~~Confidential~~

Helsinki, 11 August 2021

Addressees
Registrants of CEM JS 85-60-9 listed in the last Appendix of this decision

Date of submission of the dossier subject of a decision
20/05/2020

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: 6,6'-di-tert-butyl-4,4'-butylidenedi-m-cresol
EC number: 201-618-5
CAS number: 85-60-9

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)

Based on Article 40 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by ***16 November 2023***.

The requested information must be generated using the Substance unless otherwise specified.

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

1. Soil simulation testing also requested below (triggered by Annex VIII, Section 9.2., column 2)

2. Sediment simulation testing also requested below (triggered by Annex VIII, Section 9.2., column 2)

3. Identification of degradation products also requested below (triggered by Annex VIII, Section 9.2., column 2)

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

1. 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.

2. 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.

3. Identification of degradation products (Annex IX, 9.2.3.; test method: using an appropriate test method)

Reasons for the request(s) are explained in the following appendices entitled "Reasons to request information required under Annexes VIII to IX 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 and VIII to REACH, for registration at 10-100 tpa;
- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa.

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

For certain endpoints, ECHA requests the same study from registrants at different tonnages. In such cases, only the reasoning why the information is required at lower tonnages is provided in the corresponding Appendices. For the tonnage where the study is a standard information requirement, the full reasoning for the request including study design is given. Only one study is to be conducted; the registrants concerned must make every effort to reach an agreement as to who is to carry out the study on behalf of the other registrants under Article 53 of REACH.

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".

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 Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes".

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 to request information required under Annex VIII of REACH

This decision is based on the examination of the testing proposals you submitted.

1. Soil simulation testing

Further degradation testing must be considered if the chemical safety assessment (CSA) according to Annex I indicates the need to investigate further the degradation of the substance (Annex VIII, Section 9.2., Column 2).

Annex I, Section 4 requires that the CSA includes the PBT (persistent, bioaccumulative and toxic) and vPvB (very persistent and very bioaccumulative) assessments. In accordance with Annex XIII, Section 2.1., if the result of the screening tests or other information indicate that the substance may have PBT or vPvB properties, further testing on degradation as set out in Section 3.2 is required. In case the generation of relevant additional information would require information listed in Annexes IX or X, the registrant must submit a testing proposal.

In accordance with Annex XIII and ECHA Guidance R.11.4, a substance is considered a potential PBT/vPvB substance if the Substance itself or any of its constituent or impurity present in concentration ≥ 0.1% (w/w) or relevant transformation/degradation product meets the following criteria:

- it is potentially persistent or very persistent (P/vP) as it is not readily biodegradable (*i.e.* <60% degradation in an OECD 301B), and
- it is potentially bioaccumulative or very bioaccumulative (B/vB) as it has a high potential to partition to lipid storage (*e.g.* log K_{ow} > 4.5), and
- it meets the T criteria set in Annex XIII: NOEC or EC_{10} < 0.01 mg/L or classification as carc. 1A or 1B, muta. 1A or 1B, repro. 1A, 1B or 2, or STOT RE 1 or 2.

Your registration dossier provides the following:

- The Substance is not readily biodegradable (20% degradation after 28 days in OECD TG 301B);
- The Substance has a high potential to partition to lipid storage (Log K_{ow} of 6.4 based on OECD TG 117). In addition, your registration dossier includes a dietary study on the Substance (based on OECD TG 305), for which the BCF calculations reported in the dossier are flawed due to incorrect input parameters (in particular, the fraction of mean fish lipid during the uptake and depuration phase). Using appropriate input parameters, the OECD BCF Estimation Tool spreadsheet provides BCF values that are mostly well above 2000. Taken together, this information indicates that the Substance might be B or vB;
- The substance meets the T criteria since significant effects were observed in long-term aquatic toxicity studies according to OECD TG 210 and OECD TG 211 supporting that toxicity occurred below the water solubility water limit. Based on the water solubility limit of the substance of <4 µg/L reported in your dossier, the NOEC for both studies are therefore considered to be below the cut-off value to conclude the substance as meeting the T criteria. In addition, as explained in a recent substance evaluation (SEV) decision (communication number: SEV-D-2114534327-50-01/F), the available information on the Substance is currently inconclusive for repeated dose toxicity and toxicity to reproduction.

The information above indicates that the Substance is a potential PBT/vPvB substance. The Substance has low water solubility (< 4 µg/L based on OECD TG 105), high partition coefficient (log Kow 6.4 based on OECD TG 117) and high adsorption coefficient (log Koc of 5.48 based on OECD TG 121), indicating high potential to adsorb to soil.

Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation. Based on the adsorptive properties of the Substance, soil represents a relevant environmental compartment.

The examination of the information provided, your considerations of alternative methods, as well as the selection of the requested test and the test design are addressed under Appendix B.1.

2. Sediment simulation testing

Further degradation testing must be considered if the chemical safety assessment (CSA) according to Annex I indicates the need to investigate further the degradation of the substance (Annex VIII, Section 9.2., Column 2).

