~~Confidential~~

Helsinki, 10 October 2022

Addressees
Registrant(s) of JS_75-64-9_tert.Butylamine as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
23/01/2014

Registered substance subject to this decision ("the Substance")
Substance name: tert-butylamine
EC number: 200-888-1

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 ***15 January 2024***.

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

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: OECD TG 471, 2020) using one of the following strains: E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102

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

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

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

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you in accordance with Articles 10(a) and 12(1) of REACH. The addressees of the decision and their corresponding information requirements based on registered tonnage band are listed in Appendix 3.

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

How to comply with your information requirements

To comply with your information requirements, you must submit the information requested by this decision in an updated registration dossier by the deadline indicated above. You must also **update the chemical safety report, where** relevant, including any changes

to classification and labelling, based on the newly generated information.

You must follow the general requirements for testing and reporting new tests under REACH, see Appendix 4.

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 Mike Rasenberg, Director of Hazard Assessment

Appendix 1: Reasons for the decision
Appendix 2: Procedure
Appendix 3: Addressees of the decision and their individual information requirements
Appendix 4: Conducting and reporting new tests under REACH

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

Appendix 1: Reasons for the decision

Contents

Reasons related to the information under Annex VII of REACH

1. In vitro gene mutation study in bacteria

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

2 You have provided:

i. *In vitro* gene mutation study in bacteria (1987) with the Substance.

1.1. Assessment of the information provided

3 We have assessed this information and identified the following issue:

4 To fulfil the information requirement, the study must meet the requirements of OECD TG 471 (2020). Therefore, the following specifications must be:

a) 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)

5 The study (i) is described as "*comparable to guideline test*". However, the following specifications are not according to the requirements of OECD TG 471 (2020):

a) The required fifth strain, *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101), was not included in the study.

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

7 Therefore, the information requirement is not fulfilled.

1.2. Specification of the study design

8 To fulfil the information requirement for the Substance, the in vitro gene mutation study in bacteria (OECD TG 471, 2020) is considered suitable / should be performed using one of the following strains: E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102.

2. Short-term toxicity testing on aquatic invertebrates

9 Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII to REACH (Section 9.1.1.).

2.1. Information provided

10 You have provided a short-term toxicity study on aquatic invertebrates according to AFNOR N.F.T 90-301 with the Substance (1980)

2.2. Assessment of the information provided

11 We have assessed this information and identified the following issues:

2.2.1. The test material used to conduct the study is unclear

12 For the study referred to above, you have identified the test material as "[redacted]", without further information, including composition.

13 In the absence of composition information on the test material, the identity of the test material and its impurities cannot be assessed and you have not demonstrated that the test material is representative for the Substance.

14 Therefore, the information provided is rejected.

2.2.2. The provided study does not meet the information requirement

15 To fulfil the information requirement, a study must comply with OECD TG 202 and the requirements of OECD GD 23 if the substance is difficult to test (Article 13(3) of REACH). Therefore, the following specifications must be met:

16 Technical specifications impacting the sensitivity/reliability of the test

a) the test duration is 48 hours or longer;

17 Reporting of the methodology and results

b) the test procedure is reported (*e.g.* composition of the test medium, loading in number of *Daphnia* per test vessel);

c) the methods used to prepare stock and test solutions is reported;

d) the number of immobilised daphnids is determined at 24 and 48 hours. Data are summarised in tabular form, showing for each treatment group and control, the number of daphnids used, and immobilisation at each observation;

e) adequate information on the analytical method (including performance parameters of the method) and on the results of the analytical determination of exposure concentrations is provided.

18 Your registration dossier provides an OECD TG 202 showing the following:

19 Technical specifications impacting the sensitivity/reliability of the test

a) the test duration was 24 hours;

20 Reporting of the methodology and results

b) on the test procedure, you have not specified composition of the test medium, loading in number of *Daphnia* per test vessel, the life-stage of test animals;

c) the methods used to prepare stock and test solutions is not reported;

d) tabulated data on the number of immobilised daphnids after 24 and 48 hours for each treatment group and control are not reported;

e) on the analytical method adequate information (i.e. specificity, recovery efficiency, precision, limits of determination (detection and quantification) and working range) is not reported and the results of the analytically determined exposure concentrations are not provided.

