EUROPEAN CHEMICALS AGENCY

Helsinki, 08 June 2020

Addressees
Registrants of joint submission of PPI as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
20 November 2015

Registered substance subject to this decision ("the Substance")
Substance name: Benzene-1,2,4,5-tetracarboxylic acid, compound with 4,5-dihydro-2-phenyl-1H-imidazole (1:1)
EC number: 259-224-4
CAS number: 54553-90-1

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

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***13 September 2022***.

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 with the Substance

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

1. If negative results are obtained in test performed for the information requirement of Annex VII, Section 8.4.1. then: In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method: OECD TG 476 or TG 490) with the Substance

2. Justification for an adaptation of a Short-term repeated dose toxicity (28 days) based on the results of the Sub-chronic toxicity study (90 days) requested below (Annex VIII, Section 8.6.1.) with the Substance

3. Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.; test method: EU B.63/OECD TG 421 or EU B.64/OECD TG 422) by oral route, in rats with the Substance

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

1. Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.; test method: OECD TG 408) by oral route, in rats, with the Substance

2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: OECD TG 414) by oral route, in one species (rat or rabbit) with the Substance

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

- Appendix entitled "Reasons common to several requests";
- Appendices entitled "Reasons to request information required under Annexes VII to 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; and
- 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.

How to comply with your information requirements

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

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

Appeal

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

Failure to comply

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

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 on Reasons common to several requests

1. Assessment of your read-across approach under Annex XI, Section 1.5.

You seek to adapt the information requirements for the following standard information requirements by grouping substances in the category and applying a read-across approach in accordance with Annex XI, Section 1.5:

- In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)
- Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)
- Sub-chronic toxicity study (90-day), (Annex IX, Section 8.6.2.)
- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)

ECHA has considered the scientific and regulatory validity of your grouping and read-across approach in general before assessing the specific standard information requirements in the following appendices.

Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category (addressed under 'Scope of the grouping'). Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group.

Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance R.6 and related documents.

A. Scope of the grouping

i. Description of the grouping

In your registration dossier you have performed categorisation through identification of 5 nearest neighbours compared by prediction descriptors using OECD QSAR Toolbox. You have provided automated reports generated from the OECD QSAR Toolbox software in IUCLID Section 13 (OECD Toolbox prediction for the *in vivo* mammalian erythrocyte micronucleus test ([redacted] 2015), repeat dose toxicity ([redacted] 2015), and reproductive and developmental toxicity ([redacted] 2015)).

You define the applicability domains of the categories based on

- Aliphatic Amines by Aquatic toxicity classification by ECOSAR (all);
- classification as Mixture by Substance Type ONLY (genotoxicity, reproductive/developmental toxicity); and/or
- logKow ranges (all).

ii. Assessment of the grouping

ECHA notes the following shortcomings with regards to your grouping approach.

Applicability domain of the category

According to the ECHA Guidance, a category (grouping) hypothesis should address "*the set of inclusion and/or exclusion rules that identify the ranges of values within which reliable estimations can be made for category members for the given endpoint*".[2] Particularly, "*the applicability domain of a (sub)category would identify the structural requirements and ranges of physico-chemical, environmental fate, toxicological or ecotoxicological properties within which reliable estimations can be made for the (sub)category members*".[3] Therefore, to reliably predict properties within a category the applicability domain should be described including the borders of the category, for which chemicals the category does not hold and a justification for the inclusion and/or exclusion rules.

You describe the applicability domain of the substances covered by the grouping based on substance type classification by ECOSAR as Aliphatic Amines by Aquatic toxicity classification, classification as Mixture by Substance Type only and/or logKow boundaries.

Classification as Acid moiety AND Neutral Organics by Aquatic toxicity classification by ECOSAR is endpoint specific profiler for aquatic toxicity and indicate presence of chemical structure(s) leading to similarities in the aquatic toxicity. However, it does not introduce unambiguous inclusion/exclusion criteria for chemical structures allowed in the category substances. Furthermore, the provided applicability domain criteria based on aquatic toxicity endpoint specific profiler and physico-chemical property (logKow) cannot predict type of toxicity or the mode/ mechanism of actions (e.g. interaction with the DNA) of the substances for genotoxicity, repeat dose toxicity or reproductive toxicity.