Annex I, Section 4 requires that the CSA includes the PBT (persistent, bioaccumulative and toxic) and vPvB (very persistent and very bioaccumulative) assessments. In accordance with Annex XIII, Section 2.1., if the result of the screening tests or other information indicate that the substance may have PBT or vPvB properties, further testing on degradation as set out in Section 3.2 is required. In case the generation of relevant additional information would require information listed in Annexes IX or X, the registrant must submit a testing proposal.

As already explained in Appendix A.1, the information from your dossier indicates that the Substance is a potential PBT/vPvB substance.

Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation.

The Substance has low water solubility (< 4 µg/L based on OECD TG 105), high partition coefficient (log Kow 6.4 based on OECD TG 117) and high adsorption coefficient (log Koc of 5.48 based on OECD TG 121). Based on the adsorptive properties of the Substance, sediment represents a relevant environmental compartment.

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 requires to provide information on Biotic degradation (Section 9.2.1.) on relevant environmental compartments (i.e. surface water, sediment and soil) and on the identity of degradation products (Section 9.2.3.) for the Substance. You have submitted a testing proposal for soil 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.

The examination of the information provided, as well as the selection of the requested test and the test design are addressed under Appendix B.2. Under Article 40(3)(c), you are requested to conduct the additional test with the Substance, as specified in Appendix B.3.

3. Identification of degradation products

Further degradation testing must be considered if the chemical safety assessment (CSA) according to Annex I indicates the need to investigate further the degradation of the substance (Annex VIII, Section 9.2., Column 2).

Annex I, Section 4 requires that the CSA includes the PBT (persistent, bioaccumulative and toxic) and vPvB (very persistent and very bioaccumulative) assessments. In accordance with Annex XIII, Section 2.1., if the result of the screening tests or other information indicate that

the substance may have PBT or vPvB properties, further testing on degradation as set out in Section 3.2 is required. In case the generation of relevant additional information would require information listed in Annexes IX or X, the registrant must submit a testing proposal.

As already explained in Appendix A.1, the information from your dossier indicates that the Substance is a potential PBT/vPvB substance. Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation.

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 requires to provide information on Biotic degradation (Section 9.2.1.) and on the identity of degradation products (Section 9.2.3.) for the Substance. You have submitted a testing proposal for soil simulation testing only. In case of data gap for the identification of degradation products, it is necessary to request this information as an additional test to ensure compliance with the endpoint.

The examination of the information provided, as well as the selection of the requested test and the test design are addressed under Appendix B.3. Under Article 40(3)(c), you are requested to conduct the additional test with the Substance, as specified in Appendix B.3.

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

This decision is based on the examination of the testing proposals you submitted.

1. Soil simulation testing

Sediment 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.

Substances with a log Koc > 4 are considered to have a high potential for adsorption to soil (ECHA Guidance R.7.9.4.3.).

Under IUCLID, section 5.4.1. of your technical dossier, you provided the results of experimental study to meet the information requirement on adsorption/desorption screening. The reported log Koc is 5.48. Therefore, the Substance is considered to have a high potential for adsorption to soil and information on soil simulation testing must be provided.

1.1. Information needed to fulfil the information requirement

You have submitted a testing proposal for an Aerobic and Anaerobic Transformation in soil test (test method: OECD TG 307/ EU C.23). In support of your testing proposal, you provided the following justification:

- *"In accordance with Chapter R.11 – PBT/vPvB assessment, Figure R.11—3: Integrated Testing Strategy for persistence assessment – maximising data use and targeting testing indicates that terrestrial exposure may be the most appropriate route of environmental exposure based on the categories of use. An investigation of effects in this media is therefore proposed."*

Your registration dossier does not include any information on aerobic and anaerobic transformation in soil.

ECHA agrees that an appropriate degradation simulation study in soil is needed.

1.2. Test selection and study specifications

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

Simulation degradation studies must include two types of investigations (ECHA Guidance 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.

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).

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

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 (ECHA Guidance 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) (ECHA Guidance 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.

Relevant transformation/degradation products are at least those detected at ≥ 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; ECHA Guidance R.11.4.1.).

1.3. Outcome

Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test with the Substance, as specified above.

2. Sediment simulation testing

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 soil.

Substances with a log Koc > 4 are considered to have a high potential for adsorption to soil (ECHA Guidance R.7.9.4.3.).

Under IUCLID, section 5.4.1. of your technical dossier, you report a log Koc of 5.48 for the Substance. Therefore, the Substance is considered to have a high potential for adsorption to soil and information on soil simulation testing must be provided.

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 requires to provide information on Biotic degradation (Section 9.2.1.) on relevant environmental compartments (i.e., surface water, sediment and soil) and on the identity of degradation products (Section 9.2.3.) for the Substance. You have submitted a testing proposal for soil 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.

