~~Confidential~~

Helsinki, 25 October 2021

Addressees
Registrants of JS 448-280-7 / 107934-68-9 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
10/07/2020

Registered substance subject to this decision ("the Substance")
Substance name: 4,4'-(9H-fluoren-9-ylidene)bis(2-chloroaniline)
EC number: 407-560-9
CAS number: NS

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

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 January 2025***.

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. In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: EU B.13/14. /OECD TG 471) using one of the following strains: E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102

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

1. In vitro cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2.; test method: OECD TG 473) or In vitro micronucleus study (Annex VIII, Section 8.4.2.; test method: OECD TG 487)

2. Long-term toxicity testing on fish also requested below (triggered by Annex VIII, Section 9.1.3., column 2)

3. Simulation testing on ultimate degradation in surface water also requested below (triggered by Annex VIII, Section 9.2., column 2)

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

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

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

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

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

2. 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.

3. 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.

4. 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.

5. Identification of degradation products (Annex IX, 9.2.3.; test method: OECD TG 307 and/or 308 and/or 309)

Reasons for the request(s) are explained in the appendices entitled "Reasons to request information required under Annexes VII 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 Annex VII to REACH, for registration at 1-10 tonnes per year (tpa), or as a transported isolated intermediate in quantity above 1000 tpa;
- 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, 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. In vitro gene mutation study in bacteria

An *in vitro* gene mutation study in bacteria is an information requirement under Annex VII to REACH (Section 8.4.1.).

You have provided a key study in your dossier:

i. a study similar to OECD 471 performed with the Substance and with the following strains *S. typhimurium* TA 1535, TA 1537, TA 1538, TA 98 and TA 100 which all gave negative result ([redacted] 1988)

In your comments on the draft decision, you refer to the following supporting study in your dossier:

ii. a study similar to OECD 480 performed with Substance and with *Saccaromyces cerevisiae* ([redacted] 1988)

We have assessed this information and identified the following issues:

A. To fulfil the information requirement, the study has to meet the requirements of OECD TG 471 (1997) (ECHA Guidance R.7a, Table R.7.7–2). One of the key parameters of this test guideline include:

- The test must be performed with 5 strains: four strains of *S. typhimurium* (TA98; TA100; TA1535; TA1537 or TA97a or TA97) and one strain which is either *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101)

However, the reported data for the studies (i.) and (ii.) you have provided did not include:

- The required fifth strain, *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM1010).

The information provided does not cover one of the key parameters required by OECD TG 471.

B. To fulfil the information requirement, a study must be an *in vitro* gene mutation study in bacterial cells and comply with the OECD TG 471 (Article 13(3) of REACH and ECHA Guidance R.7, Table R.7.7-2).

The study (ii.) you provided relates to a test different from the OECD TG 471, conducted on yeast instead of bacteria. Therefore, the information provided does not cover key parameters required by the OECD TG 471.

In your comments on the draft decision, you consider that the data provided in the registration dossier cover effectively the key parameters required by the latest version of the OECD TG 471 although the currently required fifth strain is not present due to following reasons:

- *"At the time the study was run (1988), the OECD TG 471 only required 4 strains to be tested, not five."*
- *"Additionally, the OECD TG 480 using S. cerevisiae was also done concurrently. The latter serves the purpose of identifying cross-linking mutagens, the same purpose as that of using E. coli or S. typhimurium TA102 in the latest OECD TG 471."*

ECHA notes, that the OECD 480 (from 1986) which is now deleted from the active OECD TGs does not identify cross-linking mutagens. Moreover, according to OECD TG 471 the E. coli WP2 strains and S. typhimurium TA 102 may detect certain oxidising agents and hydrazines, additionally to cross-linking agents.

As explained under issues A. and B. the information provided does not cover all key parameters required by OECD TG 471.

On this basis, the information requirement is not fulfilled.

To fulfil the information requirement for the Substance, the *in vitro* gene mutation study in bacteria (OECD TG 471) should be performed using one of the following strains: *E. coli* WP2 uvrA, or *E. coli* WP2 uvrA (pKM101), or *S. typhimurium* TA102.

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

1. In vitro cytogenicity study in mammalian cells or In vitro micronucleus study

An *in vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study is an information requirement under Annex VIII to REACH (Section 8.4.2.).

