~~Confidential~~

Helsinki, 11 August 2022

Addressees
Registrants of Basic_Brown_1_Acetate as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
15/11/2021

Registered substance subject to this decision ("the Substance")
Substance name: 1,3-Benzenediamine, coupled with diazotized m-phenylenediamine, acetates
EC number: 282-617-7

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

DECISION ON TESTING PROPOSAL(S)

Based on Article 40 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by ***17 November 2025***.

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 cytogenicity study in mammalian cells or in vitro micronucleus study (triggered by Annex VII, Section 8.4., column 2); same as under "3.".

2. In vivo genetic toxicity study (triggered by Annex VII, Section 8.4., column 2); same as under "4.".

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

3. In vitro cytogenicity study in mammalian cells (test method: OECD TG 473) or In vitro micronucleus study (test method: OECD TG 487) (triggered by Annex VIII, Section 8.4., column 2).

4. *In vivo* genetic toxicity study (triggered by Annex VIII, Section 8.4., column 2) to be selected according to the following specifications:

    a. If the results of the *in vitro* test requested under section 3 are **negative**:

    In vivo mammalian alkaline comet assay (Annex VIII, Section 8.4., column 2; test method: OECD TG 489) in rats, or if justified, other rodent species, oral route, on the following tissues: liver, glandular stomach and duodenum.

    b. If the results of the *in vitro* test requested under section 3 are **positive**:

    In vivo mammalian alkaline comet assay (Annex VIII, Section 8.4., column 2; test method: OECD TG 489) combined with *in vivo* mammalian erythrocyte micronucleus test (test method: OECD TG 474) in rats, or if justified, in mice,

oral route. For the comet assay the following tissues shall be analysed: liver, glandular stomach and duodenum.

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.

As visible from the list of required information above, the same study is required under different Annexes. This is because under the REACH Regulation information may be required under different conditions, dependent on the tonnage of the registration. While the reasons for the information requirement may thus differ (see Appendix 1), only one study is to be conducted. All registrants concerned must make every effort to reach an agreement as to who is to carry out the study on behalf of the others under Article 53 of REACH.

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

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Reasons for the decision(s) related to the information under Annex VII of REACH

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

1 Further mutagenicity studies must be considered under Annex VII to REACH in case of a positive result (Section 8.4., Column 2).

2 The Guidance on IRs & CSA, Section R.7.7.6.3, further specifies that "REACH Annex VII substances for which only a bacterial gene mutation test has been conducted and for which the result is positive should be studied further, according to the requirements of Annex VIII." This is for the reason that the *in vitro* cytogenicity test under Section 8.4.2 will allow to further investigate the mutagenicity of the substance in accordance with the REACH integrated testing strategy.

3 Your dossier contains positive results for the *in vitro* gene mutation study in bacteria (OECD TG 471, 1981); however, no adequate information from an *in vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study, according to the requirements of Annex VIII, is available (as explained under section 3).

4 ECHA therefore considers that an appropriate *in vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study is necessary to further investigate the mutagenicity of the Substance and to help identify the most adequate follow-up *in vivo* study.

5 For the assessment, selection and specifications of the study to be performed, see section 3 of this Appendix.

2. In vivo genetic toxicity study

6 Further mutagenicity studies must be considered under Annex VII to REACH in case of a positive result (Section 8.4., Column 2).

7 Your dossier contains positive results for the *in vitro* gene mutation study in bacteria (OECD TG 471, 1981) which raise the concern for gene mutations.

8 ECHA considers that an *in vivo* follow-up study is necessary to address the identified concern.

9 For the assessment of the testing proposal, see section 4 of this Appendix.

Reasons for the decision(s) related to the information under Annex VIII of REACH

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

10 An *in vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study is an information requirement under Annex VIII, Section 8.4.2.

11 As already explained in section 1 above, an appropriate *in vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study is necessary to inform on the genotoxic concern(s) associated with the Substance and to help identify the most adequate follow-up *in vivo* study.

