formation not the first choice as it is expected that similar results are found in the simulation study according to OECD TG 309 and that these results can be interpreted so that a conclusion on the persistency can be derived on the remaining compartment(s)".

- 21 We have assessed this information and identified the following issues:

- 22 A registrant may only adapt this information requirement based on the general rules set out in Annex XI or the specific rules set out in Annex IX, Section 9.2.1.3., Column 2.

- 23 Your justification to omit this information does not refer to any legal ground for adaptation under Annex XI to REACH or Annex IX, Section 9.2.1.3., Column 2.

- 24 Moreover, results from a single simulation study cannot be directly extrapolated to other environmental compartments (Guidance on IRs & CSA R.11 on PBT assessment). As explained below in Appendix 4, section 2.1, you are advised to consult Guidance on IRs & CSA, Sections R.7.9, R.7.10 and R.11 on PBT assessment to determine the sequence of the tests needed to reach the conclusion on PBT/vPvB. The guidance provides advice on 1) integrated testing strategies (ITS) for the P, B and T assessments and 2) the interpretation of results in concluding whether the Substance fulfils the PBT/vPvB criteria of Annex XIII.

- 25 Therefore, you have not demonstrated that this information can be omitted. On this basis, the information requirement is not fulfilled.

2.2. Test selection and study specifications

- 26 The Aerobic and Anaerobic Transformation in soil test (test method: EU C.23/OECD TG 307) is appropriate to cover the information requirement for degradation/biodegradation (Guidance on IRs and CSA, Section R.7.9.4.1).

- 27 Simulation degradation studies must include two types of investigations (Guidance on IRs and CSA, Section R.7.9.4.1.):

- 1) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and
- 2) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.

- 28 In accordance with the specifications of OECD TG 307, you must perform the test using at least four soils representing a range of relevant soils (i.e. varying in their organic content, pH, clay content and microbial biomass).

- 29 The required test temperature is 12°C, which corresponds to the average environmental temperature for the EU (Guidance on IRs and CSA, Section R.16, Table R.16-8) and is in line with the applicable test conditions of the OECD TG 307.

- 30 In accordance with the specifications of OECD TG 307, non-extractable residues (NER) must be quantified. The reporting of results must include a scientific justification of the used extraction procedures and solvents (Guidance on IRs and CSA, Section R.7.9.4.1.). By default, total NER is regarded as non-degraded Substance. However, if reasonably justified

and analytically demonstrated a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER, such fractions could be regarded as removed when calculating the degradation half-life(s) (Guidance on IRs and CSA, Section R.11.4.1.1.3.). Further recommendations may be found in the background note on options to address non-extractable residues in regulatory persistence assessment available on the ECHA website.

- 31 Relevant transformation/degradation products are at least those detected at $\geq 10\%$ of the applied dose at any sampling time or those that are continuously increasing during the study even if their concentrations do not exceed 10% of the applied dose, as this may indicate persistence (OECD TG 307; Guidance on IRs and CSA, Section R.11.4.1.).

2.3. Outcome

- 32 Under Article 40(3)(c) of REACH, ECHA may require a registrant to carry out one or more additional tests in case of non-compliance of the testing proposal with Annexes IX, X or XI of the REACH Regulation. The information requirement on Degradation (Section 9.2.) at Annex IX covers Biotic degradation (Section 9.2.1.) and Identification of degradation products (Section 9.2.3.) for the Substance. However, you have submitted testing proposals for water simulation testing only. As explained above, the information requirement for soil simulation testing is not fulfilled. Therefore, under Article 40(3)(c), you are requested to conduct the additional test, as specified above.
- 33 In the comments to the draft decision, you agree with the request. Furthermore, you indicate your intention to follow an integrated testing strategy (ITS) for the P, B and T assessments, including sequential simulation degradation testing.