Therefore, this applicability domain does not introduce unambiguous inclusion/exclusion criteria which would identify the structural requirements and ranges of physico-chemical, environmental fate, toxicological properties within which reliable estimations can be made for the (sub)category members.

B. Predictions for properties

You have provided predictions from category members using read-across based on 5 values from 5 nearest neighbours.

ECHA notes the following deficiencies with regards to predictions of toxicological properties.

Read-across hypothesis

According to Annex XI, Section 1.5., two conditions shall be necessarily fulfilled. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group (read-across approach).

A read-across hypothesis needs to be provided, establishing why a prediction for a toxicological or ecotoxicological property is reliable. This hypothesis should be based on recognition of the structural similarities and differences between the source substance(s) and your Substance[4]. It should explain why the differences in the chemical structures should not influence the toxicological/ ecotoxicological properties or should do so in a regular pattern.

[2] ECHA Guidance R.6, Section R.6.2.4.1
[3] ECHA Guidance R.6, Section R.6.2.1.2
[4] ECHA Guidance R.6.

You have not provided a read-across hypothesis to establish a reliable prediction for the toxicological properties, based on recognition of the structural similarities and differences between the category members.

Adequacy and reliability of source studies

According to Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across should:

- be adequate for the purpose of classification and labelling and/or risk assessment;
- have adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3); and
- cover an exposure duration comparable to or longer than the corresponding test method referred to in Article 13(3) if exposure duration is a relevant parameter.

In addition, Annex XI, Section 1.5 requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must provide a justification for the read-across including, among others, robust study summary(ies) of the source study(ies).[5]

A robust study summary must cover sufficient information to make an independent assessment of the study.[6]

To support your predictions, you have provided automated reports generated from the OECD QSAR Toolbox software. These reports contain no observed (adverse) effect level NO(A)EL or mode values (positive/negative or unknown/known) values or for category members. However, you have not provided robust study summaries of the source studies.

In the absence of such documentation, ECHA cannot verify that the results to be read across are meet the criteria listed above.

Predictions for no observed adverse effect level (NO(A)EL)

Annex XI, Section 1.5. requires that the relevant properties (i.e. key parameters foreseen to be investigated in corresponding test methods) of a substance within the group may be predicted from data for reference substance(s) within the group. When conducting a hazard and risk assessment based on read-across, all results of a study conducted with the source substance are read across to the target substance. These results thereafter form the basis for establishing the no observed (adverse) effect level (NO(A)EL) for the target substance.

In order to have a reliable prediction using multiple source substances, the NOAEL values need to be based on the same key parameters. Furthermore, it is important to ensure that the read-across prediction is well founded and that the prediction accounts for the uncertainty in the approach. In cases, where there are multiple source substances, and consequently a range of possible values available to be read across, the use of the most conservative (lowest) value may be sufficient to account for the uncertainty in the read-across.[7]

For repeat dose toxicity and reproductive toxicity you have provided a list of NO(A)EL values for the source substances, and predictions for NO(A)ELs for target substance based on

[5] ECHA Guidance R.6, Section R.6.2.6.2
[6] How to report robust study summaries Practical Guide 3, Version 2.0 – November 2012
[7] ECHA Guidance R.6., Section R.6.2.2.

category members using read-across and calculating an average from 5 nearest neighbours. For developmental/reproductive toxicity prediction based on DART, you have provided list of mode values (unknown/known) and predictions for mode values based on the highest mode value from the 5 nearest neighbours.

For none of the source substance, any information on what type of toxicity forms the basis to establishing the NO(A)ELs have been provided. Therefore, we cannot verify that the predicted NO(A)EL is based on the same key parameter(s). In addition, you have not selected the most conservative NO(A)EL or provided justification why the Substance is expected be less potent than the calculated average from the 5 nearest neighbours. You have also not established NO(A)EL for developmental/reproductive toxicity predicted based on mode values (DART). Therefore, the selection of NO(A)EL for the read-across from the source substances to the Substance is not justified and the uncertainty in the approach for predictions has not been considered.

C. Conclusions on the grouping of substances and read-across approach

As explained above, you have not established that relevant properties of the Substance can be predicted from data on the analogue substance. Therefore, your adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5. and your grouping and read-across approach is rejected.