3.1. Information provided to fulfil the information requirement

12 You have submitted a testing proposal for an *in vivo* mammalian alkaline comet assay to be performed with the Substance to further investigate the mutagenicity of the substance. However, no information from an *in vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study on the Substance is available in the dossier.

13 Instead, you have adapted this information requirement by using a Grouping of substances and read-across approach based on experimental data from the following substance:

(i) An *in vivo* mammalian erythrocyte micronucleus test (OECD TG 474, 2005) with the analogue substance Direct Brown 44, EC no. 939-292-8.

(ii) Read-across justification document in IUCLID Section 13.2.

14 You provide the following reasoning for the prediction of this information requirement:

a) both the source substance and the Substance "share the same primary metabolites, aromatic amines as starting materials, and they are produced via a very similar synthetic procedure, with Direct brown 44 bearing extra sulphonamine moieties that make it more soluble.";

b) the source substance is a UVCB which contains a constituent (Solvent Brown 41) which is structurally similar to the Substance (differs by presence of acetate ions) and it is present at "[redacted]%" in the source substance on a w/w basis;

c) based on bioavailability, the constituent (Solvent Brown 41) of the source substance represents a worst case for metabolism.

15 ECHA understands that you predict the properties of the Substance using a read-across hypothesis which assumes that different compounds have the same type of effects. The properties of your Substance are predicted based on a worst-case approach.

3.2. Assessment of the information provided

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

3.2.1. Read-across adaptation rejected

17 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.

18 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).

19 We have identified the following issue(s) with the prediction of toxicological properties:

3.2.1.1. Missing supporting information

20 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 supporting information to scientifically justify the read-across explanation for prediction of properties. The set of supporting information should strengthen the rationale for the read-across in allowing to verify the crucial aspects of the read-across hypothesis and establishing that the properties of the Substance can be predicted from the data on the source substance(s) (Guidance on IRs and CSA R.6, Section R.6.2.2.1.f.).

21 Supporting information must include information to confirm your claimed worst-case prediction.

22 As indicated above, your read-across hypothesis is based on the assumption that the source substance constitutes a worst-case for the prediction of the property under consideration of the Substance. In this context, relevant, reliable and adequate information allowing to compare the properties of the Substance and of the source substance(s) is necessary to confirm a conservative prediction of the properties of the Substance from the data on the source substance(s). Such information can be obtained, for example, from bridging studies of comparable design and duration for the Substance and for the source substance(s).

23 For the source substance, you provide study (i) above, that is used in the prediction in the dossier. Apart from that study, your read-across justification or the dossier do not include any robust study summaries or descriptions of data for the source substance that would confirm a conservative prediction of the properties of the Substance.

24 More specifically, you have not provided data, such as metabolic profiles, to support your claim that it is the low molecular weight components of the source substance (i.e. Solvent Brown 41) that "represent the worst case scenario of metabolic pathway" and that drive the toxicity of the source substance.

25 Moreover, the data in the dossier do not demonstrate whether one or other constituent(s) of the source substance drive the toxicity. In the read-across justification document you refer to the major constituents (i.e. Solvent Brown 41 (ca. [redacted]%) and Direct Brown 44); further (quantitative) information on the compositions is not provided in this document.

26 In the absence of such information, you have not established that the source substance, due to the presence of Solvent Brown 41, constitutes a worst-case for the prediction of the property under consideration of the Substance. Moreover, you have not established that a reliable prediction of the property under consideration of the Substance can be derived on the basis of your read-across hypothesis. Therefore, you have not provided sufficient supporting information to scientifically justify the read-across.

3.2.1.2. Test material representative for the source substance

27 Under Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across must be adequate for the purpose of classification and labelling and/or risk assessment.

28 In order to predict the properties of the Substance, the test material used in the study on the source substance must be representative for the source substance (cf Article 10 and Recital 19 of REACH; Guidance on IRs and CSA, Section R.4.1.). Therefore, the unambiguous characterisation of the composition of the test material used to generate the source data is required to assess whether the test material is representative for the source substance.

29 In your dossier the test material used in study (i) is not adequately reported; given the high dose administered it can neither be confirmed whether there was an adequate dose of the constituent (Solvent Brown 41) nor if this constituent was present in the composition of the source substance (UVCB).