You have provided a key study in your dossier:

i. a study similar to OECD TG 473 performed with the Substance in cultured peripheral human lymphocytes which gave negative result ([redacted] 1991).

In addition, in your comments on the draft decision, you provided a column 2 adaptation under Annex VIII, Section 8.4.2., first indent: "*the study does not need to be conducted if adequate data from an in vivo cytogenicity test are available*". You provided information on the following study to support your adaptation:

ii. a study according to EU Method B.12 (Mutagenicity – *In vivo* mammalian erythrocyte micronucleus test) performed with the Substance via intraperitoneal administration in mice ([redacted] 1994).

We have assessed this information and identified the following issues:

A. To fulfil the information requirement, the study has to be an *in vitro* chromosomal aberration test or an *in vitro* micronucleus test, conducted in mammalian cells in accordance with OECD TG 473 or OECD TG 487, respectively (ECHA Guidance R.7a, Table R.7.7–2). The key parameters of these test guidelines include:
   - The maximum concentration tested must induce 55+5% of cytotoxicity compared to the negative control, or the precipitation of the tested substance. If no precipitate or limiting cytotoxicity is observed, the highest test concentration must correspond to 10 mM, 2 mg/mL or 2 µl/mL, whichever is the lowest.
   - The scoring of at least 300 metaphases per concentration
   - For thorough evaluation and to conclude a negative outcome, three experimental conditions, i.e. a short-term treatment with and without metabolic activation and also a long-term treatment without metabolic activation.

   The reported data for the study (i.) you have provided did not include:
   - Information why the maximum tested concentration of 100 µg/mL was the highest achievable concentration with metabolic activation as cytotoxicity was not observed and precipitation was not reported
   - The scoring of at least 300 metaphases per concentration as only 100 cells were analysed
   - Short-term treatment without metabolic activation as only 3 hours exposure duration with metabolic activation and 24 hours exposure duration without metabolic activation were tested.

   In your comments on the draft decision, you stated:
   - "*The maximum tested concentration of 100 µg/ml in the presence of metabolic activation was determined based on precipitation observed at this dose*";
   - "*At the time, the test was run according to the 1983 version of OECD TG 473. This version did not include any specific requirements in terms of the number of metaphases that should be observed. One hundred metaphases were observed from each culture, and duplicate cultures were available for each concentration, so in total 200 metaphases were observed per concentration*";

- "*As mentioned above, at the time, the test was run according to the 1983 version of OECD TG 473. This version did not include any specific requirements in terms of the three experimental conditions that would have been necessary. In the next version of the guidance published in 1997, it is indicated that confirmation of negative results with metabolic activation should be done on a case-by-case basis if deemed necessary*";
- "*[…] should the points raised above not be considered valid by the Agency, [redacted], as lead registrant, proposes to conduct an in vitro micronucleus study (OECD TG 487)*".

ECHA acknowledges the justification you provided on the maximum tested concentration in the presence of metabolic activation and also the analysis of 200 metaphases per concentration. ECHA also agrees that in OECD TG 473 from 1983, the incubation time is not well defined for a definite test. However, ECHA also considers that the lack of a short-term treatment without metabolic activation is the main deviation. In the absence of this information, a thorough evaluation, which would be needed to conclude a negative outcome, is not possible.

Therefore, the information provided does not cover all key parametes required by OECD TG 473.

B. Under Section 8.4.2., Column 2, first indent, Annex VIII to REACH, the study may be omitted "if *adequate data from an in vivo cytogenicity test are available*". ECHA Guidance R.7.7.6.3 clarifies that the *in vivo* study must be either a micronucleus test or a chromosomal aberration test, performed according to OECD TG 474 or 475, respectively (ECHA Guidance R.7, Table R.7.7-3).

For the data from an *in vivo* cytogenicity test to be considered adequate, the *in vivo* study you provided in your comments on the draft decision (study ii. above) has to meet the requirements of OECD TG 474, and the specifications/conditions of this test guideline include:

- The study must include a minimum of three doses/groups of treated animals, as well as a negative control group and a positive control group.