3. Sediment simulation testing

- 34 Sediment simulation testing is an information requirement under Annex IX to REACH (Section 9.2.1.4.) for substances with a high potential for adsorption to sediment.
- 35 Substances with a $\log K_{oc} > 4$ are considered to have a high potential for adsorption to sediment (Guidance on IRs and CSA, Section R.7.9.4.3.).
- 36 You have submitted a testing proposal for water simulation testing only. In case of data gap for sediment simulation study, it is necessary to request this information as an additional test to ensure compliance with the endpoint.
- 37 For the reasons already explained under request 2, the Substance is considered to have a high potential to adsorb to sediments and information on Sediment simulation testing must be provided.

3.1. Information provided to fulfil the information requirement

- 38 You have omitted this information requirement with the following justification: " The OECD TG 309 study is planned and it is expected that these results can be interpreted so that a conclusion on the persistency can be derived on the remaining compartment(s)." You further consider that the persistency of the Substance in the sediment compartment can be "read-across" from the proposed simulation study in water (OECD TG 309).
- 39 We have assessed this information and identified the following issues:
- 40 A registrant may only adapt this information requirement based on the general rules set out in Annex XI or the specific rules set out in Annex IX, Section 9.2.1.3., Column 2.

- 41 Your justification to omit this information does not refer to any legal ground for adaptation under Annex XI to REACH or Annex IX, Section 9.2.1.3., Column 2.
- 42 Moreover, results from a single simulation study cannot be directly extrapolated (or “read-across”) to other environmental compartments (Guidance on IRs & CSA R.11 on PBT assessment). As explained below in Appendix 4, section 2.1, you are advised to consult Guidance on IRs & CSA, Sections R.7.9, R.7.10 and R.11 on PBT assessment to determine the sequence of the tests needed to reach the conclusion on PBT/vPvB. The guidance provides advice on 1) integrated testing strategies (ITS) for the P, B and T assessments and 2) the interpretation of results in concluding whether the Substance fulfils the PBT/vPvB criteria of Annex XIII.
- 43 Therefore, you have not demonstrated that this information can be omitted.
- 44 On this basis, the information requirement is not fulfilled.

3.2. Test selection and study specifications

- 45 The Aerobic and Anaerobic Transformation in Aquatic Sediment Systems test (test method: OECD TG 308/ EU C.24) is appropriate to cover the information requirement for degradation/biodegradation (Guidance on IRs and CSA, Section R.7.9.4.1).
- 46 Simulation degradation studies must include two types of investigations (Guidance on IRs and CSA, Section R.7.9.4.1.):
- 1) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and
 - 2) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.
- 47 In accordance with the specifications of OECD TG 308, you must perform the test using two sediments. One sediment should have a high organic carbon content (2.5-7.5%) and a fine texture, the other sediment should have a low organic carbon content (0.5-2.5%) and a coarse texture. If the Substance may also reach marine waters, at least one of the water-sediment systems should be of marine origin.
- 48 The required test temperature is 12°C, which corresponds to the average environmental temperature for the EU (Guidance on IRs and CSA, Section R.16, Table R.16-8) and is in line with the applicable test conditions of the OECD TG 309.
- 49 In accordance with the specifications of OECD TG 308, non-extractable residues (NER) must be quantified. The reporting of results must include a scientific justification of the used extraction procedures and solvents (Guidance on IRs and CSA, Section R.7.9.4.1.). By default, total NER is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER, such fractions could be regarded as removed when calculating the degradation half-life(s) (Guidance on IRs and CSA, Section R.11.4.1.1.3.). Further recommendations may be found in the background note on options to address non-extractable residues in regulatory persistence assessment available on the ECHA website.
- 50 Relevant transformation/degradation products are at least those detected at $\geq 10\%$ of the applied dose at any sampling time or those that are continuously increasing during the study even if their concentrations do not exceed 10% of the applied dose, as this may indicate persistence (OECD TG 308; Guidance on IRs and CSA, Section R.11.4.1.).