30 Therefore, no comparison on the structural similarity with the composition of the Substance (mono-constituent) can be confirmed.

31 In the absence of the information on the composition of the test material, you have not demonstrated that the test material is representative for the source substance. Therefore, the study is not adequate for the purpose of classification and labelling and/or risk assessment.

3.2.2. Conclusions

32 As explained above, you have not established that relevant properties of the Substance can be predicted from data on the source substance. Therefore, your read-across adaptation under Annex XI, Section 1.5. is rejected and the information requirement is not fulfilled.

33 ECHA therefore considers that an appropriate *in vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study is necessary to further investigate the mutagenicity of the Substance and to help identify the most adequate follow-up *in vivo* study.

3.3. Specification of the study design

34 Either the *in vitro* cytogenicity study in mammalian cells (test method OECD TG 473) or the *in vitro* micronucleus study (test method OECD TG 487) are considered suitable.

3.4. Outcome

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

36 In your comments to the draft decision you agreed to perform the study.

4. In vivo genetic toxicity study

37 Appropriate *in vivo* mutagenicity studies must be considered under Annex VIII to REACH (Section 8.4., Column 2) in case of a positive result in any of the *in vitro* genotoxicity studies under Annex VII or VIII to REACH.

38 Your dossier contains positive results for the *in vitro* gene mutation study in bacteria (OECD TG 471, 1981) with the analogue substance Basic Brown 1 Chloride, EC no. 233-314-3.

39 ECHA considers the read-across plausible. More specifically, the mutagenic properties of the Substance in bacteria may be predicted from the data provided on the analogue substance, Basic Brown 1 Chloride, EC no. 233-314-3.

40 Therefore, ECHA agrees that an appropriate *in vivo* mutagenicity study has to be considered.

4.1. Information provided to fulfil the information requirement

41 You have submitted a testing proposal for an *In vivo* mammalian alkaline comet assay to be performed with the Substance.

42 ECHA requested your considerations for alternative methods to fulfil the information requirement for Genetic toxicity *in vivo*. You provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

43 ECHA agrees that an appropriate *in vivo* follow up genotoxicity study is necessary to address the concern identified *in vitro*.

4.2. Test selection

44 According to the Guidance on IRs & CSA, Section R.7.7.6.3, the *in vivo* mammalian alkaline comet assay ("comet assay", OECD TG 489) is suitable to follow up a positive *in vitro* result on gene mutation.

45 As explained above, under section 3, in the dossier there is no adequate information from an *in vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study, according to the requirements of Section 8.4.2., Annex VIII to REACH. Therefore, by this decision, ECHA also requests an *in vitro* cytogenicity study or an *in vitro* micronucleus study, which may raise a concern for chromosomal aberration in case of positive results.

46 In case there is also a concern for chromosomal aberration, the comet assay can be combined with an *in vivo* mammalian erythrocyte micronucleus test ("MN test", OECD TG 474) in a single study (see OECD TG 489 para. 33; OECD TG 474 para. 37c; Guidance on IRs & CSA, Section R.7.7.6.3). While the comet assay can detect primary DNA damage that may lead to gene mutations and/or structural chromosomal aberrations, the MN test can detect both structural chromosomal aberrations (clastogenicity) and numerical chromosomal aberrations (aneuploidy). A combined study will thus address both the identified concerns for chromosomal aberration as well as gene mutation.

47 The combined study, together with the results of the *in vitro* mutagenicity studies, can be used to make definitive conclusions about the mechanism(s) inducing *in vivo* mutagenicity and lack thereof. Furthermore, the combined study can help reduce the number of tests performed and the number of animals used while addressing (structural and numerical) chromosomal aberrations as well as gene mutations.

48 Therefore, you must wait for the results of the *in vitro* test requested under section 3 and, depending on these results, to conduct either a) Comet assay if the test results of request 3 are negative; or b) Comet assay combined with MN test if the test results of request 3 are positive. The deadline set in this decision allows for sequential testing.