- The reported data for the *in vivo* study (ii.) did not include:The appropriate number of doses

Only one limit dose of 2000 mg/kg bw was used in the study (ii.). According to OECD TG 474 a single dose level, at the limit dose, may be sufficient if "*a treatment regime of at least the limit dose produces no observable toxic effects (including no depression of bone marrow proliferation or other evidence of target tissue cytotoxicity), and if genotoxicity would not be expected based upon in vitro genotoxicity studies or data from structurally related substances, then a full study using three dose levels may not be considered necessary".*

However, depression of bone marrow proliferation at 48 h indicates that toxic effects were observed in the *in vivo* study (ii.). Currently, also the *in vitro* genotoxicity tests are not adequate to conclude that genotoxicity would not be expected. In addition, ECHA performed QSAR predictions for mutagenicity endpoints and these predictions indicate potential *in vitro* mutagenicity concern.

Therefore, the information provided does not cover specifications/conditions required by OECD TG 474 and the requirements of Section 8.4.2., Column 2, first indent, Annex VIII

to REACH are not met.

On this basis, the information requirement is not fulfilled.

2. Long-term toxicity testing on fish

Short-term toxicity testing on fish is an information requirement under Annex VIII to REACH (Section 9.1.3.). Long-term toxicity testing on fish must be considered (Section 9.1.3., Column 2) if the substance is poorly water soluble.

You have provided a short-term toxicity study on fish based on OECD TG 203 but no information on long-term toxicity on fish for the Substance.

We have assessed this information and identified the following issue:

Poorly water soluble substances require longer time to reach steady-state conditions. As a result, the short-term tests does not give a true measure of toxicity for this type of substances and the long-term test is required. A substance is regarded as poorly water soluble if, for instance, it has a water solubility below 1 mg/L or below the detection limit of the analytical method of the test material (ECHA Guidance R.7.8.5).

You have provided information which indicate that the Substance includes constituents that are poorly water soluble (water solubility < 5.2 E-05 g/L based on EU A.6).

Therefore, the Substance is poorly water soluble and information on long-term toxicity on fish must be provided.

The examination of the information provided, as well as the selection of the requested test and the test design are addressed under section Appendix C.1.

The examination of your comments are addressed in Appendices C.1.

3. Simulation testing on ultimate degradation in surface water, triggered by Annex VIII, Section 9.2., column 2.

and

4. Soil simulation testing, triggered by Annex VIII, Section 9.2., column 2.

and

5. Sediment simulation testing, triggered by Annex VIII, Section 9.2., column 2.

and

6. Identification of degradation products, triggered by Annex VIII, Section 9.2., column 2.

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 including simulation testing in appropriate media (e.g. water, sediment or soil) (Annex VIII, Section 9.2., Column 2).

The above mentioned information requirements (2 to 5) are triggered in case the chemical safety assessment (CSA) indicates the need for further degradation investigation (Annex I, Section 4; Annex XIII, Section 2.1), such as if the substance is a potential PBT/vPvB substance (ECHA Guidance R.11.4.). This is the case 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 (<60% degradation in an OECD 301 stduy),
- it meets the criteria vB as set out in Annex XIII (BCF > 5 000);
- it meets the T criteria set in Annex XIII: NOEC < 0.01 mg/L.

Your registration dossier provides the following:

- The Substance is not readily biodegradable (0% degradation after 28 days in an OECD TG 301D study, 2% degradation after 28 days in an OECD TG 301F study);
- The Substance meets the vB criteria as a BCF_{kl} value of 9986 L/kg was obtained in an OECD 305 study;
- The Substance meets the T criteria as a $NOEC_{reproduction}$ of 6.8 ng/L is available for Dapnia magna based on an OECD TG 211 study.

The information above indicates that the Substance is a potential PBT/vPvB substance.

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

The examination of the available information or adaptations, as well as the selection of the requested tests and the tests design are addressed respectively in Appendices C.2 to C.5.

In your comments on the draft decision, you refer to ECHA Guidance R.11 and state that "*if a substance is concluded as PBT/vPvB no further testing is required*" and that "*any further testing even if further testing is required through simulation studies, those tests should be done one after the other to reduce efforts of testing*". You further consider that there is sufficient eviden to conclude that the Substance "*fulfills the PBT and vPvB criteria as laid out in Annex XIII of the REACH regulation*".