21 Based on the above,

- there are critical methodological deficiencies resulting in the rejection of the study results. More, specifically the test duration is shorter than the minimum duration of 48 hours which may have impacted the sensitivity of the test;
- the reporting of the study is not sufficient to conduct an independent assessment of its reliability. In particular, you have not described the composition of the test medium and therefore, taking into account the properties of the Substance (i.e. high adsorption potential), it is not possible to verify whether the composition of the test medium may have impacted the exposure to the Substance during the test. Furthermore, key elements of the procedure and of the results of the test are missing.

22 Therefore, the requirements of OECD TG 202 are not met.

23 On this basis, the information requirement is not fulfilled.

2.3. Assessment of the information in your comments to the draft decision

24 In your comments to the draft decision, you state that the above study "*do not fully comply with the information requirements of REACH. As the publication does not contain the requested information, this information is no longer supported by the Registrant*". Instead, you have provided information derived from experimental data from a group of substances using the OECD QSAR Toolbox and flagged the information as QSAR.

25 As the group of substances are used as source substances to predict the property of the Substance, we understand that you have adapted the standard information requirements under Annex XI, Section 1.5 of REACH (grouping and read-across). ECHA has considered the scientific and regulatory validity of your read-across approach(es) in general before assessing the specific standard information requirements in the following sections.

26 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. 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.

27 Additional information on what is necessary when justifying a read-across approach can be found in the Guidance on IRs and CSA, Chapter R.6. and related documents (RAAF, 2017; RAAF UVCB, 2017).

2.3.1. Scope of the grouping of substances (category)

28 You have not provided a read-across justification document in your comments to the draft decision.

29 For the purpose of this decision, the following abbreviations are used for the category members:

- Erbumine (CAS RN 75-64-9)
- Amantadine (CAS RN 768-94-5)
- Cyclohexylmethylamine (CAS RN 3218-02-8)
- Undecylamine (CAS RN 7307-55-3)
- Tetradecylamine (CAS RN 2016-42-4)
- dodecyamine (CAS RN 124-22-1)
- Tridecylamine (CAS RN 2869-34-3)
- Nonylamine (CAS RN 112-20-9)
- octylamine (CAS RN 111-86-4)

- 2-Propanamine (CAS RN 75-31-0)

30 You justify the grouping of the substances as the selected substances belong to the "*Narcotic Amine (Acute aquatic toxicity MOA by OASIS) (primary grouping)".*

31 You define the applicability domain as: amines with a log Kow ranging from 0.27 to 5.75.

32 ECHA understands that this is the applicability domain of the grouping and your predictions are assessed on this basis and that your read-across hypothesis assumes that different compounds have the same type of effects. You predict the properties of your Substance based on an identified trend within the group.

2.3.2. Assessment of the information provided

2.3.2.1. Composition of the substances within the group

33 Annex XI, Section 1.5 of the REACH Regulation provides that "substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity may be considered as group."

34 Therefore, qualitative and quantitative information on the compositions of the category members must be provided to allow assessing whether the attempted predictions are compromised by the composition and/or impurities.

35 You report that the identifier (CAS RN) of the category members without further information on composition or on purity.

36 Without this information, no qualitative or quantitative comparative assessment of the compositions of the different category members can be completed. Therefore, it is not possible to assess whether the attempted predictions are compromised by the composition of the category members.

2.3.2.2. Absence of read-across documentation

37 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 include a an explanation why the properties of the Substance may be predicted from information on the source substance(s).

38 You have provided a prediction based on effect values obtained from other substances than the Substance in order to comply with the REACH information requirements. However, you have not provided documentation as to why this information is relevant for the Substance and thus why the properties of the Substance may be predicted from information on the source substances.

39 In the absence of such documentation, the properties of the Substance cannot be reliably predicted from the data on the source substances.

2.3.2.3. Inadequate read-across hypothesis

40 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 include an explanation why the properties of the Substance may be predicted from other substances in the group, i.e. a read-across hypothesis. This hypothesis should be based on recognition of the structural similarities and differences between the substances (Guidance on IRs and CSA, Section R.6.).It should explain why the differences in the chemical structures should not influence the ecotoxicological properties or should do so in a regular pattern, taking into account that variations in chemical structure can affect both toxicokinetics (uptake and

bioavailability) and toxicodynamics (e.g. interactions with receptors and enzymes) of substances (Guidance on IRs and CSA, Section R.6.2.1.3).