3.3. Outcome

- 51 Under Article 40(3)(c) of REACH, ECHA may require a registrant to carry out one or more additional tests in case of non-compliance of the testing proposal with Annexes IX, X or XI of the REACH Regulation. The information requirement on Degradation (Section 9.2.) at Annex IX covers Biotic degradation (Section 9.2.1.) and Identification of degradation products (Section 9.2.3.) for the Substance. However, you have submitted testing proposals for water simulation testing only. As explained above, the information requirement for sediment simulation testing is not fulfilled. Therefore, under Article 40(3)(c), you are requested to conduct the additional test, as specified above.
- 52 In the comments to the draft decision, you agree with the request. Furthermore, you indicate your intention to follow an integrated testing strategy (ITS) for the P, B and T assessments, including sequential simulation degradation testing.

4. Identification of degradation products

- 53 Identification of degradation products is an information requirement under Annex IX to REACH (Section 9.2.3.).

4.1. Information provided to fulfil the information requirement

- 54 You have submitted a testing proposal for identification of degradation products.
- 55 You propose to identify degradation products in conjunction with Aerobic mineralisation in Surface Water – Simulation biodegradation test (test method: EU C.23/OECD TG 309).
- 56 You have provided no information on the identity of transformation/degradation products for the Substance.
- 57 ECHA agrees that an identification of degradation products is needed.

4.2. Test selection and study specifications

- 58 Simulation degradation studies must include two types of investigations (Guidance on IRs and CSA, Section R.7.9.4.1.):
- (1) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and
 - (2) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.
- 59 Identity, stability, behaviour, and molar quantity of the degradation/transformation products relative to the Substance must be evaluated and reported. In addition, identified transformation/degradation products must be considered in the CSA including PBT assessment.
- 60 You have submitted testing proposal for water simulation testing only. As explained above, the information requirement for soil simulation testing (Request 2) and sediment simulation testing (Request 3) are not fulfilled.
- 61 Therefore, the proposed test design to identify degradation products in conjunction with OECD TG 309 study alone cannot be accepted to fulfil the information requirement and you must obtain information on identity of degradation products from the degradation studies requested in requests 1, 2 and 3.
- 62 To determine the degradation rate of the Substance, the requested study according to OECD TG 309 (request 1) must be conducted at 12°C and at a test concentration < 100 µg/L.

However, to overcome potential analytical limitations with the identification and quantification of major transformation/degradation products, you may consider running a parallel test at higher temperature (but within the frame provided by the test guideline, e.g. 20°C) and at higher application rate (i.e. > 100 µg/L).

- 63 To determine the degradation rate of the Substance, the requested studies according to OECD TG 308 and 307 (requests 2 and 3) must be conducted at 12°C and at test material application rates reflecting realistic assumptions. However, to overcome potential analytical limitations with the identification and quantification of major transformation/degradation products, you may consider running a parallel test at higher temperature (but within the frame provided by the test guideline) and at higher application rate (e.g. 10 times).

4.3. Outcome

- 64 Under Article 40(3)(b) of REACH, your testing proposal is accepted under modified conditions as specified above.
- 65 In the comments to the draft decision, you agree with the request. Furthermore, you indicate your intention to follow an integrated testing strategy (ITS) for the P, B and T assessments, including sequential simulation degradation testing.

References

The following documents may have been cited in the decision.

Guidance on information requirements and chemical safety assessment (Guidance on IRs & CSA)

- Chapter R.4 Evaluation of available information; ECHA (2011).
Chapter R.6 QSARs, read-across and grouping; ECHA (2008).
Appendix to Chapter R.6 for nanoforms; ECHA (2019).
Chapter R.7a Endpoint specific guidance, Sections R.7.1 – R.7.7; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Chapter R.7b Endpoint specific guidance, Sections R.7.8 – R.7.9; ECHA (2017).
Appendix to Chapter R.7b for nanomaterials; ECHA (2017).
Chapter R.7c Endpoint specific guidance, Sections R.7.10 – R.7.13; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Appendix R.7.13-2 Environmental risk assessment for metals and metal compounds; ECHA (2008).
Chapter R.11 PBT/vPvB assessment; ECHA (2017).
Chapter R.16 Environmental exposure assessment; ECHA (2016).

Guidance on data-sharing; ECHA (2017).

Guidance for monomers and polymers; ECHA (2023).

Guidance on intermediates; ECHA (2010).