ECHA has assessed your comments and identified the following issue:

> Section 2.1 of Annex XIII to REACH specifies that if the result from the screening tests or other information indicate that the substance may have PBT or vPvB properties, the registrant shall generate relevant additional information as set out in Section 3.2 of this Annex. In case the generation of relevant additional information would require information listed in Annexes IX or X, the registrant shall submit a testing proposal. Where the process and use conditions of the substance meet the conditions as specified in Section 3.2(b) or (c) of Annex XI the additional information may be omitted, and subsequently the substance is considered as if it is a PBT or vPvB in the registration dossier.
>
> As explained above, available information indicate that the substance may have PBT or vPvB properties. Furthermore, for the reasons explained below under Appendix C.2., you have not demonstrated that the conditions specified in Section 3.2(b) or (c) of Annex XI are met. On this basis, you have not demonstrated that this information can be omitted.

ECHA highlights that, as specified by ECHA Guidance R.11.4.1.1., no further testing or assessment of persistence of other environmental compartments is normally necessary if a conclusion "P" or "vP" is reached for one compartment. As already explained in this decision, when determining the sequence of simulation degradation testing you are advised to consider the information provided in Appendix E.

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

1. Long-term toxicity testing on fish

Long-term toxicity testing on fish is an information requirement under Annex IX to REACH (Section 9.1.6.).

You have provided a justification to omit the study which you consider to be based on Annex IX, Section 9.1., Column 2. In support of your adaptation, you provided the following justification:

- the Substance is already classified for Aquatic chronic 1 and so the T criteria is fulfilled;
- fish was not the most sensitive species in acute tests;
- based on the above mentioned information PNEC refinement in not required.

We have assessed this information and identified the following issue:

> Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to fish under Column 1. It must be understood as a trigger for providing further information on long-term toxicity to fish if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).
>
> Your adaptation is therefore rejected.

In your comments to the draft decision, you provide the following justification to omit the study:

i) You refer to the COM-ECHA REACH Evaluation Joint Action Plan activities and in particular to the first draft of the action 2 proposals to revise Annex VII to X of REACH. You state that "*one of the amendments proposed by the Agency was in particular for Column 2 of Annex IX, Section 9.1 and further clarified that these long-term aquatic toxicity tests were not necessary if the Chemical Safety Assessment (CSA) could demonstrate no risk*";

ii) you refer to Articles 13(1) and 25(1) of REACH and argue about the need to conduct testing on vertebrate animals only as a last resort. You consider that "*making the OECD TG 210 test, or more generally, a long-term toxicity test on fish, a systematic requirement in all cases, with no possibility of omission for registrants, should not and cannot be considered a* "last resort" *situation*";

iii) you question the scientific validity of such request and the relevance of the aquatic compartment as:
   - you consider the Substance as highly insoluble. You acknowledge that omitting the study based on high insolubility is none a specific rule for adating the informations requirements set-out in Section 9.1 of Annex IX to REACH. However, you consider that "*rationale supporting this adaptation is true for this substance also for long-term toxicity tests on aquatic organisms*";
   - You state that short-term tests "*were either run before entry in force of the REACH legislation or for another foreign legislation*". You indicate that these studies showed no toxicity;
   - you refer to Table R.7.8.-2 of the ECHA Guidance on IR&CSA (Chapter r7b) and you provide the following (partial) quote "*very low water solubility (i.e. in the low µg/l range) could be used as a reason to* [...] *test non-pelagic organisms preferentially*";
   - you refer to the ECHA Guidance on IR&CSA, Chapter R.7b - Section R.7.8.7 and Chapter R.7c - Table R.7.11-2 and state that "*high adsorption potential suggests that the relevant compartment is soil or sediment rather than water*" without further justification. You also state that "*the information available for soil*

organisms […] *shows that there was no toxicity to earthworms even at the highest dose of 1000 mg/kg (OECD TG 207* […]*)*";