4.3. Specification of the study design

*4.3.1. Comet assay (if the test results of request 3 are **negative**)*

49 You did not specify the species to be used for testing. According to the test method OECD TG 489, rats are the preferred species. Other rodent species can be used if scientifically justified (OECD TG 489, para. 23).

50 You proposed testing by the oral route. Having considered the anticipated routes of human exposure and adequate exposure of the target tissue(s) performance of the test by the oral route is appropriate.

51 In line with the test method OECD TG 489, the test must be performed by analysing tissues from liver as primary site of xenobiotic metabolism, glandular stomach and duodenum as sites of contact. There are several expected or possible variables between the glandular stomach and the duodenum (different tissue structure and function, different pH conditions, variable physico-chemical properties and fate of the Substance, and probable different local absorption rates of the Substance and its possible breakdown product(s)). In light of these expected or possible variables, it is necessary to analyse both tissues to ensure a sufficient evaluation of the potential for genotoxicity at the site of contact in the gastro-intestinal tract.

4.3.1.1. Germ cells

52 You may consider collecting the male gonadal cells from the seminiferous tubules in addition to the other tissues in the comet assay, as it would optimise the use of animals. You can prepare the slides for male gonadal cells and store them for up to 2 months, at room temperature, in dry conditions and protected from light. Following the generation and analysis of data on somatic cells in the comet assay, you should consider analysing the slides prepared with gonadal cells. This type of evidence may be relevant for the overall assessment of possible germ cell mutagenicity including classification and labelling according to the CLP Regulation.

*4.3.2. Comet assay combined with MN test (if the test results of request 3 are **positive**)*

53 According to the test method OECD TG 489, rats are the preferred species. Other rodent species can be used if scientifically justified. According to the test method OECD TG 474, the test may be performed in mice or rats. Therefore, the combined study must be performed in rats, or if justified, in mice.

54 Having considered the anticipated routes of human exposure and adequate exposure of the target tissue(s) performance of the test by the oral route is appropriate.

55 In line with the test method OECD TG 489, the test must be performed by analysing tissues from liver as primary site of xenobiotic metabolism, glandular stomach and duodenum as sites of contact. There are several expected or possible variables between the glandular stomach and the duodenum (different tissue structure and function, different pH conditions, variable physico-chemical properties and fate of the Substance, and probable different local absorption rates of the Substance and its possible breakdown product(s)). In light of these expected or possible variables, it is necessary to analyse both tissues to ensure a sufficient evaluation of the potential for genotoxicity at the site of contact in the gastro-intestinal tract.

56 The combination of OECD TGs 489 and 474 should not impair the validity of and the results from each individual study. Careful consideration should be given to the dosing, and tissue sampling for the comet analysis alongside the requirements of tissue sampling for the mammalian erythrocyte micronucleus test (see OECD TG 489, e.g. Bowen et al. 2011 [1]).

4.3.2.1. Germ cells

57 You may consider collecting the male gonadal cells from the seminiferous tubules in addition to the other tissues in the comet assay, as it would optimise the use of animals. You can prepare the slides for male gonadal cells and store them for up to 2 months, at room temperature, in dry conditions and protected from light. Following the generation and

analysis of data on somatic cells in the comet assay, you should consider analysing the slides prepared with gonadal cells. This type of evidence may be relevant for the overall assessment of possible germ cell mutagenicity including classification and labelling according to the CLP Regulation.

Reference:

[1] Bowen D.E. et al. 2011. Evaluation of a multi-endpoint assay in rats, combining the bone-marrow micronucleus test, the comet assay and the flow-cytometric peripheral blood micronucleus test. Mutation Research 722 7–19.

4.4. Outcome

58 Under Article 40(3)(b) your testing proposal is accepted under modified conditions, and you are requested to conduct the test with the Substance, as specified above.

59 In your comments to the draft decision you agreed to perform the study.

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

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 14 October 2021.

ECHA held a third party consultation for the testing proposal(s) from 25 November 2021 until 10 January 2022. ECHA did not receive information from third parties.

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

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

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

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 12 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;
- the information specified in Annexes VII and VIII to REACH, for registration at 10-100 tpa.

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]

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.

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