41 Your read-across hypothesis is only based on the presence of an amine moiety and a trend in the relationship between the log Kow values and acute daphnia toxicity for the category members. You consider that these elements are a sufficient basis for predicting the (eco)toxicological properties of the Substance.

42 You have not substantiated how structural and physico-chemical similarity alone would explain similarity in the predicted endpoint and thus be sufficient to justify the prediction of short-term toxicity on aquatic invertebrates.

43 Physico-chemical similarity alone does not necessarily lead to predictable or similar ecotoxicological properties. You have not provided a well-founded hypothesis to establish a reliable prediction for an ecotoxicological property, explaining why the structural differences do not influence toxicokinetics and toxicodynamics of the substances, and thus why the properties of the Substance may be predicted from information on the source substances.

2.3.2.4. Missing robust study summaries

44 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 include robust study summary for each source study used in the adaptation.

45 Robust study summary must provide a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study (Article 3(28)).

46 You have not provided detailed information on the methods, results and conclusions, allowing for an independent assessment of the studies used for the prediction. Therefore, you have failed to provide a robust study summary for each source study used in the adaptation as required by Annex XI, Section 1.5.

2.3.3. Conclusion

47 As explained above, you have not established that relevant properties of the Substance can be predicted from data on the source substance(s). Therefore, your read-across approach under Annex XI, Section 1.5. is rejected. Therefore, the additional information provided in your comments to the draft decision does not fulfil the information requirement.

2.4. Study design and test specifications

48 The Substance is difficult to test due to its high adsorption potential (Log Koc calculated to be 4.39). OECD TG 202 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 202. 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.

3. Growth inhibition study aquatic plants

49 Growth inhibition study on aquatic plants is an information requirement under Annex VII to REACH (Section 9.1.2.).

50 You have provided a study according to EPA 1971 with the Substance (1980)

3.1. Assessment of the information provided

51 We have assessed this information and identified the following issues:

3.1.1. The test material used to conduct the study is unclear

52 For the study referred to above, you have identified the test material as [redacted], without further information, including composition.

53 In the absence of composition information on the test material, the identity of the test material and its impurities cannot be assessed and you have not demonstrated that the test material is representative for the Substance.

54 Therefore, the information provided is rejected.

3.1.2. The provided study does not meet the information requirement

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

56 Reporting of the methodology and results

a) the test design is reported (*e.g.*, number of replicates, number of test concentrations and geometric progression used);

b) the test conditions are reported (*e.g.*, composition of the test medium, test temperature, test species, biomass density at the beginning of the test);

c) the methods used to prepare stock and test solutions are reported;

d) Algal biomass is normally determined based on dry weight per volume, or alternatively as cell counts or biovolume using microscopy or an electric particle counter. If an alternative method is used (*e.g.* flow cytometry, *in vitro* or *in vivo* fluorescence, or optical density), a satisfactory correlation with biomass must be demonstrated over the range of biomass occurring in the test;

e) the results of algal biomass determined in each flask at least daily during the test period are reported in a tabular form;

f) adequate information on the analytical method (including performance parameters of the method) and on the results of the analytical determination of exposure concentrations is provided;

57 Your registration dossier provides an OECD TG 201 showing the following:

58 Reporting of the methodology and results

a) on the test design, you have not specified the number of replicates, number of test

concentrations and geometric progression used;

b) on the test conditions, you have not specified composition of the test medium, test temperature and biomass density at the beginning of the test;

c) on the test procedure, you have not specified the methods used to prepare stock and test solutions;

d) you report that algal biomass was determined using *in vivo* fluorescence. However, you have not reported evidence of correlation between the measured parameter and dry weight or cell numbers over the range of biomass occurring in the test;

e) tabulated data on the algal biomass determined daily for each treatment group and control are not reported;

f) on the analytical method adequate information (i.e. specificity, recovery efficiency, precision, limits of determination (detection and quantification) and working range) is not reported and the results of the analytically determined exposure concentrations are not provided.