iv) You question the added value of such request to demonstrate safe use of the Substance with the following justification:
- "*the T criterion is already fulfilled based on the results of the long-term Daphnia study*";
- "[The requested study] *would only serve the purpose of refining the M-factor and/or the PNEC of the substance*";
- "*However, since the substance already has a M-factor of 10 000,* You state that new data could potentially lead to an even higher M-factor but "*the conclusion will stay the same as the current situation already includes all mixtures containing the substance down to 0.0025 %, which is in the lower range of the analytical precision attained when analyzing the mixtures for their composition*";
- "[The Substance] *is already considered as a PBT and vPvB substance, further* [PNEC] *refinement is irrelevant*" as "[you] *recognized that* "a conventional hazard assessment of the long-term effects and the estimation of the long-term exposure cannot be carried out with sufficient reliability for the purpose of assessing the safety of the substance" *(Guidance on IR&CSA, Chapter R.11 and Annex I, Section 4 of the REACH regulation)";*
- You refer to Section R.5.1.7. of the Guidance on IR&CSA, Chapter R.5 and state that "*Column 2 serves as an exposure-based trigger for additional tests* "belonging to the standard requirements of REACH for the relevant tonnage level" *if that test* "could lead to a change regarding one of the following: classification or declassification, assignment as PBT/vPvB or not, concern or no concern*""*. You conclude that the classification cannot be further increased, the substance is already assigned as PBT/vPvB and the concern is already being addressed.

We have assessed the information provided as part of you comments on the draft decision and notes that none of the above lines of argumentation relates to any adaptation possibility under Annex XI to REACH. Therefore, it does not provide any basis to omit the test. Nevertheless, for the sake of clarity, ECHA notes the following with regard the comments you submitted:

- On point i) above, ECHA notes that the document you are referring to is a draft proposal to revise the wording of Annex VII to XI to REACH. However, ECHA is bound by Article 41 of the REACH Regulation to assess the compliance of the information submitted with the information requirements that are currently in force. This is without prejudice to any future modification which are, for the time being, hypothetical;
- On point ii) above, while minimisation of vertebrate testing does not relate to any adaptation possibility under Annex XI to REACH, those generic rules for adaptation do apply to this information requirement. Therefore, your statement that there is "*no possibility of omission for registrants"* is erroneous;
- On point iii) above, you consider the Substance to be highly insoluble and question the relevance of aquatic toxicity tests. However, as acknowledged by you, your dossier includes a long-term toxicity study on aquatic invertebrates with a 21-day NOEC of 6.8 ng/L (Draft Decision on a Compliance Check-Comments, 29/01/2021). You used this effect value for classification and labelling, PNEC derivation and for concluding on the T criteria in the context of the PBT assessment. This information demonstrates that effects may be observed below the solubility limit of the Substance and that investigating effects on aquatic organisms is therefore relevant. Then, the references to ECHA Guidance you provided have no relevance as they relate to discussing the relevance of the soil and sediment compartment, respectively, and not to provide grounds to omit aquatic toxicity tests;
- On point iv) above, you consider that this study would not bring any added value in terms of regulatory risk management because 1) the Substance is already classified as

Aquatic chronic 1, 2) the M-factor is 10000 and 3) the Substance is treated as if it is PBT/vPvB. ECHA understands that you question the proportionality of the request. However, under Article 41 of the REACH Regulation, the purpose of the compliance check procedure is only to verify if the information submitted complies with the information required. Therefore, the compliance evaluation is performed only in relation to the information requirement, not in relation to the conditions of use of the Substance, including the determination of M-factors. The added value of the information required for the safe use of the substance may be taken into account in the context of the clarification of a concern under Substance Evaluation, or of the adoption of a risk management measure. Your argument is therefore not relevant in the context of the verification of the compliance of your dossier with information requirements. In any case, as acknowledged by you, it cannot be excluded that the requested study would not lead to a higher M-factor and the limitation of currently available analytical techniques is not as valid justification in this context. Then, for the reasons explained further below under Appendix C.2., you have not demonstrated that the criteria of Annex XI, Section 3.2(c) are met. Therefore, you have not demonstrated that appropriate risk management measures are in place in relation to your claim that the Substance is treated as if it is PBT/vPvB.

On this basis, the information requirement is not fulfilled.

Study design

To fulfil the information requirement for the Substance, the Fish, Early-life Stage Toxicity Test (test method OECD TG 210) is the most appropriate (ECHA Guidance R.7.8.2.).