2.1. Information needed to fulfil the information requirement

You have omitted this information requirement with the following justification:

i. *"The study does not need to be conducted because the substance is highly insoluble in water".*
ii. *"The water solubility of the test substance at 20°C was < 4 µg/l. This is too low to be able to conduct the test appropriately".*

While you have not specified any legal basis for your adaptation, we understand that point i. above refers to the specific rules for adaptation of the Section 9.2.1.4, Annex IX, column 2, while point ii. may be regarded as an attempt to adapt the information under Annex XI, Section 2 ('Testing is technically not feasible').

We have assessed this information and identified the following issues:

A. Under Annex IX, Section 9.2.1.4., column 2, the study may be omitted:
   - if the substance is readily biodegradable, or
   - if direct and indirect exposure of sediment is unlikely.

   You justify the adaptation based on the high insolubility of the Substance.

   However, high insolubility is not a basis to omit this information requirement under Annex IX, Section 9.2.1.4., column 2. Therefore, your adaptation is rejected.

B. Under Annex XI, Section 2, the study may be omitted if it is technically not possible to conduct the study as a consequence of the properties of the substance. For a given endpoint, the specific technical limitations of the test method(s) referred to in Article 13(3) of REACH must always be respected. For a simulation study in water, the OECD TG 308 specifies that:
   - the method is applicable to chemical substances (unlabelled or labelled) for which an analytical method with sufficient accuracy and sensitivity is available;
   - the method is applicable to slightly volatile, non-volatile, water-soluble or poorly-soluble compounds.

   You justify the adaptation based on the low solubility of the substance (reported as < 4 µg/L in your registration dossier). You have provided no additional justification for the adaptation.

   As the OECD TG 308 is applicable to poorly-soluble substances, low solubility on its own is not a valid justification to conclude on the technical unfeasibility of the study. You have provided no justification that it is not possible to develop an analytical method with sufficient accuracy and sensitivity to conduct the study. Therefore, your adaptation is rejected.

On this basis, the information requirement is not fulfilled.

2.2. Test selection and study specifications

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 (ECHA Guidance R.7.9.4.1).

Simulation degradation studies must include two types of investigations (ECHA Guidance 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.

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.

The required test temperature is 12°C, which corresponds to the average environmental temperature for the EU (ECHA Guidance R.16, Table R.16-8) and is in line with the applicable test conditions of the OECD TG 308.

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 (ECHA Guidance 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) (ECHA Guidance 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.

Relevant transformation/degradation products are at least those detected at ≥ 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; ECHA Guidance R.11.4.1.).

2.3. Outcome

Under Article 40(3)(c), you are therefore requested to conduct the additional test with the Substance, as specified above.

3. Identification of degradation products

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

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 requires to provide information on Biotic degradation (Section 9.2.1.) and on the identity of degradation products (Section 9.2.3.) for the Substance. You have submitted a testing proposal for soil simulation testing only. In case of data gap for the identification of degradation products, it is necessary to request this information as an additional test to ensure compliance with the endpoint.

3.1. Information needed to fulfil the information requirement

You have provided no information on the identity of transformation/degradation products for the Substance.

Therefore, the information requirement is not fulfilled, and an identification of degradation products is needed.

3.2. Specification of the study design

Regarding the selection of appropriate and suitable test method(s), the method(s) will have to be substance specific. Identity, stability, behaviour, and molar quantity of the degradation/transformation products relative to the Substance must be evaluated and reported, when analytically possible. In addition, degradation half-life, log K_{ow} and potential toxicity of the transformation/degradation may need to be investigated. You may obtain this information from the degradation study requested in Appendices B.1, B.2 or by some other measure. If any other method is used for the identification of the transformation/degradation products, you must provide a scientifically valid justification for the chosen method.

To determine the degradation rate of the Substance, the requested study according to OECD TG 307 (Appendix B.1.) or to OECD TG 308 (Appendix B.2) must be conducted at 12°C and at a test material application rate 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).

You may also use other appropriate and suitable test method(s) to provide information on the identity of the transformation/degradation products, for example an enhanced screening level degradation test or modelling tools. You will need to provide a scientifically valid justification for the chosen method. The provided information should include, identification, stability, behaviour, molar quantity of transformation/degradation products relative to the parent compound. In addition, degradation half-life, log K_{ow} and potential toxicity of the transformation/degradation may need to be investigated.

3.3. Outcome

Under Article 40(3)(c), you are therefore requested to provide this additional information on the Substance, as specified above.

Appendix C: 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[2].

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[3].

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

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

A. 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 ECHA Guidance R.7b (Section R.7.9.), R.7c (Section 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.

Appendix E: Procedure

The Substance is listed in the Community rolling action plan (CoRAP) and the substance evaluation started in 2019.

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 20 July 2020.

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

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

ECHA did not receive any comments within the commenting 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 F: List of references - ECHA Guidance[4] 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)[5]

RAAF - considerations on multi-constituent substances and UVCBs (RAAF UVCB, March 2017)[5]

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[6]

[4] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[5] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[6] 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 G: 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]
[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.