59 Based on the above,

- the reporting of the study is not sufficient to conduct an independent assessment of its reliability. More specifically, the information available on the study is insufficient to assess whether the validity criteria equivalent to those specified in the OECD TG 201 were met, and if the test conditions and test procedure were consistent with the specifications of the test guideline. It is also not possible to conduct an independent assessment of the test results and their interpretation.

60 Therefore, the requirements of OECD TG 201 are not met.

61 On this basis, the information requirement is not fulfilled.

62 In your comments to the draft decision, you state that the provided study "*does not fully comply with the information requirements of REACH. As the publication does not contain the requested information, this information is no longer supported by the Registrant*". Instead, you have provided the following information derived from the US EPA ECOSAR model v2.0:

i. a prediction for Green algae: 96-h EC50 using the model for the category of aliphatic amines
ii. a prediction for Green algae: chronic value (ChV) using the model for the category of aliphatic amines

63 We have assessed the information provided as part of your comments to the draft decision sand identified the following issues:

3.1.3. Scientific validity of the model under point (i) above

64 Under ECHA Guidance R.6.1.3., a (Q)SAR model must fulfil the principles described in the OECD Guidance document on the validation of (Q)SAR models (ENV/JM/MONO(2007)2) to be considered scientifically valid. As specified under ECHA Guidance on IRs and CSA, Section R.6.2.2., models are only useful for data gap filling when they are based on data of sufficiently high quality.

65 You have provided a QSAR prediction for the Substance using the ECOSAR model based on a category of aliphatic amines for endpoint Green algae: 96-h EC50.

66 Based on the information you provided, ECHA is not in a position to assess the reliability of the full dataset used to build the QSAR model. However, ECHA notes that the training set of the model includes an experimental value for the Substance based on a study rejected for the reasons already explained under sections 3.1.1. and 3.1.2. above. Therefore, it can be concluded that it relies, at least partly, on information of low quality. As you have not demonstrated that the model is based on data of sufficiently high quality, the prediction under point (i) above is rejected.

3.1.4. Lack of or inadequate documentation of the model (QMRF) for the model under point (ii) above

67 Under Appendix C of the OECD Guidance document on the validation of (Q)SAR models (ENV/JM/MONO(2007)2) and ECHA Guidance R.6.1.6.3., adequate and reliable documentation must include a (Q)SAR Model Reporting Format document (QMRF) which reports, among others, the following information:

- the predicted endpoint, including information on experimental protocol and data quality for the data used to develop the model;

68 You have provided a QSAR prediction for the Substance using the ECOSAR model based on a category of aliphatic amines for Green algae: chronic value (ChV). You have not provided a training set of the model and it cannot be retrieved from ECOSAR documentation for the class of aliphatic amines because all chemicals in the training set are indicated as confidential.

69 In absence of such information, ECHA cannot establish that the model can be used to meet this information requirement. Therefore, the prediction under point (ii) above is rejected.

3.2. Study design and test specifications

70 OECD TG 201 specifies that, for difficult to test substances, OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design' under Request 2.

References

The following documents may have been cited in the decision.

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

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

Guidance on data-sharing; ECHA (2017).

All Guidance on REACH is available online: https://echa.europa.eu/guidance-documents/guidance-on-reach

Read-across assessment framework (RAAF)

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

The RAAF and related documents are available online:
https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

***OECD Guidance documents* (OECD GDs)**

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

Appendix 2: Procedure

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 06 July 2021.

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.

The deadline of the decision is set based on standard practice for carrying out OECD TG tests. It has been exceptionally extended by 6 months from the standard deadline granted by ECHA to take into account currently longer lead times in contract research organisations.

Appendix 3: Addressees of this decision and their corresponding information requirements

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

- the information specified in Annex VII to REACH, for registration at 1-10 tonnes per year (tpa), or as a transported isolated intermediate in quantity above 1000 tpa.

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.

Appendix 4: Conducting and reporting new tests for REACH purposes

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

1.1. Test methods, GLP requirements and reporting

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

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

(3) Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries[2].

(4) Under the introductory part of Annexes VII/VIII/IX/X to REACH, where a test method offers flexibility in the study design, for example in relation to the choice of dose levels or concentrations, the chosen study design must ensure that the data generated are adequate for hazard identification and risk assessment.

1.2. Test material

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

(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.

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

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].

[3] https://echa.europa.eu/manuals