The Substance is difficult to test due to the low water solubility (< 5.2 E-05 g/L based on EU A.6) and adsorptive properties (Log Kow > 4.49 based on a OECD 107 and Log Kow of 6.49 based on QSAR calculation). OECD TG 210 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. In all cases, the approach selected must be justified and documented. Due to the properties of Substance, it may be difficult to achieve and maintain the desired exposure concentrations. Therefore, you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in OECD TG 210. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solution.

2. Simulation testing on ultimate degradation in surface water

Simulation testing on ultimate degradation in surface water is an information requirement under Annex IX to REACH (Section 9.2.1.2.).

You have provided an adaptation under Annex IX, Section 9.2.1.2., Column 2 with the following justification: " *the Substance is highly insoluble in water*".

We have assessed this information and identified the following issues:

A. Column adaptation based in high insolubility

Under Section 9.2.1.2., Column 2 of Annex IX to REACH, the study may be omitted if the substance is highly insoluble in water. While this provision does not specify what

a highly soluble substance is, ECHA Guidance R7.9.2 clarifies that this corresponds to the circumstances where "*the test will be practically very difficult to conduct without special analytical techniques.* […] *The test may still be important in certain circumstances, however, for example where hydrolysis occurs at the surface of particles of the undissolved substance leading to more soluble products, but may be considered on a case-by-case basis if needed for risk assessment purposes*". In this context, the registrant must demonstrate that it is technically not possible to conduct the study as a consequence of the low water solubility of the substance. The specific technical limitations of the OECD TG 309 must be respected, in particular:

- for the determination of biodegradation kinetics, the concentrations of the test substance must be below its water solubility, and
- the limit of quantification (LOQ) should be equal to or less than 10% of the applied concentration.

Considering the above, a simulation testing on ultimate degradation in surface water according to OECD TG 309 is considered technically feasible if the LOQ of a sensitive analytical method is at least ten times lower to the water solubility of the substance.

In section 4.8 of your technical dossier you haved provided an water solubility estimate for the Substance of < 52 µg/L based on OECD TG 105 (column elution method). However, in Section 6.1.4., you report that the mean concentration of 100% v/v Water Soluble Fractions for the Substance was determined to be 1268 ± 328 ng/L in an OECD TG 211 study. You have not reported the LOQ of the analytical method used in this study. However, you report that a 21d-NOEC of 6.2 ng/L was determined based on measured concentrations.

The OECD TG 309 must be conducted at low test concentrations to ensure that the biodegradation kinetics obtained in the test reflect those expected in the environment. In this context low solubility in itself is not valid justification to omit this information requirement. Taken together, the information from your dossier indicate that the LOQ of a sensitive abnalytical monitoring method is below 10% of the water solubility of the substance. This information supports that an OECD TG 309 study is technically. Therefore, your adaptation is rejected.

In your comments on the draft decision., you state that you do not agree to perform the study as:

i. you consider the substance to be highly insoluble in water. While this is not explicitly claimed by you, ECHA understands that you intend to omit the based on the Annex IX, Section 9.2.1.2., Column 2, second indent;
ii. you consider the study is not required since the substance is already considered by you as a "PBT and vPvB chemical" in the registration dossier. You propose to submit an adaptation under Annex XI, Section 3.2(c).

We have assessed the information from your comments on the draft decision and identified the following issue:

A. High insolubility is not demonstrated

Under Annex IX, Section 9.2.1.2, column 2, second indent, the study may be omitted if the substance is highly insoluble in water. ECHA Guidance R.7.9.2.3. clarifies that this is the case if the solubility in water is so low that the test may be practically difficult or impossible to conduct at concentrations below the water solubility limit of the substance. In the context, the OECD TG 309 specifies that the test concentration must be below the water solubility limit of the test material and that the limit of

quantification (LOQ) of the analytical method must be equal or less than 10% of the applied concentration.

In your comments on the draft decision, you state regarding water solubility that "*the value reported (< 5.2 x 10-5 g/l)* [i.e. < 52 µg/L] *corresponds to the detection limit of the method*". In the long-term toxicity study on aquatic invertebrates, you report measured values down to 6.8 ng/L.

Considering the limited sensitivity of the analytical method used to conduct the water solubility study, you have not demonstrated that a simulation study in water as described in the OECD TG 309 is not technically feasible. Therefore, your adaptation is rejected.