All guidance documents are available online: <https://echa.europa.eu/guidance-documents/guidance-on-reach>

Read-across assessment framework (RAAF)

- RAAF, 2017 Read-across assessment framework (RAAF); ECHA (2017)
RAAF UVCB, 2017 Read-across assessment framework (RAAF) – considerations on multi- constituent substances and UVCBs; ECHA (2017).

The RAAF and related documents are available online:

<https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across>

OECD Guidance documents (OECD GDs)

- OECD GD 23 Guidance document on aquatic toxicity testing of difficult substances and mixtures; No. 23 in the OECD series on testing and assessment, OECD (2019).
OECD GD 29 Guidance document on transformation/dissolution of metals and metal compounds in aqueous media; No. 29 in the OECD series on testing and assessment, OECD (2002).
OECD GD 150 Revised guidance document 150 on standardised test guidelines for evaluating chemicals for endocrine disruption; No. 150 in the OECD series on testing and assessment, OECD (2018).
OECD GD 151 Guidance document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test; No. 151 in the OECD series on testing and assessment, OECD (2013).

Appendix 2: Procedure

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 10 March 2022.

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

The deadline of the decision is set based on standard practice for carrying out OECD TG tests. It has been exceptionally extended by 12 months from the standard deadline granted by ECHA to take into account currently longer lead times in contract research organisations.

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

In your comments you agreed to the draft decision. ECHA took your comments into account and did not amend the requests.

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 3: Addressees of this decision and their corresponding information requirements

In accordance with Articles 10(a) and 12(1) of REACH, the information requirements for individual registrations are defined as follows:

- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa;

Registrant Name	Registration number	Highest REACH Annex applicable to you

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.

Appendix 4: Conducting and reporting new tests for REACH purposes

1. Requirements when conducting and reporting new tests for REACH purposes

1.1. 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 summaries².

1.2. 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.

Selection of the Test material(s)

The Test Material used to generate the new data must be selected taking into account the following:

- a) the variation in compositions reported by all members of the joint submission,
- b) the boundary composition(s) of the Substance,
- c) 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.

Information on the Test Material needed in the updated dossier

- a) 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.
- b) The reported composition must include the careful identification and description of the characteristics of the Tests Materials in accordance with OECD GLP (ENV/MC/CHEM(98)16) and EU Test Methods Regulation (EU) 440/2008 (Note, Annex), namely all the constituents must be identified as far as possible as well as their concentration. Also any constituents that have harmonised classification and labelling according to the CLP Regulation must be identified and quantified using the appropriate analytical methods,

With that detailed information, ECHA can confirm whether the Test Material is relevant

² <https://echa.europa.eu/practical-guides>

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 (<https://echa.europa.eu/manuals>).

2. General recommendations for conducting and reporting new tests

2.1. Strategy for the PBT/vPvB assessment

Under Annex XIII, the information must be based on data obtained under conditions relevant for the PBT/vPvB assessment. You must assess the PBT properties of each relevant constituent of the Substance present in concentrations at or above 0.1% (w/w) and of all relevant transformation/degradation products. Alternatively, you would have to justify why you consider these not relevant for the PBT/vPvB assessment.

You are advised to consult Guidance on IRs & CSA, Sections R.7.9, R.7.10 and R.11 on PBT assessment to determine the sequence of the tests needed to reach the conclusion on PBT/vPvB. The guidance provides advice on 1) integrated testing strategies (ITS) for the P, B and T assessments and 2) the interpretation of results in concluding whether the Substance fulfils the PBT/vPvB criteria of Annex XIII.

In particular, you are advised to first conclude whether the Substance fulfils the Annex XIII criteria for P and vP, and then continue with the assessment for bioaccumulation. When determining the sequence of simulation degradation testing you are advised to consider the intrinsic properties of the Substance, its identified uses and release patterns as these could significantly influence the environmental fate of the Substance. You must revise your PBT assessment when the new information is available.

2.2. Environmental testing for substances containing multiple constituents

Your Substance contains multiple constituents and, as indicated in Guidance on IRs & CSA, 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.

References to Guidance on REACH and other supporting documents can be found in Appendix 1.