Appendix A: Reasons to request information required under Annex VII of REACH

1. In vitro gene mutation study in bacteria with the fifth strain, S. typhimurium TA102 or E. coli WP2 or E. coli WP2 uvrA (pKM101)

An *in vitro* gene mutation study in bacteria is a standard information requirement in Annex VII to REACH.

You have provided *In vitro* bacterial mutagenicity test (OECD TG 471, GLP compliant) with the Substance (Anonymous, 1997).

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

To fulfil the information requirement, the study has to meet the requirements of OECD TG 471 (1997). The key parameter(s) of this test guideline include that 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).

You have provided a negative bacterial reverse mutation assay (OECD TG 471) covering the following strains: *S. typhimurium* TA 1535, TA 1537, TA 98 and TA 100 with and without metabolic activation.

However, the reported data for the studies did not include the appropriate 5 strains, as the information provided does not include results in the required fifth strain, S. typhimurium TA102 or E. coli WP2 uvrA or E. coli WP2 uvrA (pKM101).

The information provided does not cover key parameter(s) required by OECD TG 471. Therefore, the information requirement is not fulfilled.

In your comments to the draft decision, you agree to conduct the requested test as specified in the decision.

To fulfil the information requirement for the Substance, an *in vitro* gene mutation study in bacteria (OECD TG 471) with the required fifth strain, *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101) is considered suitable.

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

1. In vitro gene mutation study in mammalian cells

An *in vitro* gene mutation study in mammalian cells is a standard information requirement in Annex VIII to REACH in case of a negative result in the *in vitro* gene mutation test in bacteria and the *in vitro* cytogenicity test.

Your dossier contains (i) a negative result for *in vitro* cytogenicity study in mammalian cells, and (ii) inadequate data for *in vitro* gene mutation study in bacteria.

The *in vitro* gene mutation study in bacteria provided in the dossier does not fulfil the information requirement for *in vitro* gene mutation study in bacteria for the reasons provided in section A.1.

Therefore, the result of the request for information in section A.1 will determine whether the present requirement for an *in vitro* mammalian cell gene mutation study in accordance with Annex VIII, Section 8.4.3 is triggered.

You have not provided *in vitro* gene mutation study in mammalian cells. However, you provided a OECD Toolbox prediction for *in vivo* mammalian erythrocyte micronucleus test based on OECD TG 474 (Key study, Rel.2; [redacted], 2015).

As provided in Annex VIII, Section 8.4.3, Column 2, you may adapt the information requirement, provided that adequate data from a reliable *in vivo* mammalian gene mutation test are available.

While you have not provided a justification, ECHA has evaluated the provided information according to Annex VIII, Section 8.4.3, Column 2 and identified the following issue(s):

a. Adequacy of study

To fulfil this adaptation, the study must qualify as "*in vivo* mammalian gene mutation test". The *in vivo* study must be a Transgenic Rodent Somatic and Germ Cell Gene Mutation Assay, performed according to OECD TG 488.

You have provided prediction for an *in vivo* mammalian erythrocyte micronucleus test (OECD TG 474).

This prediction is not for a Transgenic Rodent Somatic and Germ Cell Gene Mutation Assay. Therefore, your adaptation is rejected.

b. Reliability of read-across prediction

You have also adapted the information provided by using a Grouping of substances and read-across approach under Annex XI, Section 1.5.

As explained in the Appendix on Reasons common to several requests your adaptation is rejected.

In conclusion, the provided *in vivo* test is not adequate. Therefore, your adaptation is rejected.

Consequently, you are required to provide information for this endpoint, if the *in vitro* gene mutation study in bacteria (A.1.) provide a negative result.

In your comments to the draft decision, you agree to conduct the requested test as specified in the decision.

Information on the study design
To fulfil the information requirement for the Substance, both the *in vitro* mammalian cell gene mutation tests using the hprt and xprt genes (OECD TG 476) and the thymidine kinase gene (OECD TG 490) are considered suitable.

2. Justification for an adaptation of a Short-term repeated dose toxicity (28 days) based on the results of the Sub-chronic toxicity study (90 days)

A Short-term repeated dose toxicity study (28 days) is a standard information requirement in Annex VIII to REACH.

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5.