B. The adaptation from Annex XI, Section 3.2 (c) is not justified

Under Section 2.1 of Annex XIII to REACH, if the result from the screening tests or other information indicate that the substance may have PBT or vPvB properties, the registrant must generate relevant additional information as set out in Section 3.2 of Annex XIII. The additional information may only be omitted if the substance meet the conditions as specified in Annex XI, Section 3.2(b) or (c) of Annex XI and subsequently the substance is then considered as if it is a PBT or vPvB in the registration dossier.

Under Annex XI, Section 3.2 (c) it must be demonstrated and documented that all of the following conditions are fulfilled:

i. the substance is not released during its life cycle;
ii. the likelihood that workers or the general public or the environment are exposed to the substance under normal or reasonably foreseeable conditions of use is negligible; and
iii. the substance is handled according to the conditions set out in Article 18(4)(a) to (f) during all manufacturing and production stages including the waste management of the substance during these stages.

The information provided in the comments and in the registration dossier is not sufficiently detailed and comprehensive to justify strictly controlled conditions (SCCs).

At least the following information is missing with regard to the (i) requirement of Annex XI, 3.2(c):

1. substance specific chemistry based argumentation on whether the substance can become available during the life cycle of the article (in use or after use, e.g. during waste treatment).
2. evidence in the form of laboratory report, confirmation from your supplier or reference to literature that if there is residual substance present in the polymer/article, the total concentration of the substance is always below the applicable threshold indicated in Art 14(2) (i.e. 0.1% if there is a PBT/vPvB concern).

At least the following information on SCCs is missing in relation the requirement (iii) of Annex XI, 3.2(c)).

1. a detailed description (or a flow chart) of all processing steps taking place at each life-cycle stage (including loading and unloading of tanks, maintenance of equipment, sampling etc.);
2. a mass balance of the substance at various processing steps during its life-cycle stages; description on how rigorous containment by technical means (please see more in Guidance and practical guide on intermediates) is ensured for all

processing steps during whole life-cycle (e.g. loading/unloading, grinding, mixing, sampling, maintenance/cleaning of equipment, waste handling etc.);
3. the recommended efficiency of Local Exchust Ventillation (LEV) and explain why LEV is needed in a closed process; any information on monitoring of emissions to water/air (or of workers) performed;
4. any other (not noted above) procedural or control technologies to minimise emission and any resulting exposure to the environment (and to workers).

As explained in Appendix B.3-5 above, the Substance is a potential PBT/vPvB substance and has high potential for adsorption to sediment. Also you have neither provided sufficient justification to omit the information based on Section 3.2(b) or (c) of Annex XI of REACH.

On this basis, the information requirement is not fulfilled.

Study design

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.

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) (ECHA Guidance R.11.4.1.1.3.).

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 309.

As specified in ECHA Guidance 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) (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 309; ECHA Guidance R.11.4.1.).

3. Soil simulation testing

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.

The Substance has a low water solubility (< 5.2 E-05 g/L), high partition coefficient (Log Kow > 4.49 based on a OECD 107 shake flask and Log Kow of 6.49, based on QSAR calculation and high adsorption coefficient (log $K_{oc,soil}$=4.52) and therefore has high potential for adsorption to soil.

You have provided an adaptation under Annex IX, Section 9.2.1.3., Column 2 with the following justification: "direct and indirect exposure of soil is unlikely".

We have assessed this information and identified the following issues:

A. *Column adaptation based on unlikleyhood of exposure to the soil*

Under Section 9.2.1.3., Column 2 of Annex IX to REACH, the study may be omitted if direct and indirect exposure to the sediment is unlikely. The requirements for absence of direct and indirect exposure to the soil must be met for all uses throughout the life-cycle including the waste stage (ECHA Guidance R.5).

In the section 3.5 of your registration dossier you report industrial uses (ERC 2 - Formulation into mixture, ERC 6D - Use of reactive process regulators in polymerisation processes at industrial site). You report that the Substance is used in resin but you have provided no information on article service life.

The industrial uses reported in your technical dossier are expected to lead to moderate release to the environment as ERC2 and ERC 6D have default emission factors to water (before STP) of 0.1% and 0.025%. Therefore, exposure to the soil compartment may occur. Furthermore, indirect exposure through spreading of sewage sludge on land cannot be excluded. Finally, you have not included any information on articles service life for the Substance. Therefore, you have not demonstrated that exposure to sediment is unlikely.

In your comments on the draft decision, you consider that this information is not needed since the Substance is already considered by you as a "PBT and vPvB chemical". You propose to submit an adaptation under Annex XI, Section 3.2(c).

For the reasons already explained under Appendix C2, your adaptation is rejected.

On this basis, the information requirement is not fulfilled.

Study design

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.).

4. 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 sediment.

The Substance has a low water solubility (< 5.2 E-05 g/L), high partition coefficient (Log Kow > 4.49 based on a OECD 107 shake flask and Log Kow of 6.49, based on QSAR calculation and high adsorption coefficient (log $K_{oc,soil}$ =4.52) and therefore has high potential for adsorption to sediment.

You have provided an adaptation under Annex IX, Section 9.2.1.4., Column 2 with the following justification: "because direct and indirect exposure of sediment is unlikely".

We have assessed this information and identified the following issue:

A. *Column adaptation based on unlikleyhood of exposrure to the sediment*

Under Section 9.2.1.4., Column 2 of Annex IX to REACH, the study may be omitted if direct and indirect exposure to the sediment is unlikely. The requirements for absence of direct and indirect exposure to the sediment must be met for all uses throughout the life-cycle including the waste stage (ECHA Guidance R.5).

In the section 3.5 of your registration dossier you report industrial uses (ERC 2 - Formulation into mixture, ERC 6D - Use of reactive process regulators in polymerisation processes at industrial site). You report that the Substance is used in resin but you have provided no information on article service life.

The industrial uses reported in your technical dossier are expected to lead to moderate release to the environment as ERC2 and ERC 6D have default emission factors to water (before STP) of 2% and 0.005%. However, considering the properties of the Substance (i.e. low solubility, high adsorption potential and low biodegradation potential), exposure to the sediment compartment cannot be excluded. Furthermore, you have not included any information on articles service life for the Substance. Therefore, you have not demonstrated that exposure to sediment is unlikely.

In your comments on the draft decision, you consider this information is not needed since the substance is already considered by you as a "PBT and vPvB chemical". You propose to submit an adaptation under Annex XI, Section 3.2(c).

However, for the reasons already explained under Appendix C2, ECHA identified deficiencies with the adaptation you intend to submit.

On this basis, the information requirement is not fulfilled.

Study design

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.).

5. Identification of degradation products

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

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

In your comments on the draft decision, you state that you do not agree to perform the study as you further consider the study is not required since the substance is already considered by you as a "PBT and vPvB chemical" in the registration dossier.
However, for the reasons already explained under Appendix C2, you have not demonstrated that the conditions set out un Annex XI, Section 3.2(c) are met and therefore that the substance is treated as if it is PBT/vPvB.

Therefore, this information requirement is not met.

This information is required for the purpose of the PBT/vPvB assessment (Annex I, Section 4) and the risk assessment (Annex I, Section 6) of the Substance.

On this basis, the information requirement is not fulfilled.

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 studies requested in Appendix IX 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 309 (Appendix B.3.) 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).

To determine the degradation rate of the Substance, the requested studies according to OECD TG 308/307 (Appendices B.4. and B.5.) 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).

Appendix D: 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 E: 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 F: 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 15 April 2020.

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

ECHA took into account your comments and did not amend the requests but amended the deadline.

The timeline indicated in the draft decision to provide the information requested is 30 months from the date of adoption of the decision. In your comments on the draft decision, you requested an extension of the timeline to 36 months. You justified your request with following statement "*In regards to the timescale, recent experience with testing laboratories in other cases shows that lead times for starting testing are increasing, and this is amplified by the COVID situation which obliges laboratories to have reduced teams on site. Furthermore, a longer timescale would accommodate for sequential testing for the simulation tests if judged necessary. We believe that 36 months would be a more appropriate timescale than 30 months (see an example attached as Annex).*"

In addition, you provided documentary evidence from the CRO to support your request to extend the deadline. On the basis of current schedules in the laboratory, we have updated the deadline to submit the requested information to 36 months.

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 G: 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 multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[6]

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

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

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

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

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

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

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

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

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[7]

[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] https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316
[7] 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 H: Addressees of this decision and their corresponding information requirements

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]
[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.