As explained in the Appendix on Reasons common to several requests your adaptation is rejected.

Therefore, the information requirement is not fulfilled.

Column 2 of Annex VIII, Section 8.6.1. provides that an experimental study for this endpoint is not needed if a reliable sub-chronic (90 days) or chronic toxicity study is available.

The present decision requests the registrants concerned to generate and submit a reliable sub-chronic toxicity study (90 days) (see Appendix C, Section 1). According to Column 2 of Annex VIII, Section 8.6.1., and to prevent unnecessary animal testing, a short term toxicity study (28 days) does not therefore need to be conducted.

You still must comply with the information requirement in Annex VIII, Section 8.6.1., and therefore you are requested to submit a justification for the adaptation provided in Column 2 of that provision.

In your comments to the draft decision, you agree to provide the requested justification for an adaptation as specified in the decision.

3. Screening for reproductive/developmental toxicity

A Screening for reproductive/developmental toxicity study (test method: EU B.63/OECD TG 421 or EU B.64/OECD TG 422) is a standard information requirement under Annex VIII to REACH, if there is no evidence from analogue substances, QSAR or *in vitro* methods that the Substance may be a developmental toxicant.

You have provided prediction for developmental toxicity based on read-across adaptation (Annex XI, Section 1.5). As explained in the 'Appendix on Reasons common to several requests' your adaptation is rejected. Therefore, there is no information available in your dossier indicating that your Substance may be a developmental toxicant.

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5.

As explained in the Appendix on Reasons common to several requests your adaptations are rejected.

Therefore, the information requirement is not fulfilled and a Screening for reproductive/developmental toxicity study is required.

Specifications for the study design

A study according to the test method EU B.63/OECD TG 421 or EU B.64/OECD TG 422 must be performed in rats with oral[8] administration of the Substance.

In your comments to the draft decision you propose to perfrom the Pre-natal developmental toxicity study (OECD TG 414) requested in this decision (Appendix C, Section 2) and to use it also to adapt the standard information requirement of Screening for reproductive/developmental toxicity study, in accordance with Column 2 of REACH Annex VIII (Section 8.7.1).

ECHA notes that it is possible to adapt the information requirement of screening for reproductive/developmental toxicity study based on the available pre-natal developmental toxicity study. However, it is strongly recommended that a registrant considers conducting a screening study in addition to the prenatal developmental toxicity study to cover the fertility and early peri/post natal development if an Extended one-generation reproductive toxicity study is not conducted[9].

[8] ECHA Guidance R.7a, Section R.7.6.2.3.2.

[9] ECHA Guidance R.7a, Section R.7.6.2.1 and Table R.7.6-1.

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

1. Sub-chronic toxicity study (90-day)

A Sub-chronic toxicity study (90 day) is a standard information requirement in Annex IX to REACH.

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5.

As explained in the Appendix on Reasons common to several requests your adaptation is rejected.

Therefore, the information requirement is not fulfilled.

In your comments to the draft decision, you agree to conduct the requested test as specified in the decision.

Specifications for the study design

Following the criteria provided in Annex IX, Section 8.6.2, Column 2, the oral route is the most appropriate route of administration to investigate repeated dose toxicity and the prefered rodent species is rat[10]. The sub-chronic toxicity study must be performed according to the OECD TG 408, in rats and with oral administration of the Substance.

2. Pre-natal developmental toxicity study in one species

A Pre-natal developmental toxicity (PNDT) study (OECD TG 414) in one species is a standard information requirement under Annex IX to REACH.

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5.

As explained in the Appendix on Reasons common to several requests your adaptation is rejected.

Therefore, the information requirement is not fulfilled.

In your comments to the draft decision, you agree to conduct the requested test as specified in the decision.

Specifications for the study design

A PNDT study according to the OECD TG 414 should be performed in rabbit or rat as the preferred species with oral administration of the Substance.

[10] ECHA Guidance R.7a, Section R.7.5.6.3.2 and Table R.7.5-1

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[11].

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[12].

[11] https://echa.europa.eu/practical-guides
[12] https://echa.europa.eu/manuals

Appendix E: 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 18 July 2019.

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.

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[13] 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)[14]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[14]

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.

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

OECD Guidance documents[15]

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.

[15] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

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]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[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.